Dossier zur Nutzenbewertung gemäß § 35a SGB V

Datopotamab deruxtecan (Datroway)

Daiichi Sankyo Deutschland GmbH

Modul 4 A

Erwachsene mit inoperablem oder metastasiertem HR-positivem, HER2-negativem Brustkrebs, die bereits eine endokrine Therapie und mindestens eine Chemotherapielinie im fortgeschrittenen Stadium erhalten haben

Anhang 4-G: Weitere Analysen zum finalen Datenschnitt vom 24.07.2024

Stand: 23.05.2025

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Gesamtüberleben

Gesamtüberleben – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Final

Table 2.3.3 Overall survival (OS) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_OS_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.3.5 Overall survival (OS) - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.8158
mFASA	63	44 (69.8)	19 (30.2)	17.5 (15.2 , 20.2)	55	36 (65.5)	19 (34.5)	14.1 (11.1 , 23.0)	1.02 (0.66, 1.59)	0.9142	
non-mFASA	269	156 (58.0)	113 (42.0)	19.7 (17.8 , 21.7)	279	157 (56.3)	122 (43.7)	18.6 (17.3 , 21.0)	0.96 (0.77, 1.19)	0.6907	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_4.sas; Output name: DE.T_OS_SUB_mFASA_Add.rtf

Gesamtüberleben – Subgruppenanalysen

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.8434
Region 1 [US, Canada, Europe]	33	26 (78.8)	7 (21.2)	16.8 (11.0, 19.9)	28	21 (75.0)	7 (25.0)	12.0 (8.8, 19.9)	1.00 (0.56, 1.79)	0.9972	
Region 2 [Rest of World]	30	18 (60.0)	12 (40.0)	18.5 (15.0, NE)	27	15 (55.6)	12 (44.4)	23.0 (9.5, NE)	1.06 (0.53, 2.11)	0.8669	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5637
Yes	52	36 (69.2)	16 (30.8)	17.8 (15.2, 21.1)	45	30 (66.7)	15 (33.3)	14.1 (11.1, 23.0)	0.98 (0.61, 1.60)	0.9499	
No	11	8 (72.7)	3 (27.3)	15.8 (4.4, NE)	10	6 (60.0)	4 (40.0)	18.8 (4.5, NE)	1.43 (0.46, 4.38)	0.5331	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	11 (57.9)	8 (42.1)	-	13	9 (69.2)	4 (30.8)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	23 (71.9)	9 (28.1)	-	30	22 (73.3)	8 (26.7)	-	-	-	
Neither taxanes nor anthracyclines	11	9 (81.8)	2 (18.2)	-	9	3 (33.3)	6 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.0670
<65 years	52	34 (65.4)	18 (34.6)	17.2 (13.7, 21.1)	41	29 (70.7)	12 (29.3)	12.9 (9.5, 18.1)	0.79 (0.48, 1.31)	0.3625	
≥65 years	11	10 (90.9)	1 (9.1)	17.8 (9.7, 21.1)	14	7 (50.0)	7 (50.0)	24.1 (8.6, NE)	2.80 (1.02, 7.67)	0.0374	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.7287
Asian	21	12 (57.1)	9 (42.9)	18.5 (11.2, NE)	21	12 (57.1)	9 (42.9)	23.0 (10.6, NE)	0.97 (0.44, 2.17)	0.9438	
Non-Asian	32	24 (75.0)	8 (25.0)	17.2 (13.7, 18.6)	26	20 (76.9)	6 (23.1)	12.2 (8.6, 18.1)	0.84 (0.46, 1.52)	0.5565	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.0502
Capecitabine	21	12 (57.1)	9 (42.9)	17.4 (10.0, NE)	9	5 (55.6)	4 (44.4)	23.0 (4.7, NE)	1.40 (0.49, 4.01)	0.5289	
Eribulin mesylate	31	23 (74.2)	8 (25.8)	17.5 (12.4, 20.2)	41	26 (63.4)	15 (36.6)	13.8 (9.5, 24.1)	1.15 (0.65, 2.03)	0.6222	
Vinorelbine	11	9 (81.8)	2 (18.2)	17.8 (11.2, 21.9)	5	5 (100)	0	9.8 (3.5, NE)	0.09 (0.02, 0.49)	0.0007	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5611
Yes	6	5 (83.3)	1 (16.7)	12.6 (4.9, NE)	6	6 (100)	0	11.4 (4.8, NE)	0.64 (0.19, 2.13)	0.4642	
No	57	39 (68.4)	18 (31.6)	18.2 (16.0, 21.1)	49	30 (61.2)	19 (38.8)	17.7 (11.7, 25.4)	1.09 (0.67, 1.75)	0.7361	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	1 (100)	0	-	-	-	
Female	62	44 (71.0)	18 (29.0)	-	54	35 (64.8)	19 (35.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	23 (74.2)	8 (25.8)	-	24	19 (79.2)	5 (20.8)	-	-	-	
Asian	21	12 (57.1)	9 (42.9)	-	21	12 (57.1)	9 (42.9)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0087
0	35	27 (77.1)	8 (22.9)	17.2 (13.7, 20.2)	33	18 (54.5)	15 (45.5)	23.5 (11.8, NE)	1.76 (0.96, 3.24)	0.0652	
≥1	28	17 (60.7)	11 (39.3)	17.6 (10.0, NE)	22	18 (81.8)	4 (18.2)	11.4 (6.7, 14.1)	0.52 (0.27, 1.02)	0.0517	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	5 (83.3)	1 (16.7)	-	-	-	
≥6 months	49	34 (69.4)	15 (30.6)	-	42	26 (61.9)	16 (38.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3752
≤12 months	22	17 (77.3)	5 (22.7)	16.6 (10.0, 19.9)	19	12 (63.2)	7 (36.8)	13.8 (11.7, NE)	1.31 (0.63, 2.76)	0.4691	
>12 months	29	19 (65.5)	10 (34.5)	18.2 (13.7, 22.8)	27	18 (66.7)	9 (33.3)	17.7 (7.8, 24.1)	0.90 (0.47, 1.71)	0.7415	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Table 2.3.2 Overall survival (OS) by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	3 (75.0)	1 (25.0)	-	0	0	0	-	-	-	
No	59	41 (69.5)	18 (30.5)	-	55	36 (65.5)	19 (34.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_OS_SUB_mFASA_FA.rtf

Gesamtüberleben – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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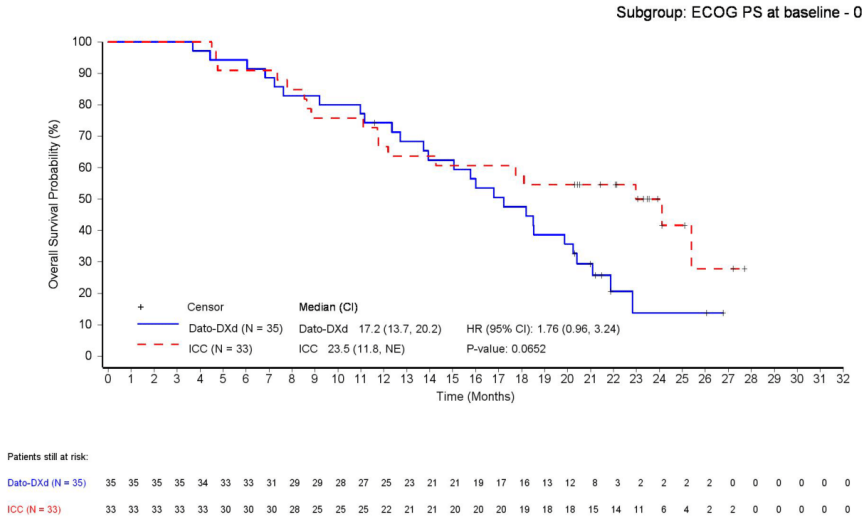
Figure 2.3.2 Overall survival by subgroup - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



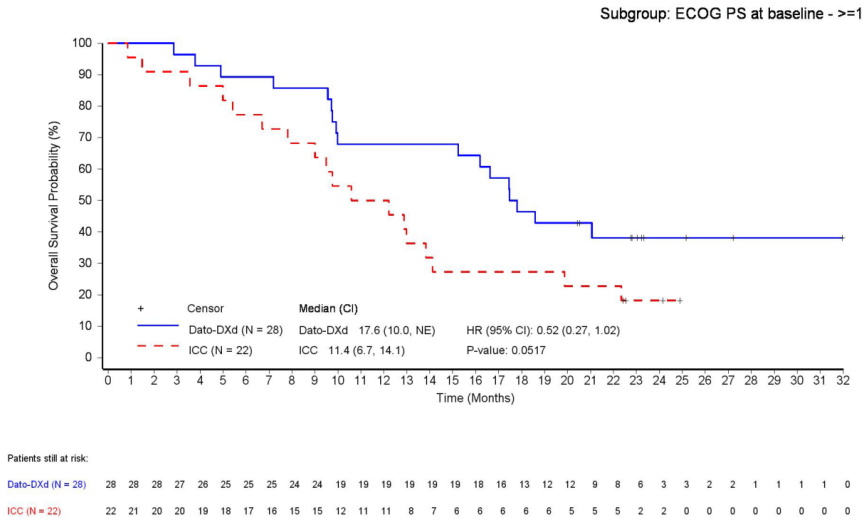
Patients still at risk:

Dato-DXd (N = 35)	35	35	35	35	34	33	33	31	29	29	28	27	25	23	21	21	19	17	16	13	12	8	3	2	2	2	2	0	0	0	0	0	0
ICC (N = 33)	33	33	33	33	33	30	30	30	28	25	25	25	22	21	21	20	20	20	19	18	18	15	14	11	6	4	2	2	0	0	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: f_2_11_2.sas; Output name: DE.F_OS_SUB_mFASA_FA.rtf

Figure 2.3.2 Overall survival by subgroup - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: f_2_11_2.sas; Output name: DE.F_OS_SUB_mFASA_FA.rtf

Progressionsfreies Überleben

Progressionsfreies Überleben (BICR)

Die Ergebnisse der Analysen zum Progressionsfreien Überleben (BICR) befinden sich in Anhang 4-I.

*Progressionsfreies Überleben (Prüfärzt*in)*

Die Ergebnisse der Analysen zum Progressionsfreien Überleben (Prüfärzt*in) befinden sich in Anhang 4-I.

Progressionsfreies Überleben unter der Folgetherapie

Progressionsfreies Überleben unter der Folgetherapie – Hauptanalyse – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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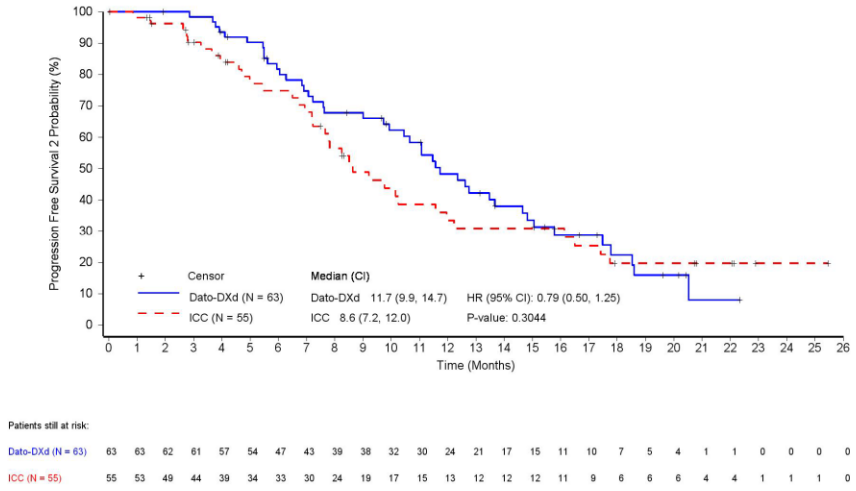
Figure 2.6.1 PFS2 - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Patients still at risk:

Dato-DXd (N = 63)	63	63	62	61	57	54	47	43	39	38	32	30	24	21	17	15	11	10	7	5	4	1	1	0	0	0	0
ICC (N = 55)	55	53	49	44	39	34	33	30	24	19	17	15	13	12	12	12	11	9	6	6	6	4	4	1	1	1	0

Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
CI: confidence interval. NE: not estimable

Data source: ADAM.ADTTE
Run date: 21FEB2025 - 11:24; Program name: F_2_3_1.sas; Output name: DE.F_PFS2_mFASA.rtf

Progressionsfreies Überleben unter der Folgetherapie – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.6.3 PFS2 - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	43 (68.3)	34 (61.8)	
Number of subjects censored, n (%)	20 (31.7)	21 (38.2)	
Median time to first event (months) [a]	11.7	8.6	
85% Confidence Interval	(10.6 , 13.5)	(7.7 , 10.3)	
Cox proportional hazards model [b]			
Hazard Ratio			0.79
85% Confidence Interval			(0.56, 1.10)
Stratified log-rank p-value [c]			0.3044

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_6.sas; Output name: DE.T_PFS2_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Statistical analyses for AMNOG (HTA Germany)

Table 2.6.5 PFS2 - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.5413
mFASA	63	43 (68.3)	20 (31.7)	11.7 (9.9 , 14.7)	55	34 (61.8)	21 (38.2)	8.6 (7.2 , 12.0)	0.85 (0.54, 1.34)	0.4957	
non-mFASA	269	154 (57.2)	115 (42.8)	12.4 (10.6 , 13.8)	279	158 (56.6)	121 (43.4)	10.8 (9.7 , 11.8)	0.74 (0.59, 0.92)	0.0069	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_PFS2_SUB_mFASA_Add.rtf

Progressionsfreies Überleben unter der Folgetherapie – Subgruppenanalysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.7733
Region 1 [US, Canada, Europe]	33	25 (75.8)	8 (24.2)	11.1 (7.2, 13.5)	28	19 (67.9)	9 (32.1)	8.5 (6.5, 12.0)	0.79 (0.43, 1.44)	0.4417	
Region 2 [Rest of World]	30	18 (60.0)	12 (40.0)	12.7 (7.6, 17.5)	27	15 (55.6)	12 (44.4)	10.3 (6.9, NE)	0.89 (0.45, 1.78)	0.7484	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.8208
Yes	52	33 (63.5)	19 (36.5)	11.5 (9.7, 14.7)	45	29 (64.4)	16 (35.6)	8.6 (7.2, 12.0)	0.81 (0.49, 1.34)	0.4102	
No	11	10 (90.9)	1 (9.1)	13.7 (3.9, 17.5)	10	5 (50.0)	5 (50.0)	7.8 (2.8, NE)	0.96 (0.32, 2.91)	0.9425	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	12 (63.2)	7 (36.8)	-	13	7 (53.8)	6 (46.2)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	23 (71.9)	9 (28.1)	-	30	23 (76.7)	7 (23.3)	-	-	-	
Neither taxanes nor anthracyclines	11	8 (72.7)	3 (27.3)	-	9	3 (33.3)	6 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.2206
<65 years	52	34 (65.4)	18 (34.6)	11.5 (7.6, 12.7)	41	28 (68.3)	13 (31.7)	7.8 (6.5, 10.3)	0.68 (0.41, 1.13)	0.1332	
≥65 years	11	9 (81.8)	2 (18.2)	15.8 (7.6, 18.6)	14	6 (42.9)	8 (57.1)	12.2 (7.8, NE)	1.47 (0.52, 4.16)	0.4619	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.7668
Asian	21	12 (57.1)	9 (42.9)	11.5 (6.0, NE)	21	10 (47.6)	11 (52.4)	10.3 (3.9, NE)	0.93 (0.40, 2.15)	0.8633	
Non-Asian	32	24 (75.0)	8 (25.0)	11.6 (7.2, 15.8)	26	18 (69.2)	8 (30.8)	8.6 (7.2, 12.2)	0.85 (0.46, 1.58)	0.6122	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3491
Capecitabine	21	11 (52.4)	10 (47.6)	11.5 (7.6, NE)	9	3 (33.3)	6 (66.7)	17.4 (4.7, NE)	1.44 (0.40, 5.24)	0.5748	
Eribulin mesylate	31	24 (77.4)	7 (22.6)	11.7 (6.0, 14.7)	41	27 (65.9)	14 (34.1)	7.8 (6.7, 12.0)	0.95 (0.54, 1.65)	0.8469	
Vinorelbine	11	8 (72.7)	3 (27.3)	11.6 (5.5, NE)	5	4 (80.0)	1 (20.0)	8.5 (3.3, NE)	0.23 (0.05, 1.07)	0.0425	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5371
Yes	6	4 (66.7)	2 (33.3)	6.9 (4.9, NE)	6	5 (83.3)	1 (16.7)	7.2 (2.6, NE)	0.54 (0.13, 2.28)	0.3932	
No	57	39 (68.4)	18 (31.6)	11.7 (9.9, 14.7)	49	29 (59.2)	20 (40.8)	8.6 (7.2, 16.1)	0.90 (0.55, 1.46)	0.6596	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	43 (69.4)	19 (30.6)	-	54	34 (63.0)	20 (37.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	23 (74.2)	8 (25.8)	-	24	17 (70.8)	7 (29.2)	-	-	-	
Asian	21	12 (57.1)	9 (42.9)	-	21	10 (47.6)	11 (52.4)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0002
0	35	27 (77.1)	8 (22.9)	11.1 (7.2, 13.7)	33	15 (45.5)	18 (54.5)	12.0 (8.2, NE)	1.85 (0.96, 3.56)	0.0621	
≥1	28	16 (57.1)	12 (42.9)	12.7 (9.7, 18.6)	22	19 (86.4)	3 (13.6)	7.2 (3.9, 9.8)	0.28 (0.13, 0.59)	0.0004	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	4 (66.7)	2 (33.3)	-	-	-	
≥6 months	49	34 (69.4)	15 (30.6)	-	42	28 (66.7)	14 (33.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7770
≤12 months	22	14 (63.6)	8 (36.4)	11.5 (9.0, 12.4)	19	13 (68.4)	6 (31.6)	9.2 (6.5, 16.1)	1.01 (0.47, 2.20)	0.9745	
>12 months	29	19 (65.5)	10 (34.5)	11.1 (7.1, 17.8)	27	16 (59.3)	11 (40.7)	8.5 (5.4, 17.4)	0.85 (0.43, 1.67)	0.6388	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Table 2.6.2 PFS2 by subgroup - Time-to-event analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	4 (100)	0	-	0	0	0	-	-	-	
No	59	39 (66.1)	20 (33.9)	-	55	34 (61.8)	21 (38.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_PFS2_SUB_mFASA_FA.rtf

Progressionsfreies Überleben unter der Folgetherapie – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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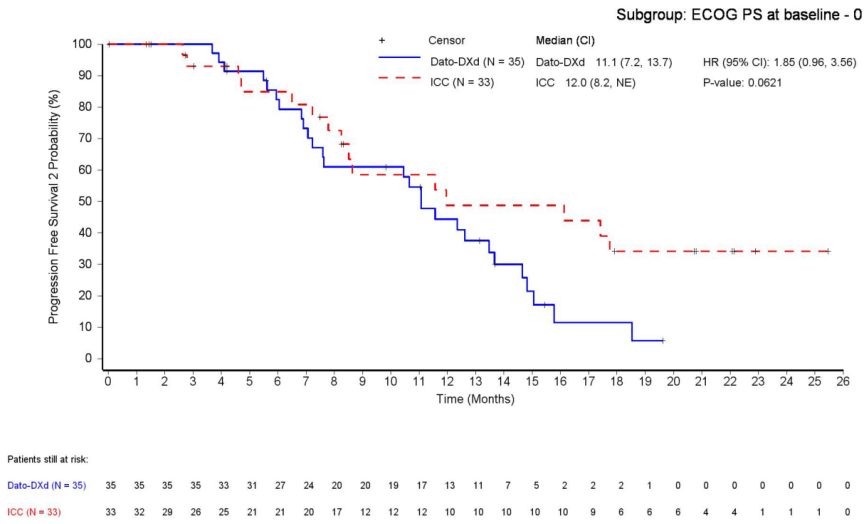
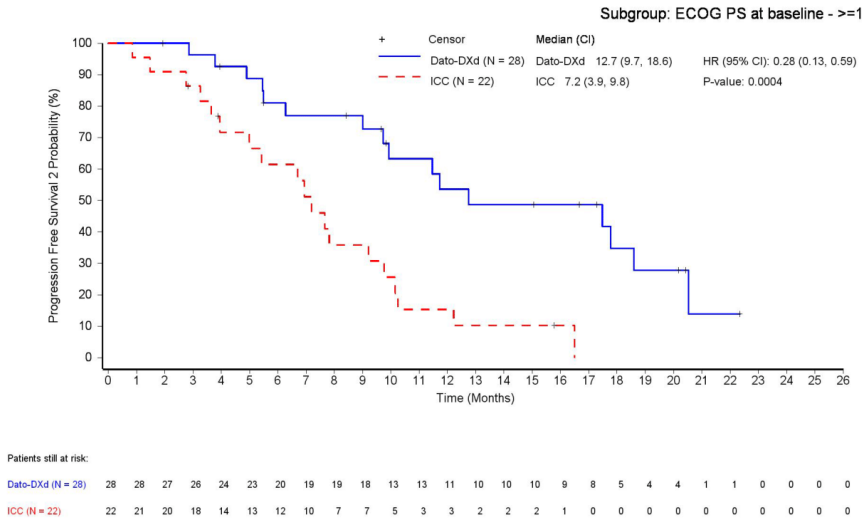
Figure 2.6.2 PFS2 by subgroup - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: f_2_11_2.sas; Output name: DE.F_PFS2_SUB_mFASA_FA.rtf

Figure 2.6.2 PFS2 by subgroup - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: f_2_11_2.sas; Output name: DE.F_PFS2_SUB_mFASA_FA.rtf

Tumoransprechen

Objektive Ansprechrate (BICR)

Objektive Ansprechrate (BICR) – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 2.7.7 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) - Responder Analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	22 (34.9)	14 (25.5)	
85% CI [a]	(26.0, 44.7)	(17.1, 35.5)	
Odds ratio (85% CI) [b]			1.57 (0.87, 2.85)
Relative risk (85% CI) [b]			1.37 (0.91, 2.08)
Risk difference (85% CI) [c]			9.47 (-2.85, 21.39)
p-value [d]			0.2418

N: number of subjects in analysis set; n: number of subjects with event; %: proportion of number of subjects in analysis set; NE: not estimable
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 28FEB2025 - 7:30; Program name: t_2_7_1.sas; Output name: DE.T_ORR_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.7.5 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) - Responder Analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)			ICC (N=334)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
mFASA vs non-mFASA										0.7017	
mFASA	63	22 (34.9)	(23.3, 48.0)	55	14 (25.5)	(14.7, 39.0)	1.57 (0.71, 3.49)	1.37 (0.78, 2.41)	9.47 (-7.36, 25.57)		0.2673
non-mFASA	269	103 (38.3)	(32.5, 44.4)	279	69 (24.7)	(19.8, 30.2)	1.89 (1.31, 2.72)	1.55 (1.20, 2.00)	13.56 (5.80, 21.20)		0.0006

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADEFF
Run date: 28FEB2025 - 7:30; Program name: t_2_7_4.sas; Output name: DE.T_ORR_SUB_mFASA_Add.rtf

Objektive Ansprechrate (BICR) – Subgruppenanalysen

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Geographic region										0.0240	
Region 1 [US, Canada, Europe]	33	17 (51.5)	(33.5, 69.2)	28	6 (21.4)	(8.3, 41.0)	3.90 (1.26, 12.08)	2.40 (1.10, 5.26)	30.09 (5.63, 50.93)		0.0166
Region 2 [Rest of World]	30	5 (16.7)	(5.6, 34.7)	27	8 (29.6)	(13.8, 50.2)	0.48 (0.13, 1.69)	0.56 (0.21, 1.51)	-12.96 (-35.02, 9.24)		0.2484

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Prior use of CDK4/6 inhibitor										0.2680	
Yes	52	20 (38.5)	(25.3, 53.0)	45	11 (24.4)	(12.9, 39.5)	1.93 (0.80, 4.66)	1.57 (0.85, 2.92)	14.02 (-4.77, 31.64)		0.1419
No	11	2 (18.2)	(2.3, 51.8)	10	3 (30.0)	(6.7, 65.2)	0.52 (0.07, 4.00)	0.61 (0.13, 2.92)	-11.82 (-47.89, 25.98)		0.5354

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Prior use of taxanes and/or anthracyclines*										-	
Taxanes alone	19	4 (21.1)	-	13	6 (46.2)	-	-	-	-		-
Anthracyclines alone	1	0	-	3	0	-	-	-	-		-
Both taxanes and anthracyclines	32	14 (43.8)	-	30	6 (20.0)	-	-	-	-		-
Neither taxanes nor anthracyclines	11	4 (36.4)	-	9	2 (22.2)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Age at randomization										0.2871	
<65 years	52	15 (28.8)	(17.1, 43.1)	41	10 (24.4)	(12.4, 40.3)	1.26 (0.50, 3.19)	1.18 (0.59, 2.35)	4.46 (-14.16, 22.07)		0.6322
≥65 years	11	7 (63.6)	(30.8, 89.1)	14	4 (28.6)	(8.4, 58.1)	4.37 (0.81, 23.69)	2.23 (0.87, 5.71)	35.06 (-4.86, 65.58)		0.0858

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Race Asian										0.0657	
Asian	21	4 (19.0)	(5.4, 41.9)	21	7 (33.3)	(14.6, 57.0)	0.47 (0.11, 1.94)	0.57 (0.20, 1.66)	-14.29 (-39.97, 12.96)		0.2982
Non-Asian	32	13 (40.6)	(23.7, 59.4)	26	5 (19.2)	(6.6, 39.4)	2.87 (0.86, 9.58)	2.11 (0.87, 5.16)	21.39 (-2.87, 42.84)		0.0825

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Pre-selected choice of chemotherapy										0.5917	
Capecitabine	21	9 (42.9)	(21.8, 66.0)	9	4 (44.4)	(13.7, 78.8)	0.94 (0.19, 4.52)	0.96 (0.40, 2.33)	-1.59 (-38.18, 33.58)		0.9370
Eribulin mesylate	31	7 (22.6)	(9.6, 41.1)	41	9 (22.0)	(10.6, 37.6)	1.04 (0.34, 3.18)	1.03 (0.43, 2.46)	0.63 (-18.48, 21.09)		0.9496
Vinorelbine	11	6 (54.5)	(23.4, 83.3)	5	1 (20.0)	(0.5, 71.6)	4.80 (0.40, 58.01)	2.73 (0.44, 17.07)	34.55 (-19.16, 68.80)		0.2113

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Brain metastases										0.3264	
Yes	6	1 (16.7)	(0.4, 64.1)	6	2 (33.3)	(4.3, 77.7)	0.40 (0.03, 6.18)	0.50 (0.06, 4.15)	-16.67 (-61.00, 34.94)		0.5233
No	57	21 (36.8)	(24.4, 50.7)	49	12 (24.5)	(13.3, 38.9)	1.80 (0.77, 4.19)	1.50 (0.83, 2.73)	12.35 (-5.51, 29.22)		0.1729

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Sex*										-	
Male	1	1 (100)	-	1	0	-	-	-	-		-
Female	62	21 (33.9)	-	54	14 (25.9)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Race*										-	
White	31	13 (41.9)	-	24	5 (20.8)	-	-	-	-		-
Asian	21	4 (19.0)	-	21	7 (33.3)	-	-	-	-		-
Other*	1	0	-	2	0	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
ECOG PS at baseline										0.3235	
0	35	10 (28.6)	(14.6, 46.3)	33	9 (27.3)	(13.3, 45.5)	1.07 (0.37, 3.08)	1.05 (0.49, 2.25)	1.30 (-20.25, 22.52)		0.9057
≥1	28	12 (42.9)	(24.5, 62.8)	22	5 (22.7)	(7.8, 45.4)	2.55 (0.73, 8.87)	1.89 (0.78, 4.55)	20.13 (-6.78, 43.66)		0.1398

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*										-	
<6 months	3	1 (33.3)	-	6	0	-	-	-	-		-
≥6 months	49	18 (36.7)	-	42	12 (28.6)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Duration of prior use of breast cancer CDK4/6 inhibitor										0.9977	
≤12 months	22	9 (40.9)	(20.7, 63.6)	19	5 (26.3)	(9.1, 51.2)	1.94 (0.51, 7.32)	1.55 (0.63, 3.84)	14.59 (-14.98, 41.34)		0.3318
>12 months	29	10 (34.5)	(17.9, 54.3)	27	6 (22.2)	(8.6, 42.3)	1.84 (0.56, 6.04)	1.55 (0.65, 3.69)	12.26 (-11.86, 34.96)		0.3145

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Table 2.7.2 Objective Response Rate (ORR) per Blinded Independent Central Review (BICR) by subgroup - Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Early relapse*										-	
Yes	4	1 (25.0)	-	0	0	-	-	-	-		-
No	59	21 (35.6)	-	55	14 (25.5)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_ORR_SUB_mFASA_FA.rtf

Dauer des Ansprechens (BICR)

Dauer des Ansprechens (BICR) – Hauptanalyse - Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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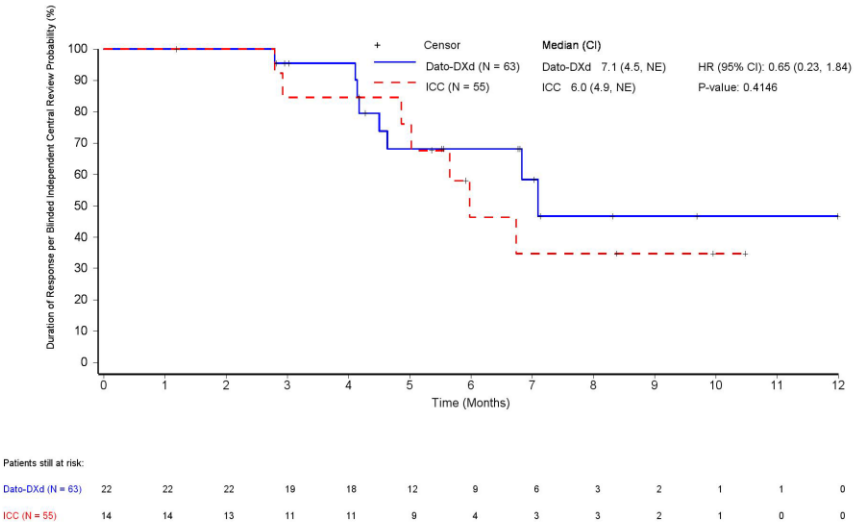
Final

Figure 2.9.1 Duration of Response (DoR) per Blinded Independent Central Review - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
CI: confidence interval, NE: not estimable

Data source: ADAM.ADTTE
Run date: 21FEB2025 - 11:24; Program name: F_2_3_1.sas; Output name: DE.F_DOR_mFASA.rtf

Dauer des Ansprechens (BICR) – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	8 (12.7)	7 (12.7)	
Number of subjects censored, n (%)	14 (22.2)	7 (12.7)	
Median time to first event (months) [a]	7.1	6.0	
85% Confidence Interval	(4.6 , NE)	(5.0 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.65
85% Confidence Interval			(0.30, 1.39)
Stratified log-rank p-value [c]			0.4146

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_6.sas; Output name: DE.T_DoR_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.8.3 Duration of Response (DoR) per Blinded Independent Central Review (BICR) - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.9991
mFASA	63	8 (12.7)	14 (22.2)	7.1 (4.5 , NE)	55	7 (12.7)	7 (12.7)	6.0 (4.9 , NE)	0.72 (0.26, 1.99)	0.5255	
non-mFASA	269	53 (19.7)	50 (18.6)	6.0 (5.6 , 7.1)	279	34 (12.2)	35 (12.5)	5.6 (4.1 , 6.8)	0.73 (0.47, 1.13)	0.1476	

N: number of subjects in analysis set; n: number of subjects with event; %: proportion of number of subjects in analysis set; ICC: Investigator's Choice of Chemotherapy;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:29; Program name: t_2_8_4.sas; Output name: DE.T_DoR_SUB_mFASA_Add.rtf

Dauer des Ansprechens (BICR) – Subgruppenanalysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.8603
Region 1 [US, Canada, Europe]	33	6 (18.2)	11 (33.3)	6.8 (4.2, NE)	28	4 (14.3)	2 (7.1)	5.5 (2.9, NE)	0.72 (0.20, 2.55)	0.6039	
Region 2 [Rest of World]	30	2 (6.7)	3 (10.0)	NE (4.1, NE)	27	3 (11.1)	5 (18.5)	6.7 (2.8, NE)	0.50 (0.08, 3.23)	0.4627	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.7658
Yes	52	7 (13.5)	13 (25.0)	7.1 (4.5, NE)	45	6 (13.3)	5 (11.1)	6.0 (2.9, NE)	0.68 (0.23, 2.02)	0.4831	
No	11	1 (9.1)	1 (9.1)	NE (4.1, NE)	10	1 (10.0)	2 (20.0)	5.7 (NE, NE)	1.00 (0.06, 15.99)	>0.9999	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	2 (10.5)	-	13	3 (23.1)	3 (23.1)	-	-	-	
Anthracyclines alone	1	0	0	-	3	0	0	-	-	-	
Both taxanes and anthracyclines	32	5 (15.6)	9 (28.1)	-	30	4 (13.3)	2 (6.7)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	3 (27.3)	-	9	0	2 (22.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.5310
<65 years	52	6 (11.5)	9 (17.3)	NE (4.2, NE)	41	6 (14.6)	4 (9.8)	6.0 (2.8, NE)	0.59 (0.19, 1.85)	0.3642	
≥65 years	11	2 (18.2)	5 (45.5)	7.1 (4.1, NE)	14	1 (7.1)	3 (21.4)	NE (5.7, NE)	1.49 (0.13, 16.84)	0.7432	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	2 (9.5)	2 (9.5)	-	21	3 (14.3)	4 (19.0)	-	-	-	
Non-Asian	32	5 (15.6)	8 (25.0)	-	26	2 (7.7)	3 (11.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	3 (14.3)	6 (28.6)	-	9	1 (11.1)	3 (33.3)	-	-	-	
Eribulin mesylate	31	1 (3.2)	6 (19.4)	-	41	5 (12.2)	4 (9.8)	-	-	-	
Vinorelbine	11	4 (36.4)	2 (18.2)	-	5	1 (20.0)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.0884
Yes	6	1 (16.7)	0	2.8 (NE, NE)	6	2 (33.3)	0	4.8 (2.8, NE)	2.45 (0.15, 39.72)	0.4795	
No	57	7 (12.3)	14 (24.6)	7.1 (4.6, NE)	49	5 (10.2)	7 (14.3)	6.0 (4.9, NE)	0.83 (0.26, 2.63)	0.7550	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	0	-	-	-	
Female	62	8 (12.9)	13 (21.0)	-	54	7 (13.0)	7 (13.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	5 (16.1)	8 (25.8)	-	24	2 (8.3)	3 (12.5)	-	-	-	
Asian	21	2 (9.5)	2 (9.5)	-	21	3 (14.3)	4 (19.0)	-	-	-	
Other*	1	0	0	-	2	0	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0714
0	35	3 (8.6)	7 (20.0)	NE (4.2, NE)	33	2 (6.1)	7 (21.2)	NE (5.7, NE)	1.89 (0.31, 11.49)	0.4812	
≥1	28	5 (17.9)	7 (25.0)	7.1 (4.1, NE)	22	5 (22.7)	0	4.9 (2.8, NE)	0.19 (0.05, 0.82)	0.0129	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	1 (33.3)	-	6	0	0	-	-	-	
≥6 months	49	7 (14.3)	11 (22.4)	-	42	6 (14.3)	6 (14.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	5 (22.7)	4 (18.2)	-	19	3 (15.8)	2 (10.5)	-	-	-	
>12 months	29	2 (6.9)	8 (27.6)	-	27	3 (11.1)	3 (11.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Table 2.8.2 Duration of Response (DoR) per Blinded Independent Central Review (BICR) by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	1 (25.0)	-	0	0	0	-	-	-	
No	59	8 (13.6)	13 (22.0)	-	55	7 (12.7)	7 (12.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_DOR_SUB_mFASA_FA.rtf

Dauer des Ansprechens (BICR) – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 2.9.2 Duration of Response per Blinded Independent Central Review by subgroup - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 10:47; Program name: f_2_11_2.sas; Output name: DE.F_DOR_SUB_mFASA_FA.rtf

Krankheitskontrollrate (BICR)

Krankheitskontrollrate (BICR) – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 2.10.5 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) - Responder Analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	49 (77.8)	37 (67.3)	
85% CI [a]	(68.7, 85.2)	(56.8, 76.6)	
Odds ratio (85% CI) [b]			1.71 (0.93, 3.11)
Relative risk (85% CI) [b]			1.16 (0.98, 1.37)
Risk difference (85% CI) [c]			10.51 (-1.35, 22.37)
p-value [d]			0.2212

N: number of subjects in analysis set; n: number of subjects with event; %: proportion of number of subjects in analysis set; NE: not estimable
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 28FEB2025 - 7:29; Program name: t_2_7_1.sas; Output name: DE.T_DCR_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.10.3 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) - Responder Analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)			ICC (N=334)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
mFASA vs non-mFASA										0.9998	
mFASA	63	49 (77.8)	(65.5, 87.3)	55	37 (67.3)	(53.3, 79.3)	1.70 (0.75, 3.86)	1.16 (0.92, 1.45)	10.51 (-5.64, 26.61)		0.2023
non-mFASA	269	204 (75.8)	(70.3, 80.8)	279	183 (65.6)	(59.7, 71.2)	1.65 (1.13, 2.39)	1.16 (1.04, 1.29)	10.25 (2.62, 17.76)		0.0085

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADEFF
Run date: 28FEB2025 - 7:29; Program name: t_2_7_4.sas; Output name: DE.T_DCR_SUB_mFASA_Add.rtf

Krankheitskontrollrate (BICR) – Subgruppenanalysen

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Geographic region										0.3909	
Region 1 [US, Canada, Europe]	33	27 (81.8)	(64.5, 93.0)	28	18 (64.3)	(44.1, 81.4)	2.50 (0.77, 8.09)	1.27 (0.92, 1.75)	17.53 (-4.84, 39.35)		0.1239
Region 2 [Rest of World]	30	22 (73.3)	(54.1, 87.7)	27	19 (70.4)	(49.8, 86.2)	1.16 (0.36, 3.68)	1.04 (0.75, 1.44)	2.96 (-20.33, 26.49)		0.8054

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Prior use of CDK4/6 inhibitor										0.9636	
Yes	52	40 (76.9)	(63.2, 87.5)	45	30 (66.7)	(51.0, 80.0)	1.67 (0.68, 4.08)	1.15 (0.89, 1.49)	10.26 (-7.69, 28.14)		0.2635
No	11	9 (81.8)	(48.2, 97.7)	10	7 (70.0)	(34.8, 93.3)	1.93 (0.25, 14.89)	1.17 (0.71, 1.91)	11.82 (-25.98, 47.89)		0.5354

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Prior use of taxanes and/or anthracyclines*										-	
Taxanes alone	19	18 (94.7)	-	13	10 (76.9)	-	-	-	-		-
Anthracyclines alone	1	1 (100)	-	3	2 (66.7)	-	-	-	-		-
Both taxanes and anthracyclines	32	21 (65.6)	-	30	18 (60.0)	-	-	-	-		-
Neither taxanes nor anthracyclines	11	9 (81.8)	-	9	7 (77.8)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Age at randomization										0.8851	
<65 years	52	38 (73.1)	(59.0, 84.4)	41	25 (61.0)	(44.5, 75.8)	1.74 (0.72, 4.18)	1.20 (0.89, 1.61)	12.10 (-7.04, 31.03)		0.2177
≥65 years	11	11 (100)	(71.5, 100.0)	14	12 (85.7)	(57.2, 98.2)	48212.04* (0.00, 5.2509E142)	1.15 (0.89, 1.48)	14.29 (-14.22, 40.53)		0.2004

*: inflated estimate due to small sample size
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Race Asian										0.4453	
Asian	21	14 (66.7)	(43.0, 85.4)	21	11 (52.4)	(29.8, 74.3)	1.82 (0.52, 6.33)	1.27 (0.77, 2.11)	14.29 (-15.48, 41.73)		0.3514
Non-Asian	32	25 (78.1)	(60.0, 90.7)	26	20 (76.9)	(56.4, 91.0)	1.07 (0.31, 3.70)	1.02 (0.77, 1.34)	1.20 (-20.31, 23.85)		0.9138

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Pre-selected choice of chemotherapy										0.4003	
Capecitabine	21	19 (90.5)	(69.6, 98.8)	9	6 (66.7)	(29.9, 92.5)	4.75 (0.64, 35.48)	1.36 (0.84, 2.20)	23.81 (-5.33, 57.45)		0.1149
Eribulin mesylate	31	22 (71.0)	(52.0, 85.8)	41	29 (70.7)	(54.5, 83.9)	1.01 (0.36, 2.82)	1.00 (0.74, 1.35)	0.24 (-21.45, 20.87)		0.9827
Vinorelbine	11	8 (72.7)	(39.0, 94.0)	5	2 (40.0)	(5.3, 85.3)	4.00 (0.43, 37.11)	1.82 (0.59, 5.64)	32.73 (-17.89, 71.00)		0.2249

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Brain metastases										0.7574	
Yes	6	4 (66.7)	(22.3, 95.7)	6	3 (50.0)	(11.8, 88.2)	2.00 (0.19, 20.61)	1.33 (0.50, 3.55)	16.67 (-37.67, 62.51)		0.5751
No	57	45 (78.9)	(66.1, 88.6)	49	34 (69.4)	(54.6, 81.7)	1.65 (0.69, 3.99)	1.14 (0.90, 1.43)	9.56 (-7.15, 26.38)		0.2623

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Sex*										-	
Male	1	1 (100)	-	1	1 (100)	-	-	-	-		-
Female	62	48 (77.4)	-	54	36 (66.7)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Race*										-	
White	31	25 (80.6)	-	24	18 (75.0)	-	-	-	-		-
Asian	21	14 (66.7)	-	21	11 (52.4)	-	-	-	-		-
Other*	1	0	-	2	2 (100)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
ECOG PS at baseline										0.5651	
0	35	28 (80.0)	(63.1, 91.6)	33	24 (72.7)	(54.5, 86.7)	1.50 (0.49, 4.64)	1.10 (0.84, 1.44)	7.27 (-13.22, 27.70)		0.4831
≥1	28	21 (75.0)	(55.1, 89.3)	22	13 (59.1)	(36.4, 79.3)	2.08 (0.62, 6.94)	1.27 (0.84, 1.91)	15.91 (-10.21, 41.05)		0.2360

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*										-	
<6 months	3	2 (66.7)	-	6	4 (66.7)	-	-	-	-		-
≥6 months	49	39 (79.6)	-	42	29 (69.0)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Duration of prior use of breast cancer CDK4/6 inhibitor										0.1157	
≤12 months	22	17 (77.3)	(54.6, 92.2)	19	16 (84.2)	(60.4, 96.6)	0.64 (0.13, 3.11)	0.92 (0.68, 1.24)	-6.94 (-31.41, 19.16)		0.5809
>12 months	29	22 (75.9)	(56.5, 89.7)	27	15 (55.6)	(35.3, 74.5)	2.51 (0.80, 7.86)	1.37 (0.92, 2.03)	20.31 (-4.75, 43.37)		0.1120

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Table 2.10.2 Disease Control Rate (DCR) per Blinded Independent Central Review (BICR) by subgroup- Responder Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)			ICC (N=55)			Dato-DXd vs ICC				
	n	No. of subjects with events (%)	95% CI [a]	n	No. of subjects with events (%)	95% CI [a]	Odds Ratio (95% CI) [b]	Relative risk (95% CI) [b]	Risk Difference (95% CI) [c]	Interaction P-value [d]	P-value [e]
Early relapse*										-	
Yes	4	2 (50.0)	-	0	0	-	-	-	-		-
No	59	47 (79.7)	-	55	37 (67.3)	-	-	-	-		-

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; ICC: Investigator's Choice of Chemotherapy; NE: not estimable.
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. Confidence interval is the continuity corrected Wald asymptotic confidence interval for the risk differences
[d] Two-sided p-value from Cochran Q-test assessing homogeneity of treatment effect
[e] Two-sided p-value based on the Cochran-Mantel-Haenszel test

Data source: ADAM.ADEFF
Run date: 06MAY2025 - 10:47; Program name: t_2_7_3.sas; Output name: DE.T_DCR_SUB_mFASA_FA.rtf

Zeit bis zur Folgetherapie

Zeit bis zur ersten Folgetherapie

Zeit bis zur ersten Folgetherapie – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Final

Table 2.11.2 First Subsequent Therapy - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_TFST_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.11.5 First Subsequent Therapy - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.9830
mFASA	63	59 (93.7)	4 (6.3)	8.3 (5.6 , 10.7)	55	53 (96.4)	2 (3.6)	4.5 (3.3 , 6.0)	0.60 (0.41, 0.88)	0.0077	
non-mFASA	269	228 (84.8)	41 (15.2)	8.2 (7.8 , 9.0)	279	250 (89.6)	29 (10.4)	5.5 (4.9 , 6.1)	0.60 (0.50, 0.71)	<0.0001	

N: number of subjects in analysis set; n: number of subjects with event; %: proportion of number of subjects in analysis set; ICC: Investigator's Choice of Chemotherapy;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_4.sas; Output name: DE.T_TFST_SUB_mFASA_Add.rtf

Zeit bis zur ersten Folgetherapie – Subgruppenanalysen

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9463
Region 1 [US, Canada, Europe]	33	31 (93.9)	2 (6.1)	8.3 (4.4, 11.1)	28	27 (96.4)	1 (3.6)	4.4 (2.2, 6.2)	0.57 (0.34, 0.96)	0.0327	
Region 2 [Rest of World]	30	28 (93.3)	2 (6.7)	8.3 (5.6, 12.0)	27	26 (96.3)	1 (3.7)	5.0 (2.5, 6.6)	0.62 (0.36, 1.07)	0.0847	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.8367
Yes	52	48 (92.3)	4 (7.7)	8.1 (5.3, 10.7)	45	44 (97.8)	1 (2.2)	4.5 (3.1, 6.2)	0.59 (0.39, 0.89)	0.0118	
No	11	11 (100)	0	8.8 (2.4, 15.8)	10	9 (90.0)	1 (10.0)	5.0 (1.6, 6.4)	0.71 (0.29, 1.76)	0.4675	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	18 (94.7)	1 (5.3)	-	13	12 (92.3)	1 (7.7)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	3 (100)	0	-	-	-	
Both taxanes and anthracyclines	32	30 (93.8)	2 (6.3)	-	30	30 (100)	0	-	-	-	
Neither taxanes nor anthracyclines	11	10 (90.9)	1 (9.1)	-	9	8 (88.9)	1 (11.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.6372
<65 years	52	48 (92.3)	4 (7.7)	6.2 (4.8, 9.9)	41	39 (95.1)	2 (4.9)	4.2 (2.2, 5.5)	0.62 (0.40, 0.95)	0.0267	
≥65 years	11	11 (100)	0	13.4 (6.3, 15.8)	14	14 (100)	0	6.0 (3.7, 10.2)	0.43 (0.18, 1.00)	0.0441	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.2106
Asian	21	19 (90.5)	2 (9.5)	6.3 (4.8, 10.1)	21	21 (100)	0	3.1 (1.6, 5.8)	0.52 (0.28, 0.99)	0.0420	
Non-Asian	32	31 (96.9)	1 (3.1)	8.1 (4.4, 11.1)	26	24 (92.3)	2 (7.7)	5.2 (3.9, 6.6)	0.77 (0.45, 1.33)	0.3525	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1815
Capecitabine	21	19 (90.5)	2 (9.5)	9.7 (3.6, 12.0)	9	8 (88.9)	1 (11.1)	9.7 (1.2, 15.8)	0.80 (0.35, 1.84)	0.5989	
Eribulin mesylate	31	29 (93.5)	2 (6.5)	6.3 (4.7, 11.1)	41	40 (97.6)	1 (2.4)	4.9 (3.3, 6.2)	0.62 (0.38, 1.00)	0.0481	
Vinorelbine	11	11 (100)	0	8.8 (4.4, 14.4)	5	5 (100)	0	2.2 (0.7, NE)	0.08 (0.01, 0.43)	0.0003	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.4643
Yes	6	6 (100)	0	5.9 (3.6, NE)	6	6 (100)	0	3.3 (1.4, NE)	0.43 (0.12, 1.55)	0.1854	
No	57	53 (93.0)	4 (7.0)	8.8 (5.6, 11.1)	49	47 (95.9)	2 (4.1)	4.5 (3.7, 6.2)	0.62 (0.42, 0.93)	0.0186	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	1 (100)	0	-	-	-	
Female	62	58 (93.5)	4 (6.5)	-	54	52 (96.3)	2 (3.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	30 (96.8)	1 (3.2)	-	24	22 (91.7)	2 (8.3)	-	-	-	
Asian	21	19 (90.5)	2 (9.5)	-	21	21 (100)	0	-	-	-	
Other*	1	1 (100)	0	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0032
0	35	33 (94.3)	2 (5.7)	6.8 (5.3, 10.1)	33	31 (93.9)	2 (6.1)	5.8 (3.9, 7.5)	0.89 (0.54, 1.45)	0.6263	
≥1	28	26 (92.9)	2 (7.1)	9.4 (4.4, 13.4)	22	22 (100)	0	3.8 (1.7, 5.0)	0.27 (0.14, 0.54)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	6 (100)	0	-	-	-	
≥6 months	49	45 (91.8)	4 (8.2)	-	42	40 (95.2)	2 (4.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.9092
≤12 months	22	22 (100)	0	7.3 (4.2, 10.1)	19	19 (100)	0	5.0 (3.3, 6.5)	0.54 (0.28, 1.02)	0.0532	
>12 months	29	25 (86.2)	4 (13.8)	8.3 (4.9, 13.4)	27	26 (96.3)	1 (3.7)	4.2 (1.7, 9.7)	0.62 (0.36, 1.07)	0.0851	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Table 2.11.2 First Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	4 (100)	0	-	0	0	0	-	-	-	
No	59	55 (93.2)	4 (6.8)	-	55	53 (96.4)	2 (3.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TFST_SUB_mFASA_FA.rtf

Zeit bis zur ersten Folgetherapie – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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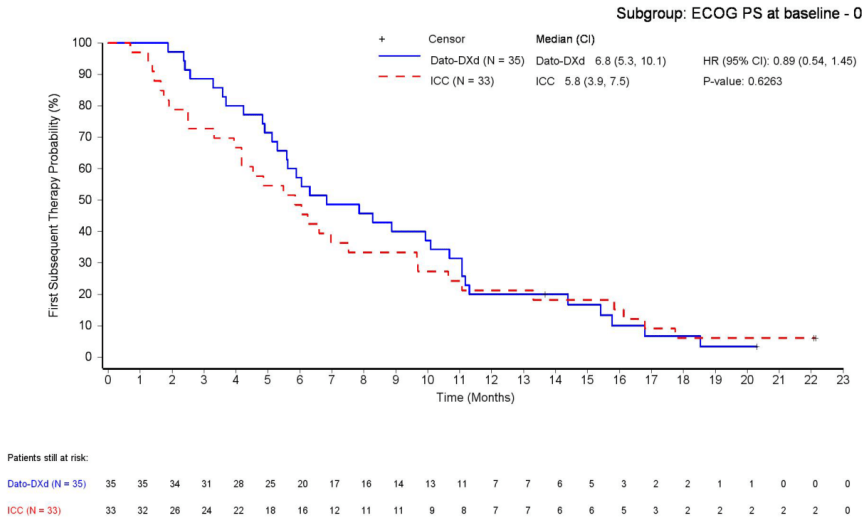
Figure 2.11.2 First Subsequent Therapy by subgroup - Kaplan Meier Plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: f_2_11_2.sas; Output name: DE.F_TFST_SUB_mFASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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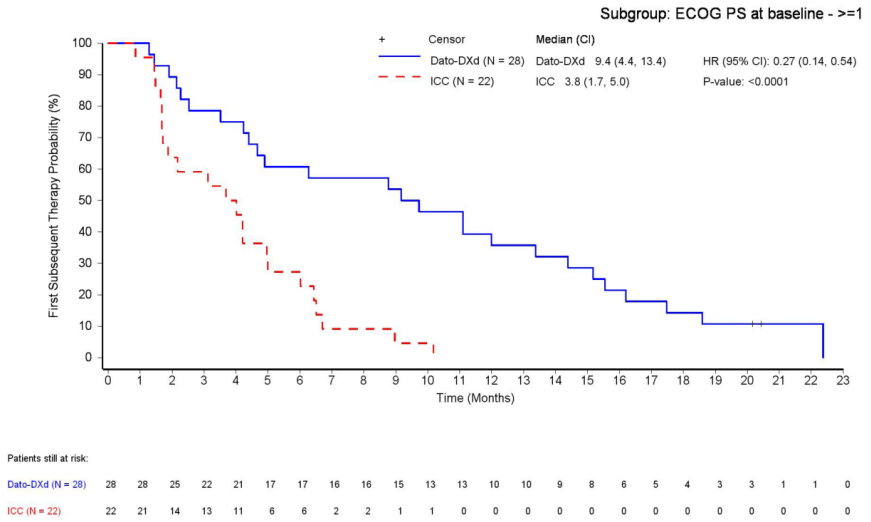
Figure 2.11.2 First Subsequent Therapy by subgroup - Kaplan Meier Plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: f_2_11_2.sas; Output name: DE.F_TFST_SUB_mFASA_FA.rtf

Zeit bis zur zweiten Folgetherapie

Zeit bis zur zweiten Folgetherapie – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 2.12.3 Second Subsequent Therapy - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	54 (85.7)	46 (83.6)	
Number of subjects censored, n (%)	9 (14.3)	9 (16.4)	
Median time to first event (months) [a]	12.0	9.7	
85% Confidence Interval	(11.2 , 15.0)	(8.7 , 11.4)	
Cox proportional hazards model [b]			
Hazard Ratio			0.81
85% Confidence Interval			(0.60, 1.09)
Stratified log-rank p-value [c]			0.3064

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_6.sas; Output name: DE.T_TSST_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Table 2.12.5 Second Subsequent Therapy - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.8315
mFASA	63	54 (85.7)	9 (14.3)	12.0 (11.0 , 15.7)	55	46 (83.6)	9 (16.4)	9.7 (8.5 , 12.2)	0.84 (0.57, 1.25)	0.3933	
non-mFASA	269	190 (70.6)	79 (29.4)	14.6 (13.4 , 16.3)	279	203 (72.8)	76 (27.2)	13.0 (11.2 , 14.4)	0.80 (0.66, 0.98)	0.0297	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; ICC: Investigator's Choice of Chemotherapy; CI: confidence interval;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADTTE
Run date: 20MAR2025 - 7:18; Program name: t_4_52_4.sas; Output name: DE.T_TSST_SUB_mFASA_Add.rtf

Zeit bis zur zweiten Folgetherapie – Subgruppenanalysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.5764
Region 1 [US, Canada, Europe]	33	29 (87.9)	4 (12.1)	11.8 (9.7, 15.7)	28	26 (92.9)	2 (7.1)	9.6 (6.7, 11.0)	0.77 (0.45, 1.32)	0.3479	
Region 2 [Rest of World]	30	25 (83.3)	5 (16.7)	13.2 (9.2, 17.5)	27	20 (74.1)	7 (25.9)	11.4 (7.8, 15.9)	0.95 (0.52, 1.71)	0.8525	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9015
Yes	52	44 (84.6)	8 (15.4)	11.8 (10.0, 16.2)	45	38 (84.4)	7 (15.6)	9.7 (7.8, 12.5)	0.83 (0.54, 1.29)	0.4161	
No	11	10 (90.9)	1 (9.1)	14.0 (4.4, 17.5)	10	8 (80.0)	2 (20.0)	9.5 (3.7, 15.9)	0.78 (0.30, 2.01)	0.6118	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	15 (78.9)	4 (21.1)	-	13	11 (84.6)	2 (15.4)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	28 (87.5)	4 (12.5)	-	30	28 (93.3)	2 (6.7)	-	-	-	
Neither taxanes nor anthracyclines	11	10 (90.9)	1 (9.1)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.2222
<65 years	52	44 (84.6)	8 (15.4)	11.7 (9.9, 14.0)	41	37 (90.2)	4 (9.8)	9.5 (7.3, 11.0)	0.69 (0.44, 1.07)	0.0936	
≥65 years	11	10 (90.9)	1 (9.1)	17.4 (7.6, 18.6)	14	9 (64.3)	5 (35.7)	13.2 (7.8, NE)	1.30 (0.53, 3.23)	0.5663	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.6590
Asian	21	17 (81.0)	4 (19.0)	11.2 (7.4, 16.2)	21	16 (76.2)	5 (23.8)	9.0 (4.8, 13.0)	0.91 (0.46, 1.80)	0.7865	
Non-Asian	32	28 (87.5)	4 (12.5)	12.0 (9.6, 16.6)	26	23 (88.5)	3 (11.5)	9.5 (8.5, 13.1)	0.74 (0.43, 1.30)	0.2973	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3445
Capecitabine	21	14 (66.7)	7 (33.3)	16.2 (8.2, 21.1)	9	6 (66.7)	3 (33.3)	14.2 (4.7, NE)	1.07 (0.41, 2.78)	0.8957	
Eribulin mesylate	31	29 (93.5)	2 (6.5)	11.7 (9.6, 15.7)	41	35 (85.4)	6 (14.6)	9.5 (7.8, 12.2)	0.97 (0.59, 1.60)	0.9200	
Vinorelbine	11	11 (100)	0	11.8 (7.2, 17.8)	5	5 (100)	0	8.8 (3.5, NE)	0.20 (0.05, 0.87)	0.0177	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.3915
Yes	6	5 (83.3)	1 (16.7)	9.3 (4.9, NE)	6	6 (100)	0	8.9 (4.8, NE)	0.56 (0.16, 1.98)	0.3581	
No	57	49 (86.0)	8 (14.0)	12.4 (11.0, 16.2)	49	40 (81.6)	9 (18.4)	9.7 (8.5, 13.0)	0.89 (0.59, 1.36)	0.6028	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	1 (100)	0	-	-	-	
Female	62	54 (87.1)	8 (12.9)	-	54	45 (83.3)	9 (16.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	27 (87.1)	4 (12.9)	-	24	21 (87.5)	3 (12.5)	-	-	-	
Asian	21	17 (81.0)	4 (19.0)	-	21	16 (76.2)	5 (23.8)	-	-	-	
Other*	1	1 (100)	0	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0011
0	35	31 (88.6)	4 (11.4)	11.7 (9.2, 15.0)	33	25 (75.8)	8 (24.2)	12.5 (8.7, 17.7)	1.43 (0.83, 2.45)	0.1931	
≥1	28	23 (82.1)	5 (17.9)	15.1 (9.7, 17.8)	22	21 (95.5)	1 (4.5)	8.5 (5.0, 10.6)	0.40 (0.21, 0.74)	0.0028	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	5 (83.3)	1 (16.7)	-	-	-	
≥6 months	49	42 (85.7)	7 (14.3)	-	42	34 (81.0)	8 (19.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.2871
≤12 months	22	21 (95.5)	1 (4.5)	11.7 (9.6, 15.3)	19	15 (78.9)	4 (21.1)	9.7 (7.3, 13.0)	1.08 (0.55, 2.10)	0.8237	
>12 months	29	23 (79.3)	6 (20.7)	12.7 (7.4, 18.2)	27	23 (85.2)	4 (14.8)	9.8 (5.4, 15.5)	0.77 (0.43, 1.38)	0.3772	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Table 2.12.2 Second Subsequent Therapy by subgroup - Time-to-event Analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	4 (100)	0	-	0	0	0	-	-	-	
No	59	50 (84.7)	9 (15.3)	-	55	46 (83.6)	9 (16.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: t_2_11_2.sas; Output name: DE.T_TSST_SUB_mFASA_FA.rtf

Zeit bis zur zweiten Folgetherapie – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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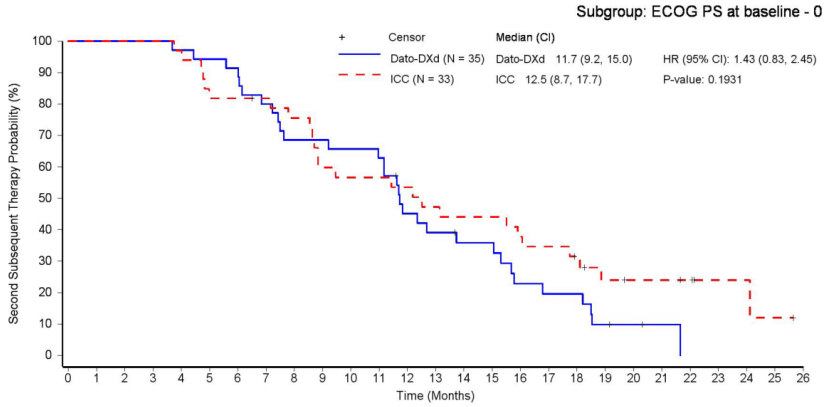
Figure 2.12.2 Second Subsequent Therapy by subgroup - Kaplan Meier Plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Patients still at risk:

Dato-DXd (N = 35)	35	35	35	35	34	33	32	28	24	24	23	22	15	13	11	11	7	6	6	3	2	1	0	0	0	0	0
ICC (N = 33)	33	33	33	33	32	27	27	26	24	19	18	18	17	15	14	14	12	11	9	6	5	5	4	2	2	1	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: f_2_11_2.sas; Output name: DE.F_TSST_SUB_mFASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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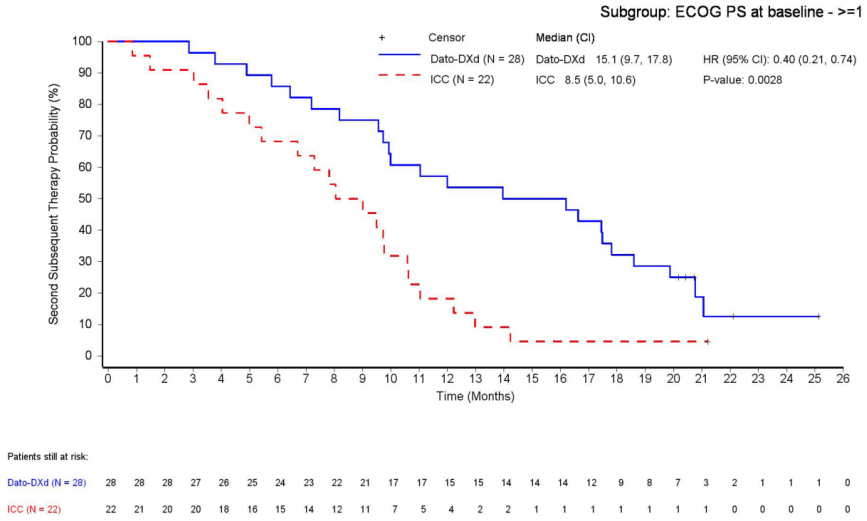
Figure 2.12.2 Second Subsequent Therapy by subgroup - Kaplan Meier Plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTE
Run date: 06MAY2025 - 11:01; Program name: f_2_11_2.sas; Output name: DE.F_TSST_SUB_mFASA_FA.rtf

EORTC QLQ-C30

EORTC QLQ-C30 – Zeit bis zur ersten Verschlechterung

EORTC QLQ-C30 – Zeit bis zur ersten Verschlechterung – Prüfung der Kriterien der Anhebungsregel

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with PRO baseline measurement, n (%)	45 (71.4)	36 (65.5)	
Number of subjects with at least one PRO post-baseline measurement, n (%)	45 (71.4)	34 (61.8)	
Number of subjects with events, n (%)	30 (47.6)	23 (41.8)	
Number of subjects censored, n (%)	33 (52.4)	32 (58.2)	
Median time to first event (months) [a]	2.8	2.1	
85% Confidence Interval	(1.4 , 4.1)	(1.4 , 3.5)	
Cox proportional hazards model [b]			
Hazard Ratio			0.75
85% Confidence Interval			(0.50, 1.13)
Stratified log-rank p-value [c]			0.3345

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

Stopped at step 3

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with PRO baseline measurement, n (%)	45 (71.4)	36 (65.5)	
Number of subjects with at least one PRO post-baseline measurement, n (%)	45 (71.4)	34 (61.8)	
Number of subjects with events, n (%)	25 (39.7)	21 (38.2)	
Number of subjects censored, n (%)	38 (60.3)	34 (61.8)	
Median time to first event (months) [a]	5.6	2.8	
85% Confidence Interval	(2.2 , 11.0)	(1.4 , 3.5)	
Cox proportional hazards model [b]			
Hazard Ratio			0.61
85% Confidence Interval			(0.39, 0.95)
Stratified log-rank p-value [c]			0.1021

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with PRO baseline measurement, n (%)	45 (71.4)	36 (65.5)	
Number of subjects with at least one PRO post-baseline measurement, n (%)	45 (71.4)	34 (61.8)	
Number of subjects with events, n (%)	18 (28.6)	15 (27.3)	
Number of subjects censored, n (%)	45 (71.4)	40 (72.7)	
Median time to first event (months) [a]	8.3	5.6	
85% Confidence Interval	(5.5 , NE)	(4.8 , 9.7)	
Cox proportional hazards model [b]			
Hazard Ratio			0.73
85% Confidence Interval			(0.44, 1.22)
Stratified log-rank p-value [c]			0.3824

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

Stopped at step 3

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with PRO baseline measurement, n (%)	45 (71.4)	36 (65.5)	
Number of subjects with at least one PRO post-baseline measurement, n (%)	45 (71.4)	34 (61.8)	
Number of subjects with events, n (%)	14 (22.2)	14 (25.5)	
Number of subjects censored, n (%)	49 (77.8)	41 (74.5)	
Median time to first event (months) [a]	NE	5.5	
85% Confidence Interval	(6.2 , NE)	(2.8 , 7.6)	
Cox proportional hazards model [b]			
Hazard Ratio			0.48
85% Confidence Interval			(0.28, 0.84)
Stratified log-rank p-value [c]			0.0546

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.6 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_QLQC30_FD_INC_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

Global Health Status

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.9274
mFASA	63	30 (47.6)	33 (52.4)	2.8 (1.4 , 5.6)	55	23 (41.8)	32 (58.2)	2.1 (1.4 , 4.1)	0.82 (0.47, 1.41)	0.4803	
non-mFASA	269	125 (46.5)	144 (53.5)	3.5 (2.1 , 5.1)	279	121 (43.4)	158 (56.6)	2.1 (1.4 , 2.8)	0.79 (0.61, 1.02)	0.0633	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Functional Scales - Physical Functioning

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.3049
mFASA	63	23 (36.5)	40 (63.5)	5.6 (2.1 , NE)	55	15 (27.3)	40 (72.7)	5.5 (1.4 , NE)	1.03 (0.53, 1.97)	0.9219	
non-mFASA	269	99 (36.8)	170 (63.2)	5.6 (3.5 , 12.4)	279	110 (39.4)	169 (60.6)	3.4 (2.1 , 4.2)	0.69 (0.52, 0.90)	0.0059	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Functional Scales - Role Functioning

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6371
mFASA	63	27 (42.9)	36 (57.1)	4.2 (1.4 , 5.7)	55	20 (36.4)	35 (63.6)	2.8 (0.8 , 6.2)	0.98 (0.55, 1.75)	0.9770	
non-mFASA	269	122 (45.4)	147 (54.6)	2.8 (2.1 , 4.2)	279	123 (44.1)	156 (55.9)	2.1 (1.4 , 2.8)	0.82 (0.63, 1.05)	0.1055	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Functional Scales - Emotional Functioning

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.9760
mFASA	63	22 (34.9)	41 (65.1)	7.1 (3.5 , NE)	55	13 (23.6)	42 (76.4)	6.3 (3.5 , NE)	0.88 (0.44, 1.77)	0.7385	
non-mFASA	269	95 (35.3)	174 (64.7)	7.0 (5.0 , 11.1)	279	85 (30.5)	194 (69.5)	5.7 (4.2 , 11.1)	0.88 (0.66, 1.19)	0.4144	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Functional Scales - Cognitive Functioning

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.5893
mFASA	63	27 (42.9)	36 (57.1)	2.2 (1.4 , 8.3)	55	23 (41.8)	32 (58.2)	2.1 (1.4 , 3.5)	0.76 (0.44, 1.33)	0.3344	
non-mFASA	269	121 (45.0)	148 (55.0)	3.5 (2.2 , 4.2)	279	112 (40.1)	167 (59.9)	2.8 (2.1 , 3.6)	0.88 (0.68, 1.14)	0.3432	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Functional Scales - Social Functioning

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6260
mFASA	63	25 (39.7)	38 (60.3)	5.6 (2.1 , 12.5)	55	21 (38.2)	34 (61.8)	2.8 (1.4 , 6.2)	0.66 (0.37, 1.20)	0.1660	
non-mFASA	269	115 (42.8)	154 (57.2)	3.5 (2.2 , 4.3)	279	115 (41.2)	164 (58.8)	2.1 (1.5 , 2.8)	0.79 (0.61, 1.03)	0.0794	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

Symptom Scales - Fatigue

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.0548
mFASA	63	30 (47.6)	33 (52.4)	2.2 (1.4 , 5.5)	55	29 (52.7)	26 (47.3)	1.3 (0.7 , 1.4)	0.49 (0.29, 0.81)	0.0057	
non-mFASA	269	143 (53.2)	126 (46.8)	2.0 (1.4 , 2.8)	279	137 (49.1)	142 (50.9)	1.4 (1.4 , 1.5)	0.85 (0.67, 1.07)	0.1615	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6068
mFASA	63	23 (36.5)	40 (63.5)	7.0 (2.8 , NE)	55	15 (27.3)	40 (72.7)	4.8 (1.4 , NE)	0.91 (0.47, 1.75)	0.7720	
non-mFASA	269	132 (49.1)	137 (50.9)	2.8 (2.1 , 3.6)	279	108 (38.7)	171 (61.3)	3.4 (1.5 , 5.9)	1.05 (0.82, 1.36)	0.6846	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

Symptom Scales - Pain

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.0032
mFASA	63	18 (28.6)	45 (71.4)	9.7 (4.2 , NE)	55	22 (40.0)	33 (60.0)	2.1 (0.8 , 2.8)	0.36 (0.19, 0.67)	0.0009	
non-mFASA	269	126 (46.8)	143 (53.2)	2.8 (2.1 , 4.8)	279	112 (40.1)	167 (59.9)	2.8 (2.1 , 4.2)	0.98 (0.76, 1.27)	0.8709	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Dyspnea

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6473
mFASA	63	18 (28.6)	45 (71.4)	8.3 (4.2 , NE)	55	15 (27.3)	40 (72.7)	5.6 (2.8 , NE)	0.67 (0.34, 1.35)	0.2663	
non-mFASA	269	77 (28.6)	192 (71.4)	12.5 (7.6 , NE)	279	102 (36.6)	177 (63.4)	3.5 (2.8 , 6.9)	0.55 (0.41, 0.74)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Insomnia

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.7427
mFASA	63	21 (33.3)	42 (66.7)	10.5 (4.2 , NE)	55	12 (21.8)	43 (78.2)	10.3 (5.6 , NE)	1.00 (0.49, 2.06)	0.9953	
non-mFASA	269	98 (36.4)	171 (63.6)	7.1 (4.2 , 9.0)	279	84 (30.1)	195 (69.9)	4.8 (2.8 , NE)	0.93 (0.69, 1.24)	0.6213	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Appetite Loss

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.0258
mFASA	63	21 (33.3)	42 (66.7)	8.3 (2.7 , NE)	55	20 (36.4)	35 (63.6)	1.4 (0.8 , 9.7)	0.49 (0.26, 0.90)	0.0215	
non-mFASA	269	126 (46.8)	143 (53.2)	2.9 (2.8 , 4.2)	279	107 (38.4)	172 (61.6)	2.9 (2.1 , 5.7)	1.02 (0.78, 1.32)	0.9047	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Constipation

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.0444
mFASA	63	24 (38.1)	39 (61.9)	5.5 (2.8 , NE)	55	17 (30.9)	38 (69.1)	3.5 (1.3 , NE)	0.82 (0.44, 1.53)	0.5579	
non-mFASA	269	145 (53.9)	124 (46.1)	2.1 (1.4 , 2.8)	279	98 (35.1)	181 (64.9)	4.2 (2.8 , 5.7)	1.60 (1.24, 2.07)	0.0003	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Diarrhea

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.2387
mFASA	63	14 (22.2)	49 (77.8)	NE (5.6 , NE)	55	14 (25.5)	41 (74.5)	5.5 (2.8 , NE)	0.47 (0.22, 0.99)	0.0438	
non-mFASA	269	83 (30.9)	186 (69.1)	10.5 (7.7 , 19.4)	279	77 (27.6)	202 (72.4)	8.8 (5.6 , NE)	0.81 (0.59, 1.10)	0.1754	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.4 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Common Symptoms - Financial Difficulties

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6394
mFASA	63	19 (30.2)	44 (69.8)	12.5 (3.5 , NE)	55	12 (21.8)	43 (78.2)	NE (3.4 , NE)	1.01 (0.49, 2.09)	0.9793	
non-mFASA	269	76 (28.3)	193 (71.7)	10.4 (9.0 , NE)	279	73 (26.2)	206 (73.8)	8.4 (4.9 , NE)	0.79 (0.57, 1.09)	0.1437	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-C30 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_Add.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0874
Region 1 [US, Canada, Europe]	33	14 (42.4)	19 (57.6)	2.1 (1.3, 8.3)	28	7 (25.0)	21 (75.0)	3.5 (1.4, NE)	1.43 (0.57, 3.55)	0.4408	
Region 2 [Rest of World]	30	16 (53.3)	14 (46.7)	2.8 (1.4, 6.2)	27	16 (59.3)	11 (40.7)	1.4 (0.7, 2.8)	0.54 (0.27, 1.07)	0.0883	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9044
Yes	52	23 (44.2)	29 (55.8)	2.8 (1.4, 6.2)	45	18 (40.0)	27 (60.0)	2.8 (1.4, 4.2)	0.83 (0.45, 1.53)	0.5448	
No	11	7 (63.6)	4 (36.4)	2.1 (0.8, NE)	10	5 (50.0)	5 (50.0)	1.4 (0.7, NE)	0.71 (0.22, 2.27)	0.6109	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	9 (47.4)	10 (52.6)	-	13	4 (30.8)	9 (69.2)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	16 (50.0)	16 (50.0)	-	30	12 (40.0)	18 (60.0)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	6 (66.7)	3 (33.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.1697
<65 years	52	23 (44.2)	29 (55.8)	2.8 (1.4, 8.3)	41	16 (39.0)	25 (61.0)	1.4 (0.8, 6.3)	0.72 (0.38, 1.37)	0.3382	
≥65 years	11	7 (63.6)	4 (36.4)	1.4 (0.7, 2.8)	14	7 (50.0)	7 (50.0)	2.4 (0.7, 4.1)	1.71 (0.59, 4.93)	0.3331	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.1917
Asian	21	10 (47.6)	11 (52.4)	4.1 (1.4, NE)	21	12 (57.1)	9 (42.9)	1.4 (0.7, 4.2)	0.52 (0.22, 1.21)	0.1251	
Non-Asian	32	18 (56.3)	14 (43.8)	2.1 (1.4, 4.2)	26	11 (42.3)	15 (57.7)	2.8 (0.8, NE)	1.12 (0.53, 2.39)	0.7648	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8312
Capecitabine	21	10 (47.6)	11 (52.4)	1.4 (0.8, 6.2)	9	5 (55.6)	4 (44.4)	1.4 (0.7, NE)	1.16 (0.39, 3.40)	0.7763	
Eribulin mesylate	31	15 (48.4)	16 (51.6)	2.1 (1.4, 5.6)	41	17 (41.5)	24 (58.5)	1.7 (0.8, 4.1)	0.83 (0.41, 1.66)	0.6131	
Vinorelbine	11	5 (45.5)	6 (54.5)	8.3 (1.3, NE)	5	1 (20.0)	4 (80.0)	NE (0.7, NE)	0.70 (0.07, 6.82)	0.7547	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5356
Yes	6	3 (50.0)	3 (50.0)	NE (0.7, NE)	6	2 (33.3)	4 (66.7)	1.4 (0.8, NE)	0.92 (0.15, 5.59)	0.9177	
No	57	27 (47.4)	30 (52.6)	2.8 (1.4, 4.2)	49	21 (42.9)	28 (57.1)	2.1 (1.4, 4.1)	0.86 (0.48, 1.52)	0.6162	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	29 (46.8)	33 (53.2)	-	54	23 (42.6)	31 (57.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	17 (54.8)	14 (45.2)	-	24	10 (41.7)	14 (58.3)	-	-	-	
Asian	21	10 (47.6)	11 (52.4)	-	21	12 (57.1)	9 (42.9)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.1197
0	35	15 (42.9)	20 (57.1)	5.6 (1.4, NE)	33	13 (39.4)	20 (60.6)	1.4 (0.7, 6.3)	0.57 (0.27, 1.21)	0.1418	
≥1	28	15 (53.6)	13 (46.4)	2.1 (0.8, 2.8)	22	10 (45.5)	12 (54.5)	2.1 (0.8, 4.2)	1.30 (0.58, 2.90)	0.5269	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	24 (49.0)	25 (51.0)	-	42	18 (42.9)	24 (57.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.2963
≤12 months	22	9 (40.9)	13 (59.1)	1.5 (0.8, NE)	19	7 (36.8)	12 (63.2)	2.8 (0.7, NE)	1.17 (0.43, 3.16)	0.7643	
>12 months	29	13 (44.8)	16 (55.2)	2.8 (1.4, 8.3)	27	12 (44.4)	15 (55.6)	1.4 (0.7, 4.1)	0.58 (0.26, 1.29)	0.1790	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Global Health Status

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	3 (75.0)	1 (25.0)	-	0	0	0	-	-	-	
No	59	27 (45.8)	32 (54.2)	-	55	23 (41.8)	32 (58.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9755
Region 1 [US, Canada, Europe]	33	12 (36.4)	21 (63.6)	5.6 (0.7, 9.0)	28	8 (28.6)	20 (71.4)	3.5 (0.7, NE)	1.04 (0.43, 2.55)	0.9081	
Region 2 [Rest of World]	30	11 (36.7)	19 (63.3)	NE (2.1, NE)	27	7 (25.9)	20 (74.1)	NE (0.7, NE)	0.98 (0.38, 2.52)	>0.9999	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.7154
Yes	52	18 (34.6)	34 (65.4)	5.6 (1.4, NE)	45	12 (26.7)	33 (73.3)	5.5 (0.8, NE)	1.11 (0.53, 2.30)	0.7824	
No	11	5 (45.5)	6 (54.5)	4.1 (0.7, NE)	10	3 (30.0)	7 (70.0)	NE (0.7, NE)	0.77 (0.18, 3.34)	0.7431	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	4 (21.1)	15 (78.9)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	14 (43.8)	18 (56.3)	-	30	6 (20.0)	24 (80.0)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	3 (33.3)	6 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9022
<65 years	52	19 (36.5)	33 (63.5)	5.6 (2.1, NE)	41	10 (24.4)	31 (75.6)	5.5 (1.4, NE)	1.08 (0.50, 2.32)	0.8419	
≥65 years	11	4 (36.4)	7 (63.6)	0.8 (0.7, NE)	14	5 (35.7)	9 (64.3)	2.1 (0.7, NE)	0.95 (0.26, 3.57)	0.9296	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.3342
Asian	21	7 (33.3)	14 (66.7)	NE (0.8, NE)	21	4 (19.0)	17 (81.0)	NE (0.7, NE)	1.39 (0.40, 4.75)	0.5763	
Non-Asian	32	14 (43.8)	18 (56.3)	5.6 (1.4, NE)	26	11 (42.3)	15 (57.7)	2.1 (0.7, NE)	0.73 (0.33, 1.62)	0.4515	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9300
Capecitabine	21	8 (38.1)	13 (61.9)	1.4 (0.7, NE)	9	4 (44.4)	5 (55.6)	1.8 (0.7, NE)	0.96 (0.29, 3.20)	0.9765	
Eribulin mesylate	31	11 (35.5)	20 (64.5)	5.6 (2.1, NE)	41	10 (24.4)	31 (75.6)	5.5 (1.4, NE)	1.07 (0.46, 2.53)	0.8704	
Vinorelbine	11	4 (36.4)	7 (63.6)	9.0 (0.7, NE)	5	1 (20.0)	4 (80.0)	NE (0.7, NE)	0.63 (0.06, 7.03)	0.7074	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5580
Yes	6	3 (50.0)	3 (50.0)	NE (0.7, NE)	6	1 (16.7)	5 (83.3)	NE (1.4, NE)	2.40 (0.25, 23.17)	0.4479	
No	57	20 (35.1)	37 (64.9)	5.6 (2.1, NE)	49	14 (28.6)	35 (71.4)	5.5 (0.8, NE)	0.95 (0.48, 1.89)	0.9113	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	22 (35.5)	40 (64.5)	-	54	15 (27.8)	39 (72.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	13 (41.9)	18 (58.1)	-	24	10 (41.7)	14 (58.3)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0704
0	35	9 (25.7)	26 (74.3)	9.0 (5.6, NE)	33	8 (24.2)	25 (75.8)	5.5 (0.7, NE)	0.62 (0.24, 1.63)	0.3474	
≥1	28	14 (50.0)	14 (50.0)	1.4 (0.7, 4.1)	22	7 (31.8)	15 (68.2)	3.5 (0.7, NE)	2.05 (0.82, 5.11)	0.1123	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	18 (36.7)	31 (63.3)	-	42	12 (28.6)	30 (71.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.0691
≤12 months	22	9 (40.9)	13 (59.1)	2.1 (0.7, NE)	19	4 (21.1)	15 (78.9)	NE (0.7, NE)	2.42 (0.74, 7.98)	0.1321	
>12 months	29	8 (27.6)	21 (72.4)	5.6 (1.4, NE)	27	9 (33.3)	18 (66.7)	1.4 (0.7, NE)	0.56 (0.21, 1.46)	0.2407	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	22 (37.3)	37 (62.7)	-	55	15 (27.3)	40 (72.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.1702
Region 1 [US, Canada, Europe]	33	13 (39.4)	20 (60.6)	4.2 (0.7, 5.6)	28	6 (21.4)	22 (78.6)	NE (0.8, NE)	1.61 (0.61, 4.26)	0.3303	
Region 2 [Rest of World]	30	14 (46.7)	16 (53.3)	4.2 (0.8, NE)	27	14 (51.9)	13 (48.1)	2.8 (0.7, 6.2)	0.71 (0.34, 1.48)	0.3809	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.0462
Yes	52	23 (44.2)	29 (55.8)	2.1 (0.8, 5.5)	45	14 (31.1)	31 (68.9)	5.6 (0.8, NE)	1.36 (0.70, 2.64)	0.3564	
No	11	4 (36.4)	7 (63.6)	NE (0.7, NE)	10	6 (60.0)	4 (40.0)	1.5 (0.7, 6.2)	0.35 (0.10, 1.25)	0.0938	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	7 (36.8)	12 (63.2)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	15 (46.9)	17 (53.1)	-	30	10 (33.3)	20 (66.7)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7086
<65 years	52	22 (42.3)	30 (57.7)	4.2 (1.4, 5.7)	41	13 (31.7)	28 (68.3)	2.8 (0.7, NE)	0.97 (0.49, 1.93)	0.9593	
≥65 years	11	5 (45.5)	6 (54.5)	0.8 (0.7, NE)	14	7 (50.0)	7 (50.0)	5.6 (0.7, 6.2)	1.20 (0.38, 3.80)	0.7254	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.3221
Asian	21	9 (42.9)	12 (57.1)	5.7 (0.8, NE)	21	10 (47.6)	11 (52.4)	2.8 (0.7, NE)	0.69 (0.28, 1.70)	0.4453	
Non-Asian	32	16 (50.0)	16 (50.0)	4.2 (0.8, 5.6)	26	10 (38.5)	16 (61.5)	2.8 (0.8, NE)	1.25 (0.56, 2.75)	0.5902	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9056
Capecitabine	21	9 (42.9)	12 (57.1)	1.4 (0.7, NE)	9	4 (44.4)	5 (55.6)	0.7 (0.7, NE)	1.07 (0.33, 3.50)	0.8271	
Eribulin mesylate	31	15 (48.4)	16 (51.6)	4.2 (0.8, 5.6)	41	15 (36.6)	26 (63.4)	2.8 (0.8, 6.2)	1.08 (0.53, 2.21)	0.8176	
Vinorelbine	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	5	1 (20.0)	4 (80.0)	NE (2.1, NE)	0.89 (0.09, 8.70)	0.9194	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.4869
Yes	6	4 (66.7)	2 (33.3)	1.1 (0.7, NE)	6	2 (33.3)	4 (66.7)	6.2 (0.8, NE)	1.61 (0.29, 8.85)	0.5968	
No	57	23 (40.4)	34 (59.6)	4.2 (1.4, 5.7)	49	18 (36.7)	31 (63.3)	2.8 (0.8, NE)	0.91 (0.49, 1.69)	0.7906	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	26 (41.9)	36 (58.1)	-	54	20 (37.0)	34 (63.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	15 (48.4)	16 (51.6)	-	24	9 (37.5)	15 (62.5)	-	-	-	
Asian	21	9 (42.9)	12 (57.1)	-	21	10 (47.6)	11 (52.4)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0183
0	35	14 (40.0)	21 (60.0)	5.6 (0.8, NE)	33	14 (42.4)	19 (57.6)	1.5 (0.7, 5.6)	0.50 (0.23, 1.07)	0.0791	
≥1	28	13 (46.4)	15 (53.6)	2.1 (0.7, 4.2)	22	6 (27.3)	16 (72.7)	NE (0.8, NE)	2.13 (0.81, 5.64)	0.1184	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	23 (46.9)	26 (53.1)	-	42	15 (35.7)	27 (64.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.0439
≤12 months	22	10 (45.5)	12 (54.5)	1.4 (0.7, 4.2)	19	4 (21.1)	15 (78.9)	NE (0.8, NE)	2.97 (0.92, 9.56)	0.0572	
>12 months	29	12 (41.4)	17 (58.6)	5.5 (0.8, 5.6)	27	11 (40.7)	16 (59.3)	1.5 (0.7, 5.6)	0.71 (0.31, 1.63)	0.4238	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	26 (44.1)	33 (55.9)	-	55	20 (36.4)	35 (63.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.1965
Region 1 [US, Canada, Europe]	33	10 (30.3)	23 (69.7)	5.6 (2.2, NE)	28	4 (14.3)	24 (85.7)	6.3 (3.5, NE)	1.60 (0.50, 5.14)	0.4266	
Region 2 [Rest of World]	30	12 (40.0)	18 (60.0)	13.8 (2.8, NE)	27	9 (33.3)	18 (66.7)	6.2 (0.7, NE)	0.68 (0.28, 1.67)	0.4245	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5316
Yes	52	16 (30.8)	36 (69.2)	7.1 (2.8, NE)	45	10 (22.2)	35 (77.8)	7.9 (3.5, NE)	0.97 (0.44, 2.14)	0.9471	
No	11	6 (54.5)	5 (45.5)	4.9 (0.7, NE)	10	3 (30.0)	7 (70.0)	6.2 (0.7, NE)	0.71 (0.16, 3.12)	0.6642	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	14 (43.8)	18 (56.3)	-	30	3 (10.0)	27 (90.0)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.3679
<65 years	52	19 (36.5)	33 (63.5)	5.6 (3.5, 13.8)	41	8 (19.5)	33 (80.5)	6.3 (3.5, NE)	1.06 (0.46, 2.47)	0.8693	
≥65 years	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	14	5 (35.7)	9 (64.3)	6.2 (0.7, NE)	0.65 (0.15, 2.72)	0.5447	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9712
Asian	21	8 (38.1)	13 (61.9)	4.9 (2.8, NE)	21	6 (28.6)	15 (71.4)	7.9 (1.4, NE)	0.91 (0.31, 2.67)	0.8858	
Non-Asian	32	13 (40.6)	19 (59.4)	7.1 (2.2, NE)	26	7 (26.9)	19 (73.1)	6.2 (3.5, NE)	0.89 (0.35, 2.29)	0.8196	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9109
Capecitabine	21	8 (38.1)	13 (61.9)	5.5 (2.2, 13.8)	9	4 (44.4)	5 (55.6)	7.9 (0.7, NE)	0.68 (0.20, 2.36)	0.5683	
Eribulin mesylate	31	12 (38.7)	19 (61.3)	4.9 (1.5, NE)	41	9 (22.0)	32 (78.0)	6.2 (3.5, NE)	1.15 (0.48, 2.74)	0.7472	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (4.8, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.2768
Yes	6	4 (66.7)	2 (33.3)	3.2 (0.7, NE)	6	1 (16.7)	5 (83.3)	6.2 (NE, NE)	NE (NE, NE)	0.1696	
No	57	18 (31.6)	39 (68.4)	11.0 (4.8, NE)	49	12 (24.5)	37 (75.5)	6.3 (3.5, NE)	0.76 (0.36, 1.60)	0.4798	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	21 (33.9)	41 (66.1)	-	54	13 (24.1)	41 (75.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	12 (38.7)	19 (61.3)	-	24	6 (25.0)	18 (75.0)	-	-	-	
Asian	21	8 (38.1)	13 (61.9)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.2368
0	35	11 (31.4)	24 (68.6)	11.0 (4.9, NE)	33	8 (24.2)	25 (75.8)	6.3 (0.7, NE)	0.64 (0.26, 1.61)	0.3633	
≥1	28	11 (39.3)	17 (60.7)	3.5 (1.5, NE)	22	5 (22.7)	17 (77.3)	7.9 (3.5, NE)	1.49 (0.50, 4.40)	0.4729	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	0	6 (100)	-	-	-	
≥6 months	49	17 (34.7)	32 (65.3)	-	42	12 (28.6)	30 (71.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.0419
≤12 months	22	6 (27.3)	16 (72.7)	NE (1.4, NE)	19	1 (5.3)	18 (94.7)	NE (7.9, NE)	5.23 (0.62, 43.93)	0.0894	
>12 months	29	10 (34.5)	19 (65.5)	7.1 (2.8, NE)	27	10 (37.0)	17 (63.0)	3.5 (0.7, 6.3)	0.49 (0.20, 1.20)	0.1167	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	21 (35.6)	38 (64.4)	-	55	13 (23.6)	42 (76.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.6945
Region 1 [US, Canada, Europe]	33	14 (42.4)	19 (57.6)	2.0 (0.8, 4.9)	28	11 (39.3)	17 (60.7)	1.4 (0.7, 3.5)	0.83 (0.37, 1.82)	0.6298	
Region 2 [Rest of World]	30	13 (43.3)	17 (56.7)	4.8 (1.4, NE)	27	12 (44.4)	15 (55.6)	2.8 (1.4, 6.2)	0.67 (0.30, 1.48)	0.3117	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5982
Yes	52	21 (40.4)	31 (59.6)	2.1 (0.8, NE)	45	19 (42.2)	26 (57.8)	2.1 (0.8, 3.5)	0.72 (0.39, 1.34)	0.2852	
No	11	6 (54.5)	5 (45.5)	2.2 (0.8, NE)	10	4 (40.0)	6 (60.0)	2.8 (1.4, NE)	0.95 (0.25, 3.57)	0.9443	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	7 (36.8)	12 (63.2)	-	13	6 (46.2)	7 (53.8)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	16 (50.0)	16 (50.0)	-	30	11 (36.7)	19 (63.3)	-	-	-	
Neither taxanes nor anthracyclines	11	4 (36.4)	7 (63.6)	-	9	4 (44.4)	5 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9856
<65 years	52	22 (42.3)	30 (57.7)	3.5 (1.4, 8.3)	41	15 (36.6)	26 (63.4)	2.1 (0.8, NE)	0.81 (0.42, 1.57)	0.5341	
≥65 years	11	5 (45.5)	6 (54.5)	0.8 (0.7, NE)	14	8 (57.1)	6 (42.9)	1.8 (0.7, 5.6)	0.83 (0.27, 2.55)	0.7455	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.4106
Asian	21	8 (38.1)	13 (61.9)	8.3 (0.8, NE)	21	10 (47.6)	11 (52.4)	2.8 (0.8, 5.6)	0.52 (0.20, 1.37)	0.1745	
Non-Asian	32	18 (56.3)	14 (43.8)	2.0 (0.8, 4.8)	26	13 (50.0)	13 (50.0)	2.1 (0.7, 4.2)	0.92 (0.45, 1.88)	0.8132	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.5449
Capecitabine	21	10 (47.6)	11 (52.4)	1.4 (0.8, 2.8)	9	6 (66.7)	3 (33.3)	1.4 (0.7, 2.1)	0.86 (0.31, 2.38)	0.7692	
Eribulin mesylate	31	13 (41.9)	18 (58.1)	4.8 (0.8, NE)	41	15 (36.6)	26 (63.4)	2.8 (0.8, 5.6)	0.89 (0.42, 1.88)	0.7526	
Vinorelbine	11	4 (36.4)	7 (63.6)	8.3 (2.0, NE)	5	2 (40.0)	3 (60.0)	1.3 (0.8, NE)	0.26 (0.04, 1.62)	0.1219	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.1928
Yes	6	2 (33.3)	4 (66.7)	NE (0.7, NE)	6	3 (50.0)	3 (50.0)	0.8 (0.8, NE)	0.33 (0.05, 2.09)	0.2438	
No	57	25 (43.9)	32 (56.1)	2.1 (0.8, 4.9)	49	20 (40.8)	29 (59.2)	2.1 (1.4, 4.2)	0.88 (0.49, 1.59)	0.6577	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	26 (41.9)	36 (58.1)	-	54	23 (42.6)	31 (57.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	18 (58.1)	13 (41.9)	-	24	12 (50.0)	12 (50.0)	-	-	-	
Asian	21	8 (38.1)	13 (61.9)	-	21	10 (47.6)	11 (52.4)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.1739
0	35	15 (42.9)	20 (57.1)	3.5 (0.8, NE)	33	14 (42.4)	19 (57.6)	2.1 (0.7, 2.8)	0.54 (0.26, 1.12)	0.0941	
≥1	28	12 (42.9)	16 (57.1)	1.7 (0.8, NE)	22	9 (40.9)	13 (59.1)	3.5 (0.8, NE)	1.11 (0.46, 2.70)	0.8379	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	20 (40.8)	29 (59.2)	-	42	19 (45.2)	23 (54.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.5027
≤12 months	22	9 (40.9)	13 (59.1)	2.5 (0.7, NE)	19	8 (42.1)	11 (57.9)	1.8 (0.7, 5.6)	0.90 (0.35, 2.34)	0.8048	
>12 months	29	11 (37.9)	18 (62.1)	2.8 (0.8, NE)	27	12 (44.4)	15 (55.6)	2.1 (0.7, 3.5)	0.58 (0.25, 1.31)	0.1946	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	3 (75.0)	1 (25.0)	-	0	0	0	-	-	-	
No	59	24 (40.7)	35 (59.3)	-	55	23 (41.8)	32 (58.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9661
Region 1 [US, Canada, Europe]	33	13 (39.4)	20 (60.6)	2.8 (1.4, 5.6)	28	11 (39.3)	17 (60.7)	1.4 (0.7, 2.8)	0.62 (0.28, 1.40)	0.2478	
Region 2 [Rest of World]	30	12 (40.0)	18 (60.0)	11.0 (1.4, NE)	27	10 (37.0)	17 (63.0)	6.2 (1.4, NE)	0.68 (0.28, 1.61)	0.3639	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5957
Yes	52	19 (36.5)	33 (63.5)	4.9 (2.1, 12.5)	45	16 (35.6)	29 (64.4)	2.8 (0.8, NE)	0.70 (0.36, 1.38)	0.2986	
No	11	6 (54.5)	5 (45.5)	5.7 (0.7, NE)	10	5 (50.0)	5 (50.0)	2.1 (0.7, NE)	0.57 (0.17, 1.91)	0.3397	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	7 (36.8)	12 (63.2)	-	13	7 (53.8)	6 (46.2)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	13 (40.6)	19 (59.4)	-	30	10 (33.3)	20 (66.7)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.8540
<65 years	52	20 (38.5)	32 (61.5)	5.6 (2.1, NE)	41	15 (36.6)	26 (63.4)	2.8 (1.4, 6.2)	0.67 (0.34, 1.33)	0.2447	
≥65 years	11	5 (45.5)	6 (54.5)	2.8 (0.7, NE)	14	6 (42.9)	8 (57.1)	1.1 (0.7, NE)	0.63 (0.18, 2.22)	0.4638	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.6716
Asian	21	6 (28.6)	15 (71.4)	12.5 (5.7, NE)	21	8 (38.1)	13 (61.9)	11.1 (0.7, NE)	0.46 (0.15, 1.42)	0.1687	
Non-Asian	32	17 (53.1)	15 (46.9)	2.2 (1.4, 11.0)	26	13 (50.0)	13 (50.0)	1.8 (0.7, 3.5)	0.68 (0.33, 1.41)	0.2826	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.0078
Capecitabine	21	8 (38.1)	13 (61.9)	2.2 (0.7, NE)	9	7 (77.8)	2 (22.2)	0.7 (0.7, 2.8)	0.38 (0.13, 1.10)	0.0722	
Eribulin mesylate	31	15 (48.4)	16 (51.6)	2.8 (1.4, 5.7)	41	11 (26.8)	30 (73.2)	3.5 (1.5, NE)	1.32 (0.60, 2.92)	0.4940	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (0.7, NE)	5	3 (60.0)	2 (40.0)	1.3 (0.7, NE)	0.15 (0.02, 0.89)	0.0168	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5177
Yes	6	2 (33.3)	4 (66.7)	NE (1.4, NE)	6	2 (33.3)	4 (66.7)	1.4 (1.4, NE)	0.40 (0.05, 2.93)	0.3479	
No	57	23 (40.4)	34 (59.6)	4.9 (1.4, 12.5)	49	19 (38.8)	30 (61.2)	2.8 (0.8, 6.2)	0.71 (0.38, 1.32)	0.2732	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	24 (38.7)	38 (61.3)	-	54	21 (38.9)	33 (61.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	17 (54.8)	14 (45.2)	-	24	13 (54.2)	11 (45.8)	-	-	-	
Asian	21	6 (28.6)	15 (71.4)	-	21	8 (38.1)	13 (61.9)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.7806
0	35	15 (42.9)	20 (57.1)	4.9 (1.4, NE)	33	11 (33.3)	22 (66.7)	2.8 (0.7, NE)	0.72 (0.33, 1.57)	0.4001	
≥1	28	10 (35.7)	18 (64.3)	11.0 (1.4, NE)	22	10 (45.5)	12 (54.5)	3.5 (0.7, NE)	0.56 (0.23, 1.41)	0.2175	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	18 (36.7)	31 (63.3)	-	42	17 (40.5)	25 (59.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.1397
≤12 months	22	8 (36.4)	14 (63.6)	11.0 (0.7, NE)	19	5 (26.3)	14 (73.7)	11.1 (0.7, NE)	1.05 (0.33, 3.31)	0.9633	
>12 months	29	10 (34.5)	19 (65.5)	4.9 (1.4, NE)	27	12 (44.4)	15 (55.6)	1.5 (0.7, 3.5)	0.48 (0.20, 1.11)	0.0832	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	23 (39.0)	36 (61.0)	-	55	21 (38.2)	34 (61.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0328
Region 1 [US, Canada, Europe]	33	15 (45.5)	18 (54.5)	2.1 (1.4, 2.8)	28	12 (42.9)	16 (57.1)	1.5 (0.7, 3.5)	0.93 (0.42, 2.02)	0.8358	
Region 2 [Rest of World]	30	15 (50.0)	15 (50.0)	2.8 (0.8, NE)	27	17 (63.0)	10 (37.0)	0.7 (0.7, 1.4)	0.32 (0.15, 0.66)	0.0015	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.7279
Yes	52	23 (44.2)	29 (55.8)	2.1 (0.8, 5.6)	45	24 (53.3)	21 (46.7)	1.4 (0.7, 1.5)	0.51 (0.28, 0.91)	0.0197	
No	11	7 (63.6)	4 (36.4)	2.2 (1.4, NE)	10	5 (50.0)	5 (50.0)	0.7 (0.7, NE)	0.45 (0.14, 1.48)	0.1868	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	6 (31.6)	13 (68.4)	-	13	6 (46.2)	7 (53.8)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	3 (100)	0	-	-	-	
Both taxanes and anthracyclines	32	19 (59.4)	13 (40.6)	-	30	14 (46.7)	16 (53.3)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	6 (66.7)	3 (33.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.1522
<65 years	52	26 (50.0)	26 (50.0)	2.2 (1.4, 5.5)	41	20 (48.8)	21 (51.2)	1.4 (0.7, 1.5)	0.59 (0.33, 1.06)	0.0782	
≥65 years	11	4 (36.4)	7 (63.6)	1.4 (0.8, NE)	14	9 (64.3)	5 (35.7)	0.7 (0.7, 2.0)	0.31 (0.09, 1.01)	0.0412	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.0041
Asian	21	9 (42.9)	12 (57.1)	8.3 (0.8, NE)	21	15 (71.4)	6 (28.6)	0.7 (0.7, NE)	0.20 (0.07, 0.53)	0.0006	
Non-Asian	32	19 (59.4)	13 (40.6)	2.1 (1.4, 2.8)	26	14 (53.8)	12 (46.2)	1.5 (0.7, 3.5)	0.92 (0.46, 1.85)	0.8085	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.2627
Capecitabine	21	10 (47.6)	11 (52.4)	0.8 (0.7, 5.5)	9	7 (77.8)	2 (22.2)	0.7 (0.7, 2.0)	0.68 (0.26, 1.81)	0.4265	
Eribulin mesylate	31	17 (54.8)	14 (45.2)	2.0 (1.4, 2.8)	41	19 (46.3)	22 (53.7)	0.8 (0.7, 1.5)	0.64 (0.33, 1.24)	0.1842	
Vinorelbine	11	3 (27.3)	8 (72.7)	NE (2.1, NE)	5	3 (60.0)	2 (40.0)	1.4 (1.3, NE)	0.00 (0.00, NE)	0.0002	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.3355
Yes	6	4 (66.7)	2 (33.3)	2.8 (1.4, NE)	6	3 (50.0)	3 (50.0)	0.8 (0.7, NE)	0.18 (0.03, 1.15)	0.0361	
No	57	26 (45.6)	31 (54.4)	2.1 (1.4, 5.6)	49	26 (53.1)	23 (46.9)	1.4 (0.7, 1.5)	0.53 (0.31, 0.92)	0.0232	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	29 (46.8)	33 (53.2)	-	54	29 (53.7)	25 (46.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	18 (58.1)	13 (41.9)	-	24	13 (54.2)	11 (45.8)	-	-	-	
Asian	21	9 (42.9)	12 (57.1)	-	21	15 (71.4)	6 (28.6)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.4165
0	35	17 (48.6)	18 (51.4)	2.2 (1.4, 8.3)	33	16 (48.5)	17 (51.5)	0.7 (0.7, 1.5)	0.42 (0.21, 0.84)	0.0167	
≥1	28	13 (46.4)	15 (53.6)	2.1 (0.8, 5.5)	22	13 (59.1)	9 (40.9)	1.4 (0.7, 2.0)	0.65 (0.30, 1.40)	0.2788	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	23 (46.9)	26 (53.1)	-	42	25 (59.5)	17 (40.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3423
≤12 months	22	10 (45.5)	12 (54.5)	2.1 (0.7, 8.3)	19	9 (47.4)	10 (52.6)	1.4 (0.7, 3.4)	0.67 (0.26, 1.70)	0.3875	
>12 months	29	12 (41.4)	17 (58.6)	2.8 (0.8, NE)	27	16 (59.3)	11 (40.7)	0.7 (0.7, 1.5)	0.38 (0.18, 0.82)	0.0124	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Fatigue

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	28 (47.5)	31 (52.5)	-	55	29 (52.7)	26 (47.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.3183
Region 1 [US, Canada, Europe]	33	12 (36.4)	21 (63.6)	4.2 (0.8, 7.1)	28	6 (21.4)	22 (78.6)	4.8 (0.7, NE)	1.25 (0.47, 3.35)	0.6686	
Region 2 [Rest of World]	30	11 (36.7)	19 (63.3)	9.0 (2.1, NE)	27	9 (33.3)	18 (66.7)	3.5 (1.4, NE)	0.70 (0.29, 1.71)	0.4336	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9870
Yes	52	17 (32.7)	35 (67.3)	5.6 (2.8, NE)	45	12 (26.7)	33 (73.3)	3.5 (1.4, NE)	0.89 (0.43, 1.88)	0.7611	
No	11	6 (54.5)	5 (45.5)	9.0 (0.7, NE)	10	3 (30.0)	7 (70.0)	7.0 (0.7, NE)	1.06 (0.25, 4.54)	0.9355	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	6 (31.6)	13 (68.4)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	13 (40.6)	19 (59.4)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	4 (36.4)	7 (63.6)	-	9	4 (44.4)	5 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.4399
<65 years	52	20 (38.5)	32 (61.5)	5.6 (2.2, NE)	41	11 (26.8)	30 (73.2)	4.8 (1.4, NE)	1.00 (0.48, 2.11)	0.9897	
≥65 years	11	3 (27.3)	8 (72.7)	NE (0.8, NE)	14	4 (28.6)	10 (71.4)	2.1 (0.7, NE)	0.64 (0.14, 2.88)	0.5681	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.6792
Asian	21	8 (38.1)	13 (61.9)	9.0 (0.8, NE)	21	6 (28.6)	15 (71.4)	3.5 (1.4, NE)	0.98 (0.34, 2.84)	0.9679	
Non-Asian	32	13 (40.6)	19 (59.4)	5.6 (2.2, NE)	26	9 (34.6)	17 (65.4)	4.8 (1.4, NE)	0.77 (0.33, 1.82)	0.5338	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8492
Capecitabine	21	7 (33.3)	14 (66.7)	7.0 (0.8, NE)	9	3 (33.3)	6 (66.7)	NE (0.7, NE)	1.06 (0.27, 4.11)	0.9076	
Eribulin mesylate	31	10 (32.3)	21 (67.7)	7.1 (0.8, NE)	41	11 (26.8)	30 (73.2)	4.8 (1.4, NE)	0.76 (0.32, 1.80)	0.5306	
Vinorelbine	11	6 (54.5)	5 (45.5)	5.6 (0.7, NE)	5	1 (20.0)	4 (80.0)	NE (1.4, NE)	0.76 (0.07, 8.35)	0.8184	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5690
Yes	6	3 (50.0)	3 (50.0)	NE (0.7, NE)	6	2 (33.3)	4 (66.7)	3.5 (1.4, NE)	0.48 (0.07, 3.12)	0.4760	
No	57	20 (35.1)	37 (64.9)	7.0 (2.8, NE)	49	13 (26.5)	36 (73.5)	4.8 (1.4, NE)	0.98 (0.49, 1.98)	0.9624	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	23 (37.1)	39 (62.9)	-	54	15 (27.8)	39 (72.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	12 (38.7)	19 (61.3)	-	24	8 (33.3)	16 (66.7)	-	-	-	
Asian	21	8 (38.1)	13 (61.9)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.8976
0	35	15 (42.9)	20 (57.1)	4.2 (2.2, 9.0)	33	8 (24.2)	25 (75.8)	4.8 (0.7, NE)	0.90 (0.38, 2.14)	0.8299	
≥1	28	8 (28.6)	20 (71.4)	NE (0.8, NE)	22	7 (31.8)	15 (68.2)	3.5 (1.4, NE)	0.87 (0.31, 2.44)	0.7908	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	18 (36.7)	31 (63.3)	-	42	12 (28.6)	30 (71.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.6335
≤12 months	22	5 (22.7)	17 (77.3)	NE (0.8, NE)	19	3 (15.8)	16 (84.2)	NE (0.7, NE)	1.15 (0.27, 4.83)	0.8472	
>12 months	29	12 (41.4)	17 (58.6)	4.2 (0.7, 7.1)	27	9 (33.3)	18 (66.7)	3.5 (1.4, NE)	0.80 (0.33, 1.94)	0.6153	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	21 (35.6)	38 (64.4)	-	55	15 (27.3)	40 (72.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.6294
Region 1 [US, Canada, Europe]	33	8 (24.2)	25 (75.8)	9.0 (4.2, NE)	28	9 (32.1)	19 (67.9)	2.2 (0.8, NE)	0.41 (0.16, 1.10)	0.0661	
Region 2 [Rest of World]	30	10 (33.3)	20 (66.7)	9.7 (2.8, NE)	27	13 (48.1)	14 (51.9)	1.8 (0.7, 2.8)	0.32 (0.14, 0.74)	0.0057	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.3961
Yes	52	16 (30.8)	36 (69.2)	5.6 (3.5, NE)	45	19 (42.2)	26 (57.8)	2.1 (0.8, 2.8)	0.41 (0.21, 0.80)	0.0070	
No	11	2 (18.2)	9 (81.8)	NE (0.8, NE)	10	3 (30.0)	7 (70.0)	NE (0.7, NE)	0.17 (0.02, 1.68)	0.0929	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	10 (33.3)	20 (66.7)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	6 (66.7)	3 (33.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.6301
<65 years	52	15 (28.8)	37 (71.2)	9.0 (4.2, NE)	41	15 (36.6)	26 (63.4)	2.2 (0.8, NE)	0.38 (0.18, 0.79)	0.0078	
≥65 years	11	3 (27.3)	8 (72.7)	9.7 (0.8, NE)	14	7 (50.0)	7 (50.0)	1.4 (0.7, 2.8)	0.33 (0.08, 1.34)	0.0995	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5716
Asian	21	7 (33.3)	14 (66.7)	NE (0.8, NE)	21	10 (47.6)	11 (52.4)	2.1 (0.7, 2.8)	0.38 (0.14, 1.02)	0.0449	
Non-Asian	32	9 (28.1)	23 (71.9)	NE (4.2, NE)	26	12 (46.2)	14 (53.8)	2.2 (0.7, NE)	0.28 (0.11, 0.69)	0.0035	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3183
Capecitabine	21	8 (38.1)	13 (61.9)	4.2 (0.7, NE)	9	6 (66.7)	3 (33.3)	1.4 (0.7, NE)	0.63 (0.22, 1.84)	0.3736	
Eribulin mesylate	31	9 (29.0)	22 (71.0)	9.7 (2.8, NE)	41	14 (34.1)	27 (65.9)	2.2 (0.7, NE)	0.37 (0.16, 0.88)	0.0195	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (3.5, NE)	5	2 (40.0)	3 (60.0)	2.8 (0.8, NE)	0.00 (0.00, NE)	0.0086	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.1935
Yes	6	3 (50.0)	3 (50.0)	4.2 (3.5, NE)	6	3 (50.0)	3 (50.0)	0.8 (0.7, NE)	0.00 (0.00, NE)	0.0051	
No	57	15 (26.3)	42 (73.7)	NE (4.2, NE)	49	19 (38.8)	30 (61.2)	2.2 (0.8, 2.8)	0.40 (0.20, 0.81)	0.0078	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	17 (27.4)	45 (72.6)	-	54	22 (40.7)	32 (59.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	9 (29.0)	22 (71.0)	-	24	11 (45.8)	13 (54.2)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	10 (47.6)	11 (52.4)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.8201
0	35	12 (34.3)	23 (65.7)	9.0 (3.5, NE)	33	12 (36.4)	21 (63.6)	1.4 (0.7, 10.3)	0.38 (0.17, 0.86)	0.0171	
≥1	28	6 (21.4)	22 (78.6)	NE (1.4, NE)	22	10 (45.5)	12 (54.5)	2.8 (0.7, NE)	0.38 (0.14, 1.05)	0.0489	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	16 (32.7)	33 (67.3)	-	42	18 (42.9)	24 (57.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.8066
≤12 months	22	5 (22.7)	17 (77.3)	NE (1.4, NE)	19	8 (42.1)	11 (57.9)	2.8 (0.8, NE)	0.38 (0.12, 1.20)	0.0880	
>12 months	29	10 (34.5)	19 (65.5)	5.6 (1.4, NE)	27	12 (44.4)	15 (55.6)	0.8 (0.7, 2.8)	0.35 (0.14, 0.83)	0.0143	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	17 (28.8)	42 (71.2)	-	55	22 (40.0)	33 (60.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0093
Region 1 [US, Canada, Europe]	33	11 (33.3)	22 (66.7)	4.2 (0.8, 8.3)	28	4 (14.3)	24 (85.7)	9.7 (5.6, NE)	2.04 (0.65, 6.42)	0.2152	
Region 2 [Rest of World]	30	7 (23.3)	23 (76.7)	NE (5.5, NE)	27	11 (40.7)	16 (59.3)	4.8 (0.7, NE)	0.32 (0.12, 0.83)	0.0143	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.3029
Yes	52	15 (28.8)	37 (71.2)	8.3 (2.8, NE)	45	12 (26.7)	33 (73.3)	5.6 (2.8, NE)	0.82 (0.38, 1.76)	0.6185	
No	11	3 (27.3)	8 (72.7)	NE (2.1, NE)	10	3 (30.0)	7 (70.0)	NE (0.7, NE)	0.31 (0.06, 1.63)	0.1479	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	17 (89.5)	-	13	4 (30.8)	9 (69.2)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	11 (34.4)	21 (65.6)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.3345
<65 years	52	15 (28.8)	37 (71.2)	8.3 (4.2, NE)	41	9 (22.0)	32 (78.0)	9.7 (1.4, NE)	0.82 (0.36, 1.91)	0.6656	
≥65 years	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	14	6 (42.9)	8 (57.1)	4.8 (0.7, NE)	0.45 (0.11, 1.81)	0.2528	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5456
Asian	21	5 (23.8)	16 (76.2)	NE (4.1, NE)	21	7 (33.3)	14 (66.7)	5.6 (0.8, NE)	0.47 (0.15, 1.51)	0.1944	
Non-Asian	32	11 (34.4)	21 (65.6)	8.3 (2.1, NE)	26	8 (30.8)	18 (69.2)	5.6 (0.7, NE)	0.74 (0.29, 1.87)	0.5271	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3466
Capecitabine	21	4 (19.0)	17 (81.0)	NE (0.8, NE)	9	6 (66.7)	3 (33.3)	2.8 (0.7, NE)	0.32 (0.09, 1.13)	0.0605	
Eribulin mesylate	31	10 (32.3)	21 (67.7)	5.7 (2.1, NE)	41	9 (22.0)	32 (78.0)	5.6 (0.8, NE)	0.93 (0.38, 2.30)	0.8750	
Vinorelbine	11	4 (36.4)	7 (63.6)	8.3 (2.0, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.4842	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.1083
Yes	6	1 (16.7)	5 (83.3)	NE (2.1, NE)	6	2 (33.3)	4 (66.7)	0.8 (0.7, NE)	0.00 (0.00, NE)	0.0389	
No	57	17 (29.8)	40 (70.2)	8.3 (4.1, NE)	49	13 (26.5)	36 (73.5)	5.6 (2.8, NE)	0.80 (0.38, 1.65)	0.5485	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	17 (27.4)	45 (72.6)	-	54	15 (27.8)	39 (72.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	11 (35.5)	20 (64.5)	-	24	7 (29.2)	17 (70.8)	-	-	-	
Asian	21	5 (23.8)	16 (76.2)	-	21	7 (33.3)	14 (66.7)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.3922
0	35	11 (31.4)	24 (68.6)	6.3 (4.2, NE)	33	11 (33.3)	22 (66.7)	5.6 (0.7, 9.7)	0.54 (0.23, 1.25)	0.1479	
≥1	28	7 (25.0)	21 (75.0)	NE (2.0, NE)	22	4 (18.2)	18 (81.8)	NE (0.8, NE)	1.26 (0.37, 4.32)	0.7080	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	0	6 (100)	-	-	-	
≥6 months	49	15 (30.6)	34 (69.4)	-	42	13 (31.0)	29 (69.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.0818
≤12 months	22	6 (27.3)	16 (72.7)	5.5 (0.7, NE)	19	3 (15.8)	16 (84.2)	NE (2.8, NE)	2.01 (0.50, 8.06)	0.3188	
>12 months	29	8 (27.6)	21 (72.4)	8.3 (2.0, NE)	27	10 (37.0)	17 (63.0)	5.6 (0.7, NE)	0.40 (0.15, 1.03)	0.0546	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	17 (28.8)	42 (71.2)	-	55	15 (27.3)	40 (72.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.1884
Region 1 [US, Canada, Europe]	33	11 (33.3)	22 (66.7)	7.8 (0.7, NE)	28	4 (14.3)	24 (85.7)	10.3 (5.6, NE)	1.65 (0.51, 5.33)	0.3998	
Region 2 [Rest of World]	30	10 (33.3)	20 (66.7)	13.8 (4.9, NE)	27	8 (29.6)	19 (70.4)	6.2 (1.4, NE)	0.67 (0.26, 1.71)	0.4012	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.2445
Yes	52	17 (32.7)	35 (67.3)	7.8 (3.5, NE)	45	9 (20.0)	36 (80.0)	10.3 (5.6, NE)	1.27 (0.56, 2.85)	0.5682	
No	11	4 (36.4)	7 (63.6)	NE (0.7, NE)	10	3 (30.0)	7 (70.0)	6.2 (0.7, NE)	0.52 (0.10, 2.61)	0.4138	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	11 (34.4)	21 (65.6)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	4 (44.4)	5 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7219
<65 years	52	19 (36.5)	33 (63.5)	10.5 (2.1, NE)	41	9 (22.0)	32 (78.0)	5.7 (5.6, NE)	0.98 (0.43, 2.26)	0.9648	
≥65 years	11	2 (18.2)	9 (81.8)	NE (4.9, NE)	14	3 (21.4)	11 (78.6)	16.6 (0.7, NE)	1.01 (0.14, 7.22)	0.9955	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.8645
Asian	21	6 (28.6)	15 (71.4)	NE (4.9, NE)	21	5 (23.8)	16 (76.2)	16.6 (1.4, NE)	0.88 (0.27, 2.91)	0.8479	
Non-Asian	32	13 (40.6)	19 (59.4)	10.5 (1.4, NE)	26	7 (26.9)	19 (73.1)	6.2 (1.4, NE)	0.76 (0.28, 2.05)	0.5732	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8938
Capecitabine	21	7 (33.3)	14 (66.7)	7.0 (0.7, NE)	9	3 (33.3)	6 (66.7)	16.6 (1.4, NE)	1.37 (0.35, 5.36)	0.6557	
Eribulin mesylate	31	12 (38.7)	19 (61.3)	10.5 (1.5, NE)	41	9 (22.0)	32 (78.0)	6.2 (1.4, NE)	0.92 (0.37, 2.29)	0.8602	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (0.7, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.4997	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9670
Yes	6	3 (50.0)	3 (50.0)	NE (0.7, NE)	6	1 (16.7)	5 (83.3)	6.2 (NE, NE)	1.57 (0.16, 15.14)	0.6928	
No	57	18 (31.6)	39 (68.4)	10.5 (4.9, NE)	49	11 (22.4)	38 (77.6)	10.3 (5.6, NE)	1.01 (0.47, 2.15)	0.9841	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	20 (32.3)	42 (67.7)	-	54	12 (22.2)	42 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	12 (38.7)	19 (61.3)	-	24	6 (25.0)	18 (75.0)	-	-	-	
Asian	21	6 (28.6)	15 (71.4)	-	21	5 (23.8)	16 (76.2)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.7149
0	35	12 (34.3)	23 (65.7)	10.5 (1.5, NE)	33	7 (21.2)	26 (78.8)	10.3 (1.4, NE)	1.26 (0.47, 3.37)	0.6424	
≥1	28	9 (32.1)	19 (67.9)	11.0 (3.5, NE)	22	5 (22.7)	17 (77.3)	6.2 (1.4, NE)	0.91 (0.29, 2.85)	0.8685	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	0	6 (100)	-	-	-	
≥6 months	49	16 (32.7)	33 (67.3)	-	42	11 (26.2)	31 (73.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.6744
≤12 months	22	6 (27.3)	16 (72.7)	11.0 (0.7, NE)	19	3 (15.8)	16 (84.2)	NE (0.7, NE)	1.45 (0.36, 5.82)	0.5985	
>12 months	29	10 (34.5)	19 (65.5)	7.8 (1.4, NE)	27	7 (25.9)	20 (74.1)	10.3 (0.7, NE)	1.01 (0.38, 2.68)	0.9858	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	20 (33.9)	39 (66.1)	-	55	12 (21.8)	43 (78.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0493
Region 1 [US, Canada, Europe]	33	10 (30.3)	23 (69.7)	5.6 (1.4, NE)	28	6 (21.4)	22 (78.6)	NE (1.4, NE)	0.99 (0.35, 2.75)	0.9865	
Region 2 [Rest of World]	30	11 (36.7)	19 (63.3)	11.1 (2.1, NE)	27	14 (51.9)	13 (48.1)	1.4 (0.7, 2.8)	0.28 (0.12, 0.64)	0.0014	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.6526
Yes	52	15 (28.8)	37 (71.2)	11.1 (2.1, NE)	45	16 (35.6)	29 (64.4)	1.4 (0.8, 9.7)	0.47 (0.23, 0.97)	0.0375	
No	11	6 (54.5)	5 (45.5)	4.1 (0.8, NE)	10	4 (40.0)	6 (60.0)	2.8 (0.7, NE)	0.52 (0.13, 1.97)	0.3251	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	8 (42.1)	11 (57.9)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	9 (30.0)	21 (70.0)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.8330
<65 years	52	16 (30.8)	36 (69.2)	8.3 (2.7, NE)	41	14 (34.1)	27 (65.9)	1.4 (0.8, NE)	0.53 (0.25, 1.09)	0.0836	
≥65 years	11	5 (45.5)	6 (54.5)	9.0 (0.7, NE)	14	6 (42.9)	8 (57.1)	1.4 (0.7, NE)	0.42 (0.11, 1.53)	0.1743	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.1555
Asian	21	7 (33.3)	14 (66.7)	11.1 (2.1, NE)	21	12 (57.1)	9 (42.9)	1.4 (0.7, 2.1)	0.25 (0.09, 0.69)	0.0044	
Non-Asian	32	12 (37.5)	20 (62.5)	8.3 (2.1, NE)	26	8 (30.8)	18 (69.2)	2.8 (0.8, NE)	0.73 (0.30, 1.81)	0.5109	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.6769
Capecitabine	21	6 (28.6)	15 (71.4)	11.1 (0.8, NE)	9	6 (66.7)	3 (33.3)	1.4 (0.7, 9.7)	0.43 (0.14, 1.35)	0.1332	
Eribulin mesylate	31	12 (38.7)	19 (61.3)	3.5 (1.4, NE)	41	12 (29.3)	29 (70.7)	1.4 (0.8, NE)	0.71 (0.32, 1.59)	0.4180	
Vinorelbine	11	3 (27.3)	8 (72.7)	9.0 (4.1, NE)	5	2 (40.0)	3 (60.0)	1.4 (1.4, NE)	0.00 (0.00, NE)	0.0068	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.0906
Yes	6	2 (33.3)	4 (66.7)	NE (1.4, NE)	6	3 (50.0)	3 (50.0)	0.8 (0.7, NE)	0.09 (0.01, 0.92)	0.0140	
No	57	19 (33.3)	38 (66.7)	8.3 (2.1, NE)	49	17 (34.7)	32 (65.3)	1.4 (1.4, NE)	0.57 (0.29, 1.11)	0.1009	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	20 (32.3)	42 (67.7)	-	54	20 (37.0)	34 (63.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	11 (35.5)	20 (64.5)	-	24	7 (29.2)	17 (70.8)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	12 (57.1)	9 (42.9)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9122
0	35	13 (37.1)	22 (62.9)	8.3 (2.1, NE)	33	12 (36.4)	21 (63.6)	1.4 (0.7, 2.8)	0.46 (0.20, 1.02)	0.0536	
≥1	28	8 (28.6)	20 (71.4)	11.1 (2.1, NE)	22	8 (36.4)	14 (63.6)	1.4 (0.8, NE)	0.45 (0.16, 1.27)	0.1259	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	17 (34.7)	32 (65.3)	-	42	16 (38.1)	26 (61.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7246
≤12 months	22	5 (22.7)	17 (77.3)	NE (0.8, NE)	19	6 (31.6)	13 (68.4)	5.6 (0.7, NE)	0.53 (0.16, 1.74)	0.2883	
>12 months	29	9 (31.0)	20 (69.0)	8.3 (1.4, NE)	27	11 (40.7)	16 (59.3)	1.4 (0.7, 2.8)	0.38 (0.15, 0.94)	0.0296	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	19 (32.2)	40 (67.8)	-	55	20 (36.4)	35 (63.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.4350
Region 1 [US, Canada, Europe]	33	12 (36.4)	21 (63.6)	3.5 (2.8, 6.9)	28	7 (25.0)	21 (75.0)	3.5 (0.8, NE)	1.06 (0.42, 2.71)	0.8979	
Region 2 [Rest of World]	30	12 (40.0)	18 (60.0)	5.5 (2.1, NE)	27	10 (37.0)	17 (63.0)	3.4 (0.7, NE)	0.67 (0.29, 1.55)	0.3695	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.6016
Yes	52	19 (36.5)	33 (63.5)	3.5 (2.8, NE)	45	15 (33.3)	30 (66.7)	3.4 (0.8, NE)	0.77 (0.39, 1.52)	0.4688	
No	11	5 (45.5)	6 (54.5)	5.5 (1.5, NE)	10	2 (20.0)	8 (80.0)	NE (0.7, NE)	1.18 (0.22, 6.14)	0.8483	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	7 (36.8)	12 (63.2)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	11 (34.4)	21 (65.6)	-	30	7 (23.3)	23 (76.7)	-	-	-	
Neither taxanes nor anthracyclines	11	6 (54.5)	5 (45.5)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.2712
<65 years	52	20 (38.5)	32 (61.5)	4.2 (2.8, NE)	41	10 (24.4)	31 (75.6)	NE (1.3, NE)	1.06 (0.49, 2.26)	0.8644	
≥65 years	11	4 (36.4)	7 (63.6)	5.5 (0.7, NE)	14	7 (50.0)	7 (50.0)	1.4 (0.7, NE)	0.48 (0.14, 1.65)	0.2369	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.2397
Asian	21	7 (33.3)	14 (66.7)	NE (1.5, NE)	21	8 (38.1)	13 (61.9)	9.7 (0.7, NE)	0.50 (0.18, 1.41)	0.1972	
Non-Asian	32	15 (46.9)	17 (53.1)	5.5 (2.8, 6.9)	26	9 (34.6)	17 (65.4)	3.5 (0.8, NE)	1.15 (0.50, 2.63)	0.7538	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1660
Capecitabine	21	3 (14.3)	18 (85.7)	NE (6.9, NE)	9	4 (44.4)	5 (55.6)	5.6 (0.7, NE)	0.29 (0.06, 1.28)	0.0852	
Eribulin mesylate	31	16 (51.6)	15 (48.4)	2.9 (1.5, 5.5)	41	12 (29.3)	29 (70.7)	3.5 (0.8, NE)	1.30 (0.61, 2.76)	0.4750	
Vinorelbine	11	5 (45.5)	6 (54.5)	2.8 (1.4, NE)	5	1 (20.0)	4 (80.0)	NE (1.3, NE)	1.08 (0.12, 9.37)	0.9432	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.7549
Yes	6	3 (50.0)	3 (50.0)	5.5 (2.8, NE)	6	1 (16.7)	5 (83.3)	NE (0.8, NE)	1.05 (0.11, 10.41)	0.9692	
No	57	21 (36.8)	36 (63.2)	4.2 (2.8, NE)	49	16 (32.7)	33 (67.3)	3.5 (0.8, NE)	0.81 (0.42, 1.55)	0.5414	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	23 (37.1)	39 (62.9)	-	54	17 (31.5)	37 (68.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	14 (45.2)	17 (54.8)	-	24	8 (33.3)	16 (66.7)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	8 (38.1)	13 (61.9)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0108
0	35	14 (40.0)	21 (60.0)	5.5 (2.8, NE)	33	13 (39.4)	20 (60.6)	1.3 (0.7, 3.5)	0.36 (0.17, 0.77)	0.0082	
≥1	28	10 (35.7)	18 (64.3)	2.8 (0.8, NE)	22	4 (18.2)	18 (81.8)	9.7 (1.4, NE)	2.19 (0.68, 7.08)	0.1856	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	0	6 (100)	-	-	-	
≥6 months	49	20 (40.8)	29 (59.2)	-	42	14 (33.3)	28 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.1354
≤12 months	22	8 (36.4)	14 (63.6)	2.8 (0.7, NE)	19	6 (31.6)	13 (68.4)	9.7 (0.8, NE)	1.31 (0.45, 3.80)	0.6277	
>12 months	29	10 (34.5)	19 (65.5)	4.2 (2.8, NE)	27	10 (37.0)	17 (63.0)	0.8 (0.7, NE)	0.45 (0.18, 1.09)	0.0807	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	23 (39.0)	36 (61.0)	-	55	17 (30.9)	38 (69.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9822
Region 1 [US, Canada, Europe]	33	6 (18.2)	27 (81.8)	NE (4.2, NE)	28	6 (21.4)	22 (78.6)	5.5 (0.8, NE)	0.52 (0.16, 1.64)	0.2547	
Region 2 [Rest of World]	30	8 (26.7)	22 (73.3)	NE (5.5, NE)	27	8 (29.6)	19 (70.4)	7.6 (2.8, NE)	0.44 (0.16, 1.20)	0.1040	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.4985
Yes	52	10 (19.2)	42 (80.8)	NE (5.6, NE)	45	11 (24.4)	34 (75.6)	4.9 (2.0, NE)	0.41 (0.17, 0.98)	0.0401	
No	11	4 (36.4)	7 (63.6)	NE (0.8, NE)	10	3 (30.0)	7 (70.0)	7.6 (0.7, NE)	0.70 (0.15, 3.15)	0.6375	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	4 (21.1)	15 (78.9)	-	13	4 (30.8)	9 (69.2)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	8 (25.0)	24 (75.0)	-	30	4 (13.3)	26 (86.7)	-	-	-	
Neither taxanes nor anthracyclines	11	2 (18.2)	9 (81.8)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7698
<65 years	52	10 (19.2)	42 (80.8)	NE (5.5, NE)	41	9 (22.0)	32 (78.0)	5.5 (2.8, NE)	0.47 (0.19, 1.17)	0.1003	
≥65 years	11	4 (36.4)	7 (63.6)	9.0 (0.7, NE)	14	5 (35.7)	9 (64.3)	4.9 (0.7, NE)	0.58 (0.15, 2.21)	0.4138	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9426
Asian	21	5 (23.8)	16 (76.2)	9.0 (4.8, NE)	21	5 (23.8)	16 (76.2)	4.9 (2.8, NE)	0.49 (0.14, 1.73)	0.2607	
Non-Asian	32	9 (28.1)	23 (71.9)	NE (4.2, NE)	26	9 (34.6)	17 (65.4)	5.5 (0.8, NE)	0.51 (0.20, 1.30)	0.1533	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9777
Capecitabine	21	4 (19.0)	17 (81.0)	NE (5.6, NE)	9	3 (33.3)	6 (66.7)	4.9 (0.7, NE)	0.45 (0.10, 2.05)	0.2917	
Eribulin mesylate	31	8 (25.8)	23 (74.2)	NE (4.2, NE)	41	11 (26.8)	30 (73.2)	5.5 (2.0, NE)	0.56 (0.22, 1.42)	0.2123	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (2.8, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.6171	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.1670
Yes	6	3 (50.0)	3 (50.0)	2.8 (0.7, NE)	6	1 (16.7)	5 (83.3)	7.6 (NE, NE)	2.00 (0.20, 19.64)	0.5445	
No	57	11 (19.3)	46 (80.7)	NE (5.6, NE)	49	13 (26.5)	36 (73.5)	4.9 (2.0, NE)	0.38 (0.17, 0.87)	0.0176	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	14 (22.6)	48 (77.4)	-	54	14 (25.9)	40 (74.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	8 (25.8)	23 (74.2)	-	24	8 (33.3)	16 (66.7)	-	-	-	
Asian	21	5 (23.8)	16 (76.2)	-	21	5 (23.8)	16 (76.2)	-	-	-	
Other*	1	1 (100)	0	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0065
0	35	5 (14.3)	30 (85.7)	NE (6.2, NE)	33	10 (30.3)	23 (69.7)	4.2 (0.7, 5.5)	0.16 (0.05, 0.48)	0.0003	
≥1	28	9 (32.1)	19 (67.9)	5.6 (2.8, NE)	22	4 (18.2)	18 (81.8)	7.6 (2.8, NE)	1.48 (0.45, 4.89)	0.5172	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	12 (24.5)	37 (75.5)	-	42	11 (26.2)	31 (73.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.0770
≤12 months	22	5 (22.7)	17 (77.3)	NE (2.8, NE)	19	4 (21.1)	15 (78.9)	NE (0.8, NE)	0.91 (0.24, 3.44)	0.8924	
>12 months	29	4 (13.8)	25 (86.2)	NE (5.6, NE)	27	8 (29.6)	19 (70.4)	2.8 (0.7, 4.9)	0.16 (0.04, 0.57)	0.0019	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	13 (22.0)	46 (78.0)	-	55	14 (25.5)	41 (74.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0966
Region 1 [US, Canada, Europe]	33	12 (36.4)	21 (63.6)	3.5 (1.3, 7.6)	28	4 (14.3)	24 (85.7)	NE (1.5, NE)	1.91 (0.61, 5.95)	0.2600	
Region 2 [Rest of World]	30	7 (23.3)	23 (76.7)	NE (12.5, NE)	27	8 (29.6)	19 (70.4)	NE (1.4, NE)	0.55 (0.20, 1.54)	0.2518	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.7654
Yes	52	16 (30.8)	36 (69.2)	7.6 (2.8, NE)	45	10 (22.2)	35 (77.8)	NE (1.5, NE)	1.06 (0.48, 2.35)	0.8773	
No	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	10	2 (20.0)	8 (80.0)	7.0 (1.4, NE)	0.77 (0.13, 4.69)	0.7795	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	4 (21.1)	15 (78.9)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9706
<65 years	52	16 (30.8)	36 (69.2)	7.6 (2.8, NE)	41	9 (22.0)	32 (78.0)	7.0 (1.5, NE)	0.99 (0.43, 2.26)	0.9780	
≥65 years	11	3 (27.3)	8 (72.7)	12.5 (0.8, NE)	14	3 (21.4)	11 (78.6)	NE (0.7, NE)	0.89 (0.18, 4.45)	0.8812	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.0651
Asian	21	3 (14.3)	18 (85.7)	NE (12.5, NE)	21	6 (28.6)	15 (71.4)	NE (0.7, NE)	0.37 (0.09, 1.49)	0.1471	
Non-Asian	32	15 (46.9)	17 (53.1)	3.5 (2.1, NE)	26	6 (23.1)	20 (76.9)	7.0 (3.4, NE)	1.69 (0.65, 4.37)	0.2761	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1288
Capecitabine	21	6 (28.6)	15 (71.4)	12.5 (0.8, NE)	9	6 (66.7)	3 (33.3)	1.4 (0.7, 3.4)	0.37 (0.12, 1.15)	0.0682	
Eribulin mesylate	31	10 (32.3)	21 (67.7)	5.6 (2.2, NE)	41	6 (14.6)	35 (85.4)	NE (4.8, NE)	1.72 (0.62, 4.73)	0.2973	
Vinorelbine	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.3189	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.6475
Yes	6	3 (50.0)	3 (50.0)	2.8 (1.4, NE)	6	1 (16.7)	5 (83.3)	NE (0.7, NE)	1.74 (0.18, 16.81)	0.6274	
No	57	16 (28.1)	41 (71.9)	12.5 (3.5, NE)	49	11 (22.4)	38 (77.6)	NE (3.4, NE)	0.93 (0.43, 2.02)	0.8567	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	18 (29.0)	44 (71.0)	-	54	12 (22.2)	42 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_QLQC30_FD_SUB_mFASA_FA.rtf

Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	14 (45.2)	17 (54.8)	-	24	6 (25.0)	18 (75.0)	-	-	-	
Asian	21	3 (14.3)	18 (85.7)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Other*	1	1 (100)	0	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.2814
0	35	11 (31.4)	24 (68.6)	7.6 (2.2, NE)	33	9 (27.3)	24 (72.7)	4.8 (1.4, NE)	0.76 (0.31, 1.85)	0.5465	
≥1	28	8 (28.6)	20 (71.4)	12.5 (2.1, NE)	22	3 (13.6)	19 (86.4)	NE (7.0, NE)	1.76 (0.46, 6.69)	0.4010	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	15 (30.6)	34 (69.4)	-	42	8 (19.0)	34 (81.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.5448
≤12 months	22	7 (31.8)	15 (68.2)	5.6 (1.4, NE)	19	4 (21.1)	15 (78.9)	NE (0.7, NE)	1.41 (0.41, 4.84)	0.5818	
>12 months	29	8 (27.6)	21 (72.4)	7.6 (1.4, NE)	27	6 (22.2)	21 (77.8)	NE (1.5, NE)	0.88 (0.30, 2.57)	0.8251	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 3.27.2 EORTC QLQ-C30 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	18 (30.5)	41 (69.5)	-	55	12 (21.8)	43 (78.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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EORTC QLQ-C30 – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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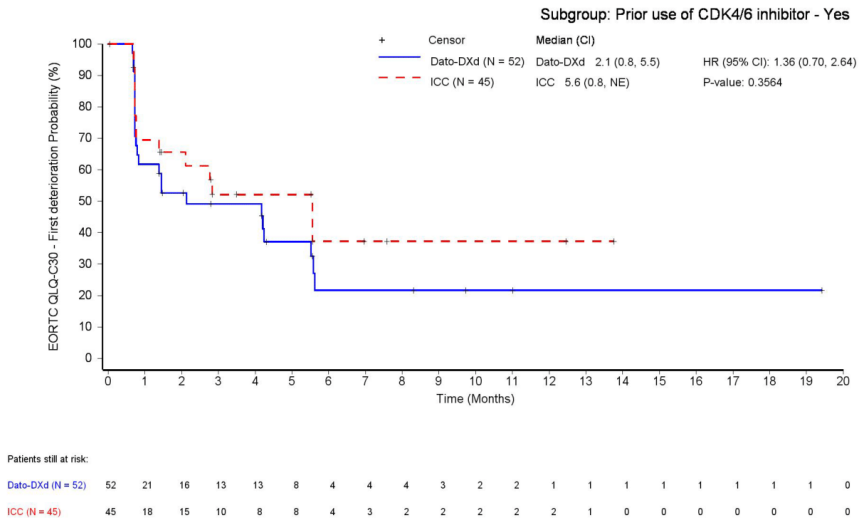
Final

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
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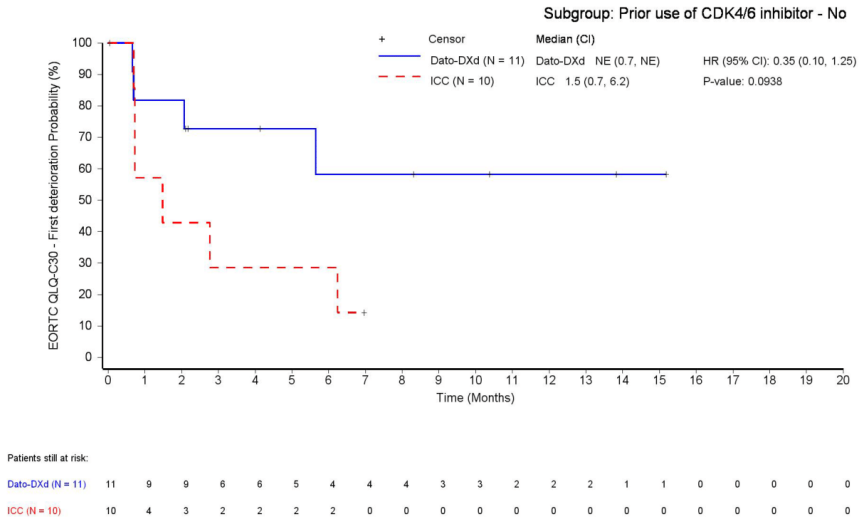
Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning



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Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning

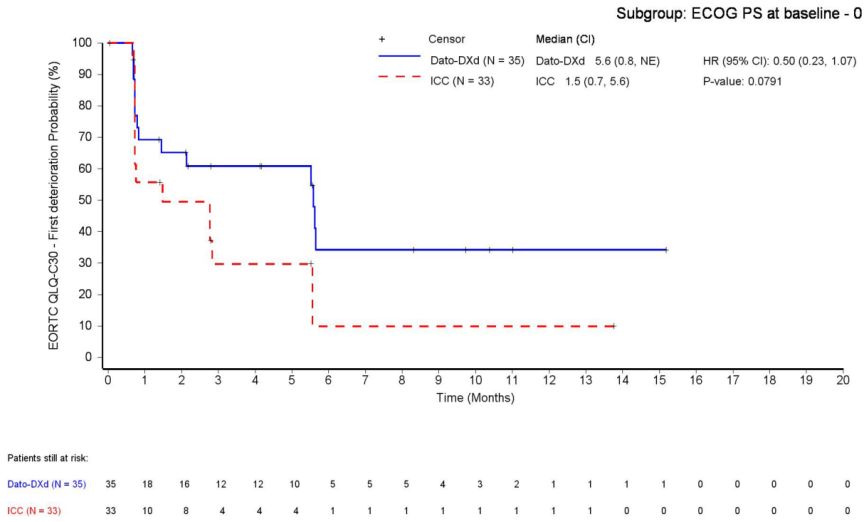

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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning

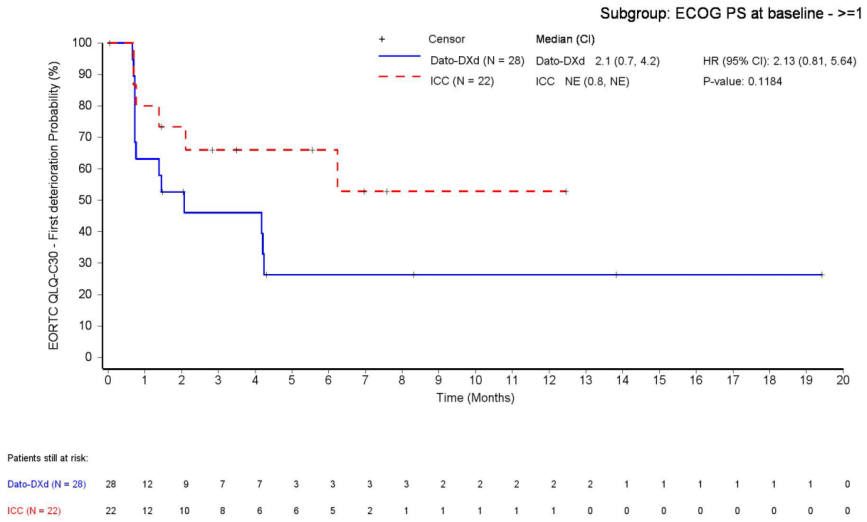

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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning

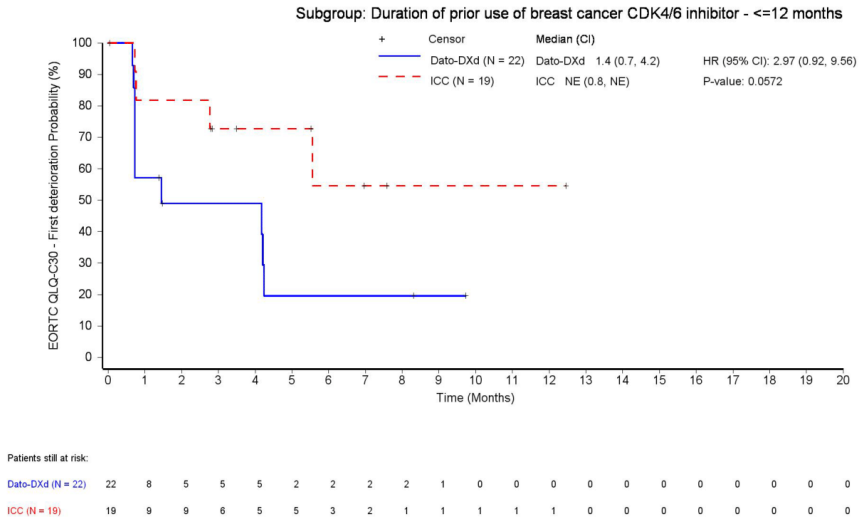

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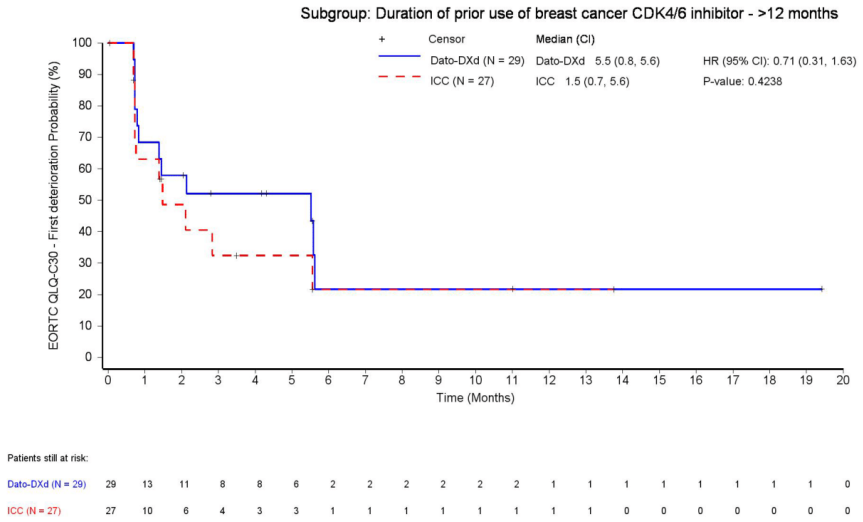
Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Role Functioning



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Data source: ADAM.ADQSTTE
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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Emotional Functioning

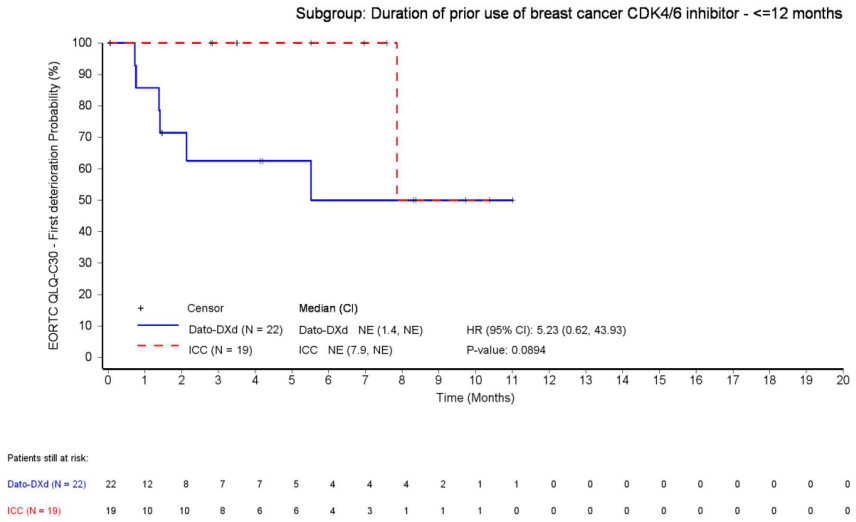

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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Emotional Functioning

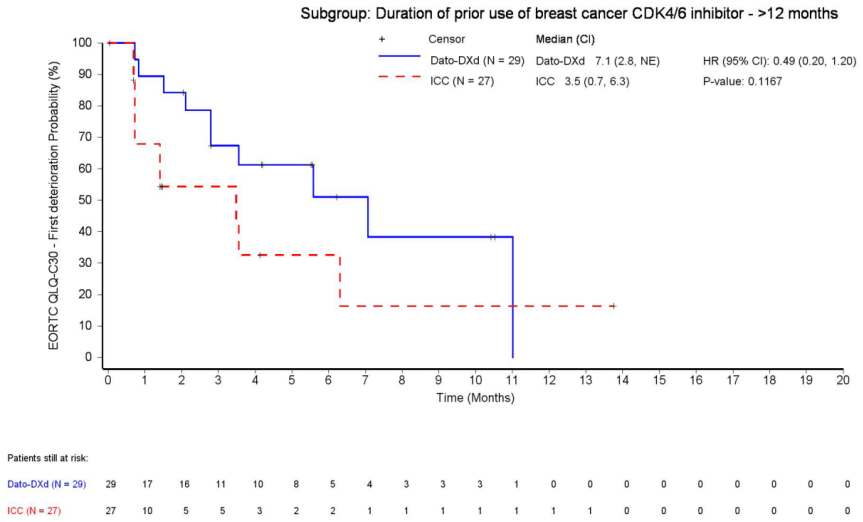

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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Social Functioning

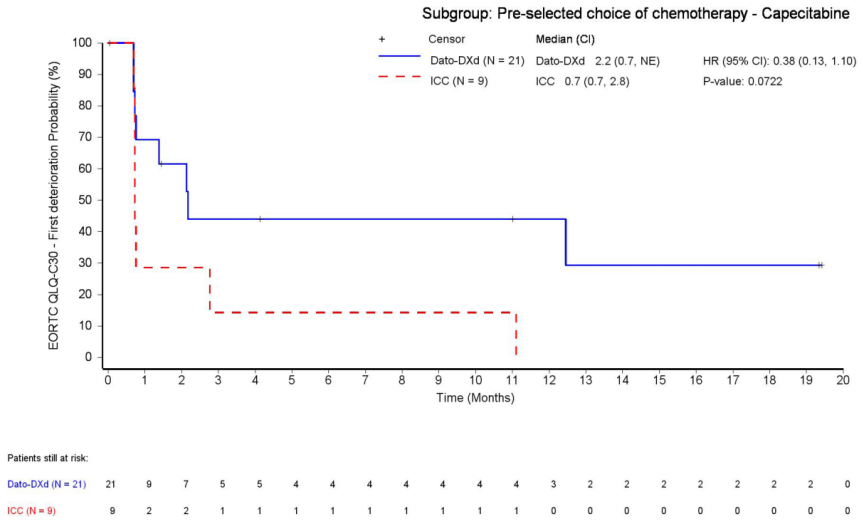

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Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Social Functioning

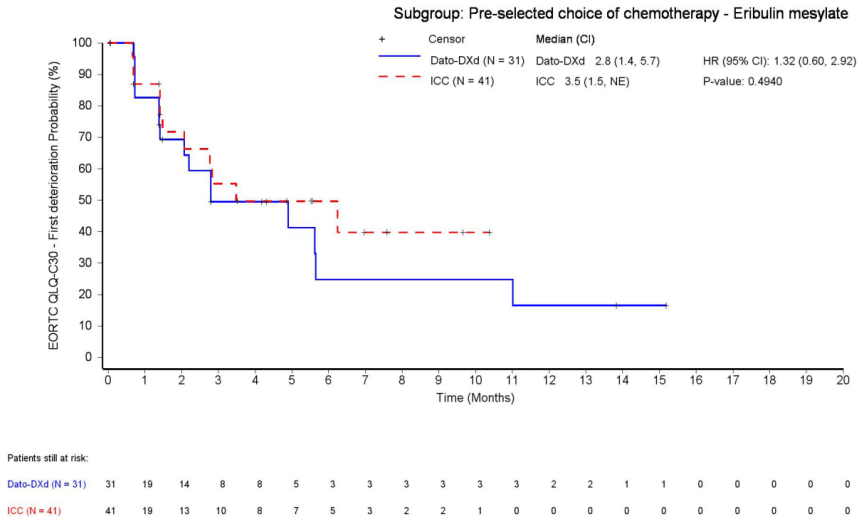

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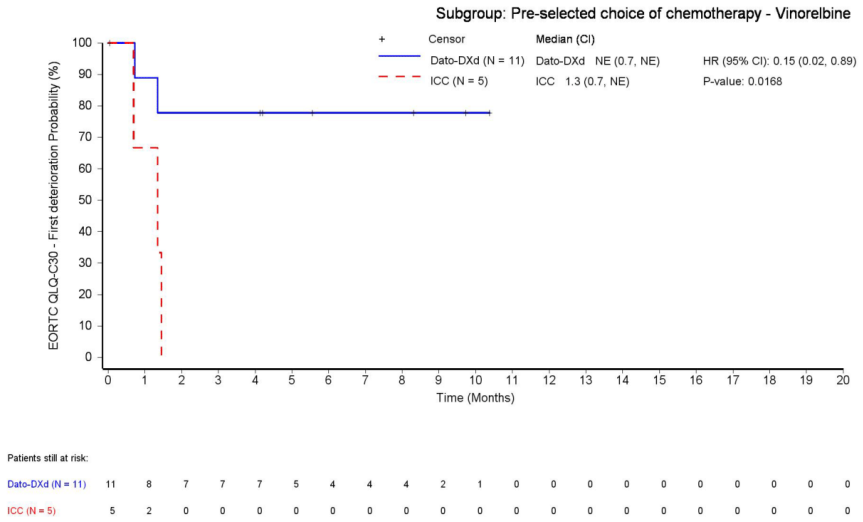
Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Functional Scales - Social Functioning

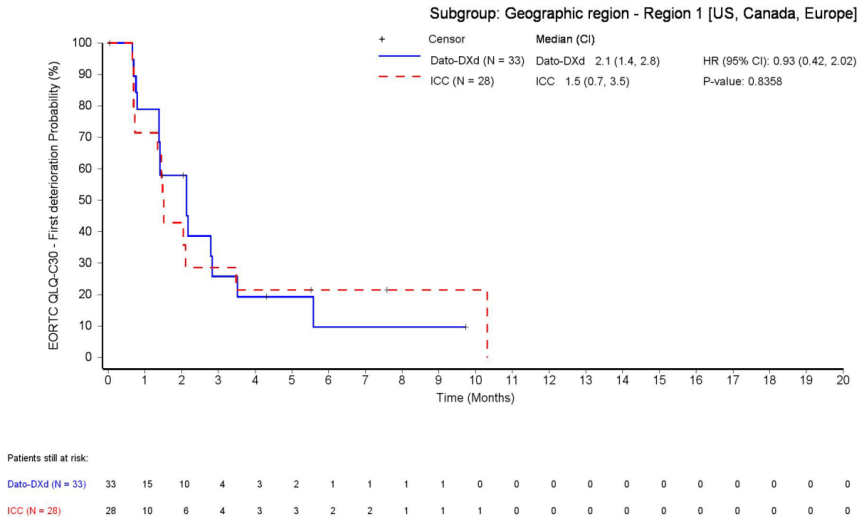


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

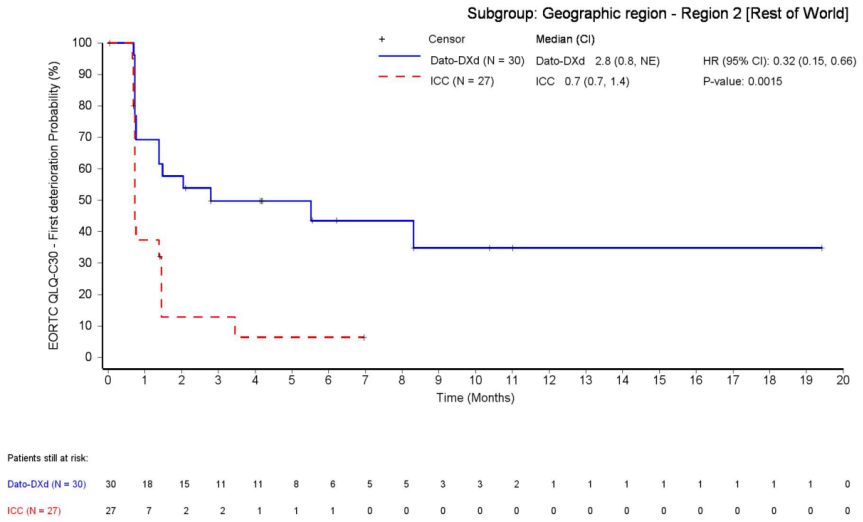


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

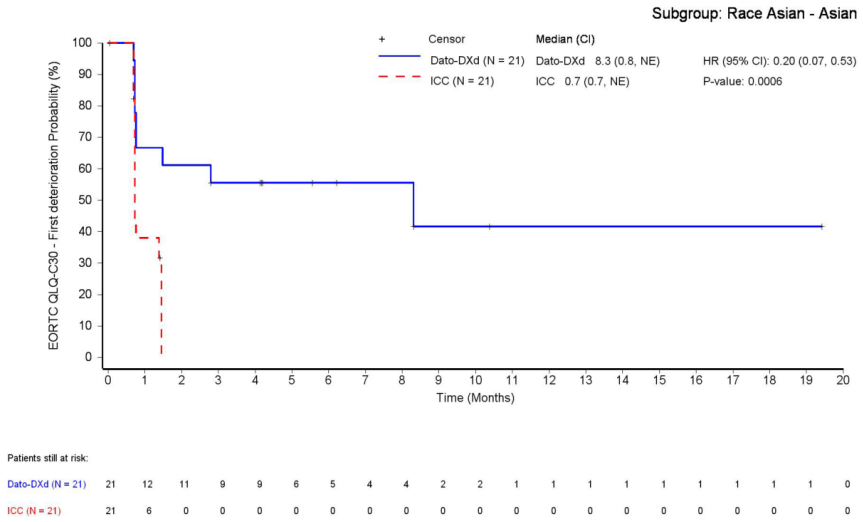


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

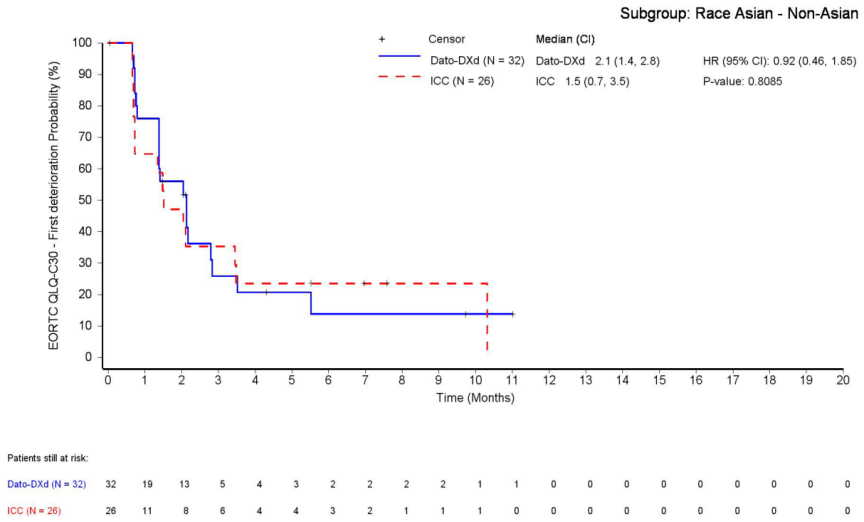


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

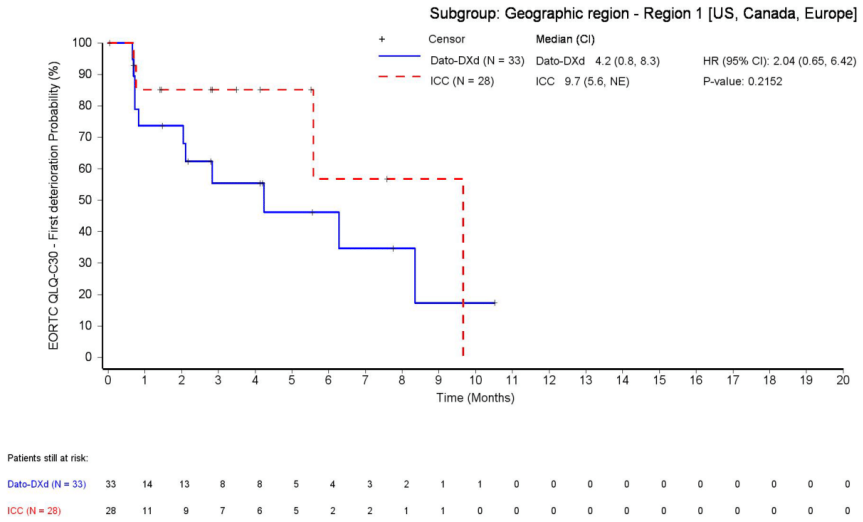


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Dyspnea

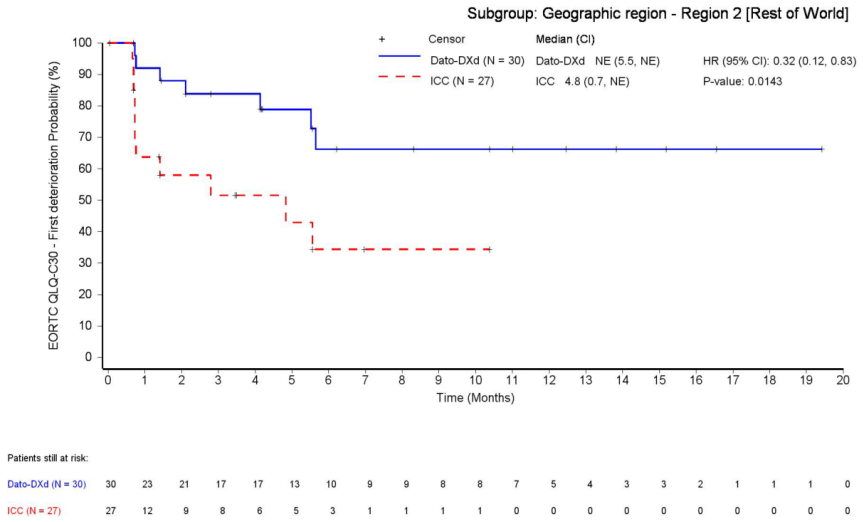


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Dyspnea

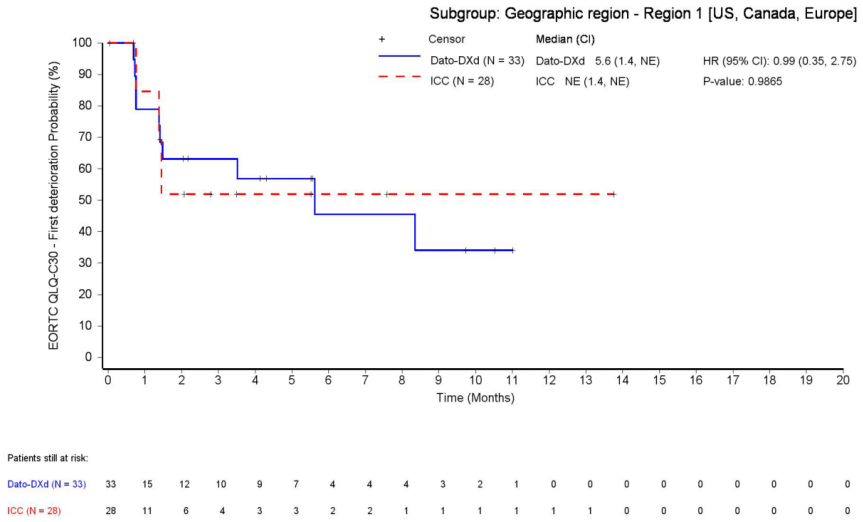


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Appetite Loss

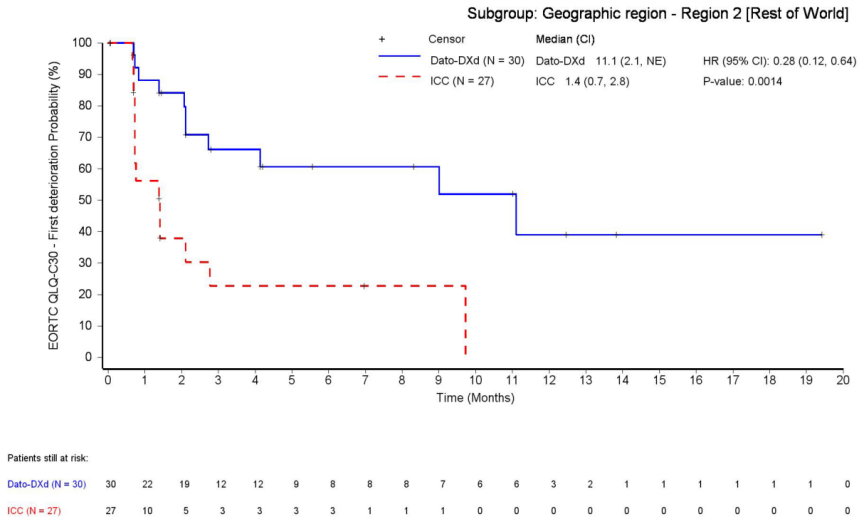


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Appetite Loss

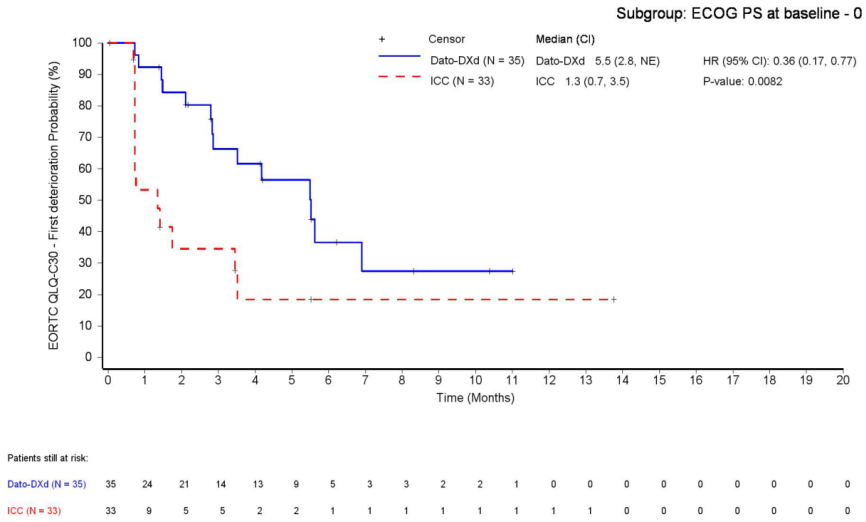


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Constipation

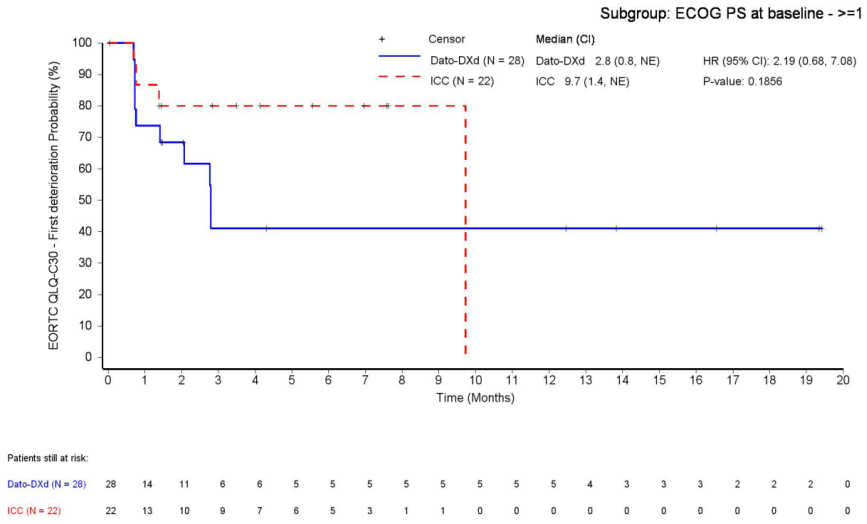


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Constipation

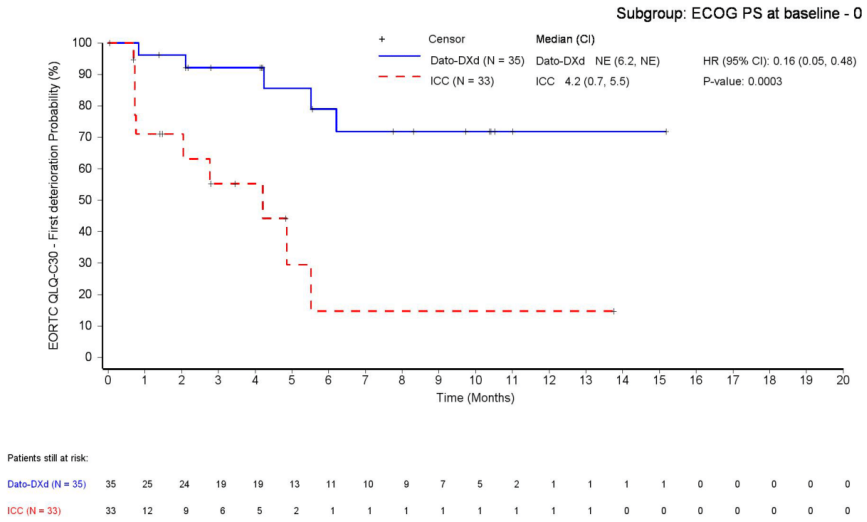


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Diarrhea

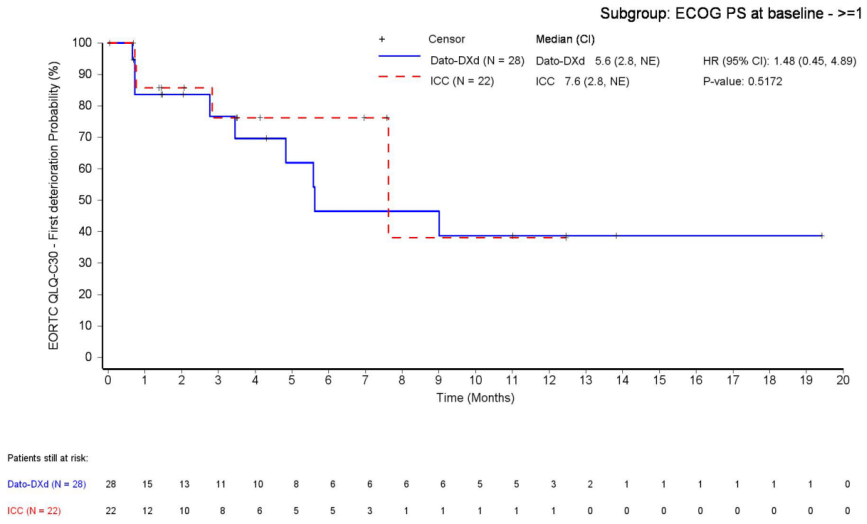


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

Figure 3.27.2 EORTC QLQ-C30 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Common Symptoms - Diarrhea



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQC30_FD_SUB_mFASA_FA.rtf

EORTC QLQ-C30 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert

EORTC QLQ-C30 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Final

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Global Health Status

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.8452
Dato-DXd	45	
ICC	32	
Time		0.8973
Treatment x Time		0.4630

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Global Health Status

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-7.0 [-11.1, -2.9]	-6.2 [-13.6, 1.3]	-0.8 [-9.3, 7.6]	-0.05 [-0.51, 0.41]
Treatment estimate by planned visit:				
Week 3	-5.4 [-10.8, -0.1]	-3.3 [-9.9, 3.3]	-2.2 [-10.6, 6.3]	
Week 6	-1.4 [-7.1, 4.3]	-6.6 [-13.8, 0.7]	5.1 [-4.1, 14.4]	
Week 9	-5.0 [-10.9, 0.8]	-5.9 [-13.5, 1.8]	0.8 [-8.8, 10.5]	
Week 12	-8.5 [-14.5, -2.4]	-6.2 [-14.1, 1.7]	-2.3 [-12.2, 7.7]	
Week 15	-0.1 [-6.4, 6.2]	-9.3 [-18.0, -0.5]	9.2 [-1.6, 20.0]	
Week 18	-5.2 [-11.9, 1.5]	-9.0 [-19.8, 1.7]	3.9 [-8.8, 16.5]	
Week 21	-7.3 [-14.3, -0.3]	-15.4 [-26.5, -4.4]	8.1 [-5.0, 21.2]	
Week 24	-8.9 [-16.4, -1.3]	-10.2 [-22.1, 1.6]	1.4 [-12.6, 15.4]	
Week 27	-8.1 [-16.2, 0.0]	-4.4 [-17.5, 8.7]	-3.7 [-19.1, 11.7]	
Week 30	-5.8 [-13.9, 2.4]	-5.9 [-19.0, 7.2]	0.2 [-15.3, 15.6]	
Week 33	-7.9 [-16.2, 0.3]	-2.6 [-17.9, 12.8]	-5.4 [-22.8, 12.1]	
Week 36	-10.3 [-18.9, -1.7]	-5.9 [-21.2, 9.4]	-4.4 [-21.9, 13.2]	
Week 39	-8.3 [-17.0, 0.5]	0.9 [-15.5, 17.2]	-9.1 [-27.7, 9.4]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Global Health Status

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-12.5 [-23.5, -1.5]	3.9 [-12.9, 20.7]	-16.4 [-36.5, 3.7]	
Week 45	-7.5 [-18.3, 3.4]	-2.0 [-20.8, 16.8]	-5.5 [-27.2, 16.3]	
Week 48	-12.6 [-24.3, -0.9]	-5.0 [-33.9, 23.8]	-7.6 [-38.7, 23.6]	
Week 54	-10.2 [-23.3, 2.9]	-15.4 [-48.0, 17.1]	5.2 [-29.8, 40.3]	
Week 60	-1.1 [-14.8, 12.6]	-8.5 [-42.7, 25.7]	7.4 [-29.4, 44.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.9526
Dato-DXd	45	
ICC	32	
Time		0.5561
Treatment x Time		0.5460

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-5.2 [-10.0, -0.3]	-4.9 [-13.0, 3.2]	-0.3 [-9.8, 9.2]	-0.01 [-0.48, 0.45]
Treatment estimate by planned visit:				
Week 3	-2.6 [-7.9, 2.6]	-3.1 [-9.5, 3.3]	0.5 [-7.8, 8.7]	
Week 6	-1.3 [-6.7, 4.1]	-4.6 [-11.3, 2.2]	3.2 [-5.4, 11.9]	
Week 9	-3.0 [-8.6, 2.5]	-6.6 [-13.6, 0.4]	3.6 [-5.4, 12.5]	
Week 12	-2.1 [-7.8, 3.6]	-8.7 [-16.0, -1.4]	6.6 [-2.7, 15.9]	
Week 15	-1.7 [-7.6, 4.2]	-7.7 [-15.6, 0.2]	6.0 [-3.9, 15.9]	
Week 18	-0.6 [-6.8, 5.6]	-4.6 [-13.7, 4.6]	3.9 [-7.1, 15.0]	
Week 21	-0.6 [-7.0, 5.9]	-5.8 [-15.5, 3.9]	5.3 [-6.4, 16.9]	
Week 24	-8.8 [-15.6, -2.0]	-8.0 [-18.5, 2.4]	-0.8 [-13.3, 11.8]	
Week 27	-7.0 [-14.2, 0.3]	-4.5 [-16.0, 7.0]	-2.4 [-16.1, 11.2]	
Week 30	-8.2 [-15.6, -0.7]	-2.3 [-14.2, 9.6]	-5.9 [-20.0, 8.2]	
Week 33	-7.3 [-14.9, 0.4]	-4.5 [-17.9, 8.9]	-2.8 [-18.2, 12.7]	
Week 36	-13.5 [-21.4, -5.5]	1.5 [-12.3, 15.3]	-14.9 [-30.9, 1.0]	
Week 39	-11.2 [-19.4, -3.1]	0.7 [-14.0, 15.4]	-11.9 [-28.7, 4.9]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Physical Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-7.5 [-16.9, 1.9]	-0.8 [-16.1, 14.5]	-6.7 [-24.7, 11.3]	
Week 45	-10.6 [-20.2, -1.0]	-6.7 [-23.5, 10.1]	-3.9 [-23.3, 15.4]	
Week 48	-5.7 [-16.1, 4.7]	-1.7 [-24.8, 21.4]	-4.0 [-29.3, 21.3]	
Week 54	-1.3 [-12.7, 10.1]	-3.2 [-30.0, 23.7]	1.9 [-27.3, 31.1]	
Week 60	-0.5 [-12.7, 11.6]	-17.8 [-47.0, 11.5]	17.2 [-14.5, 48.9]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.7149
Dato-DXd	45	
ICC	32	
Time		0.2512
Treatment x Time		0.8366

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-7.9 [-13.3, -2.5]	-9.9 [-19.7, -0.2]	2.1 [-9.1, 13.2]	0.09 [-0.37, 0.55]
Treatment estimate by planned visit:				
Week 3	-6.0 [-12.8, 0.8]	-1.3 [-9.7, 7.0]	-4.6 [-15.4, 6.1]	
Week 6	-2.3 [-9.5, 4.8]	-7.4 [-16.5, 1.8]	5.0 [-6.6, 16.7]	
Week 9	-1.8 [-9.1, 5.6]	-13.5 [-23.2, -3.9]	11.8 [-0.4, 23.9]	
Week 12	-4.4 [-12.1, 3.2]	-14.2 [-24.1, -4.2]	9.8 [-2.8, 22.3]	
Week 15	-0.6 [-8.6, 7.4]	-11.1 [-22.1, -0.1]	10.5 [-3.0, 24.1]	
Week 18	-4.0 [-12.4, 4.4]	-6.4 [-19.7, 6.9]	2.4 [-13.4, 18.2]	
Week 21	-6.5 [-15.3, 2.4]	-14.8 [-28.6, -1.1]	8.4 [-8.0, 24.8]	
Week 24	-13.7 [-23.2, -4.3]	-17.9 [-32.6, -3.1]	4.1 [-13.4, 21.7]	
Week 27	-13.6 [-23.7, -3.4]	-16.8 [-33.2, -0.4]	3.2 [-16.1, 22.5]	
Week 30	-7.0 [-17.3, 3.3]	-5.1 [-21.6, 11.4]	-2.0 [-21.4, 17.5]	
Week 33	-7.9 [-18.4, 2.5]	0.7 [-18.5, 19.9]	-8.6 [-30.5, 13.2]	
Week 36	-15.3 [-26.1, -4.5]	-10.5 [-29.8, 8.8]	-4.8 [-26.9, 17.3]	
Week 39	-9.9 [-21.0, 1.2]	-6.9 [-27.5, 13.6]	-3.0 [-26.3, 20.4]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Role Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-9.5 [-23.2, 4.1]	-1.5 [-22.7, 19.6]	-8.0 [-33.2, 17.2]	
Week 45	-16.0 [-29.6, -2.4]	-11.2 [-34.8, 12.5]	-4.8 [-32.1, 22.4]	
Week 48	-11.8 [-26.4, 2.9]	-12.7 [-48.1, 22.8]	0.9 [-37.4, 39.3]	
Week 54	-8.6 [-24.9, 7.7]	-13.8 [-54.2, 26.6]	5.2 [-38.3, 48.8]	
Week 60	-3.1 [-20.2, 14.1]	-14.6 [-57.4, 28.2]	11.5 [-34.6, 57.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.0113
Dato-DXd	45	
ICC	32	
Time		0.0934
Treatment x Time		0.6995

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	4.7 [0.8, 8.5]	-5.7 [-12.7, 1.3]	10.4 [2.4, 18.4]	0.64 [0.17, 1.11]
Treatment estimate by planned visit:				
Week 3	5.6 [0.7, 10.6]	0.8 [-5.4, 7.0]	4.8 [-3.1, 12.7]	
Week 6	4.7 [-0.6, 10.0]	3.4 [-3.4, 10.2]	1.3 [-7.3, 9.9]	
Week 9	5.2 [-0.3, 10.6]	0.0 [-7.1, 7.2]	5.2 [-3.8, 14.2]	
Week 12	1.7 [-3.9, 7.4]	0.9 [-6.5, 8.3]	0.8 [-8.5, 10.1]	
Week 15	4.3 [-1.6, 10.2]	-5.6 [-13.8, 2.5]	9.9 [-0.1, 20.0]	
Week 18	8.6 [2.4, 14.9]	-2.4 [-12.3, 7.5]	11.0 [-0.7, 22.7]	
Week 21	4.3 [-2.2, 10.8]	-6.8 [-17.0, 3.4]	11.1 [-1.0, 23.2]	
Week 24	-2.4 [-9.4, 4.6]	-13.2 [-24.1, -2.3]	10.8 [-2.2, 23.7]	
Week 27	1.4 [-6.1, 8.9]	-4.7 [-16.8, 7.4]	6.1 [-8.2, 20.3]	
Week 30	3.5 [-4.1, 11.1]	1.9 [-10.2, 14.1]	1.6 [-12.7, 15.9]	
Week 33	5.7 [-2.0, 13.4]	-6.2 [-20.5, 8.0]	11.9 [-4.3, 28.1]	
Week 36	8.1 [0.1, 16.1]	-0.3 [-14.6, 13.9]	8.4 [-7.9, 24.7]	
Week 39	5.2 [-3.0, 13.3]	-11.9 [-27.1, 3.3]	17.1 [-0.1, 34.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Emotional Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	5.3 [-4.8, 15.5]	-11.2 [-26.8, 4.5]	16.5 [-2.2, 35.2]	
Week 45	6.2 [-3.9, 16.3]	-6.2 [-23.7, 11.3]	12.4 [-7.8, 32.6]	
Week 48	6.4 [-4.5, 17.2]	-14.2 [-40.7, 12.4]	20.5 [-8.2, 49.2]	
Week 54	4.4 [-7.7, 16.5]	-13.9 [-44.0, 16.2]	18.2 [-14.2, 50.7]	
Week 60	6.0 [-6.7, 18.7]	-13.7 [-45.4, 18.0]	19.7 [-14.5, 53.8]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.3003
Dato-DXd	45	
ICC	32	
Time		0.8727
Treatment x Time		0.8586

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-7.2 [-11.3, -3.1]	-2.7 [-10.1, 4.7]	-4.5 [-13.0, 4.0]	-0.26 [-0.72, 0.20]
Treatment estimate by planned visit:				
Week 3	-2.2 [-7.4, 3.0]	-2.0 [-8.4, 4.4]	-0.2 [-8.4, 8.1]	
Week 6	-2.3 [-7.9, 3.2]	-2.0 [-9.1, 5.0]	-0.3 [-9.3, 8.6]	
Week 9	-3.9 [-9.6, 1.8]	-5.3 [-12.7, 2.2]	1.4 [-8.0, 10.7]	
Week 12	-6.8 [-12.7, -0.9]	-1.9 [-9.6, 5.7]	-4.9 [-14.6, 4.8]	
Week 15	-5.2 [-11.4, 0.9]	-6.7 [-15.2, 1.8]	1.5 [-9.0, 11.9]	
Week 18	-3.7 [-10.2, 2.9]	-1.5 [-11.8, 8.8]	-2.1 [-14.3, 10.1]	
Week 21	-5.1 [-11.9, 1.8]	-8.9 [-19.5, 1.8]	3.8 [-8.8, 16.5]	
Week 24	-10.0 [-17.4, -2.7]	-8.7 [-20.1, 2.7]	-1.4 [-14.9, 12.2]	
Week 27	-8.3 [-16.2, -0.5]	-2.7 [-15.4, 10.0]	-5.6 [-20.5, 9.3]	
Week 30	-5.9 [-13.8, 2.1]	0.2 [-12.5, 12.9]	-6.1 [-21.1, 8.9]	
Week 33	-9.7 [-17.8, -1.7]	2.9 [-11.9, 17.8]	-12.7 [-29.6, 4.2]	
Week 36	-7.5 [-15.9, 0.8]	0.9 [-14.0, 15.8]	-8.5 [-25.6, 8.6]	
Week 39	-10.6 [-19.1, -2.1]	0.3 [-15.6, 16.2]	-10.9 [-29.0, 7.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Cognitive Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-6.5 [-17.0, 4.1]	-7.2 [-23.7, 9.2]	0.8 [-18.8, 20.3]	
Week 45	-12.0 [-22.5, -1.5]	-5.8 [-24.2, 12.5]	-6.2 [-27.4, 15.0]	
Week 48	-7.7 [-19.0, 3.6]	-2.3 [-29.9, 25.2]	-5.4 [-35.2, 24.4]	
Week 54	-7.9 [-20.5, 4.8]	0.2 [-31.1, 31.5]	-8.0 [-41.8, 25.7]	
Week 60	-13.6 [-26.8, -0.4]	2.0 [-31.1, 35.1]	-15.6 [-51.2, 20.0]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.5749
Dato-DXd	45	
ICC	32	
Time		0.4279
Treatment x Time		0.9973

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-0.4 [-5.5, 4.7]	-3.4 [-12.7, 5.9]	3.0 [-7.6, 13.6]	0.14 [-0.32, 0.60]
Treatment estimate by planned visit:				
Week 3	-0.4 [-6.9, 6.2]	-1.9 [-10.0, 6.2]	1.5 [-8.9, 12.0]	
Week 6	4.2 [-2.7, 11.2]	0.6 [-8.3, 9.6]	3.6 [-7.7, 14.9]	
Week 9	-1.0 [-8.1, 6.2]	-6.4 [-15.8, 3.0]	5.4 [-6.4, 17.2]	
Week 12	-4.3 [-11.7, 3.2]	-4.8 [-14.5, 4.9]	0.5 [-11.6, 12.7]	
Week 15	-0.1 [-7.8, 7.7]	-4.7 [-15.4, 5.9]	4.7 [-8.5, 17.8]	
Week 18	0.3 [-7.9, 8.5]	-2.6 [-15.6, 10.4]	2.9 [-12.5, 18.2]	
Week 21	0.3 [-8.3, 8.9]	-5.3 [-18.7, 8.1]	5.6 [-10.3, 21.6]	
Week 24	-8.1 [-17.3, 1.1]	-9.8 [-24.1, 4.6]	1.6 [-15.4, 18.6]	
Week 27	-3.5 [-13.4, 6.3]	-10.1 [-26.0, 5.8]	6.6 [-12.2, 25.3]	
Week 30	0.6 [-9.4, 10.6]	2.9 [-13.1, 18.9]	-2.3 [-21.2, 16.5]	
Week 33	-2.4 [-12.6, 7.7]	2.7 [-16.0, 21.4]	-5.1 [-26.4, 16.2]	
Week 36	-4.4 [-14.9, 6.1]	2.4 [-16.3, 21.2]	-6.9 [-28.3, 14.6]	
Week 39	-3.4 [-14.1, 7.4]	2.4 [-17.6, 22.3]	-5.7 [-28.4, 17.0]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Functional Scales - Social Functioning

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	4.0 [-9.4, 17.3]	2.2 [-18.4, 22.8]	1.8 [-22.7, 26.3]	
Week 45	-1.9 [-15.1, 11.4]	-3.0 [-26.0, 20.0]	1.1 [-25.4, 27.7]	
Week 48	-3.6 [-17.8, 10.7]	-6.5 [-41.3, 28.4]	2.9 [-34.8, 40.6]	
Week 54	6.6 [-9.4, 22.5]	-8.9 [-48.5, 30.6]	15.5 [-27.2, 58.2]	
Week 60	9.8 [-7.0, 26.5]	-10.7 [-52.4, 31.1]	20.4 [-24.6, 65.5]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.0742
Dato-DXd	45	
ICC	32	
Time		0.8446
Treatment x Time		0.6906

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	2.1 [-2.4, 6.7]	10.7 [2.5, 19.0]	-8.6 [-18.1, 0.9]	-0.45 [-0.91, 0.02]
Treatment estimate by planned visit:				
Week 3	2.1 [-3.8, 8.0]	8.3 [0.9, 15.6]	-6.2 [-15.6, 3.3]	
Week 6	2.1 [-4.2, 8.4]	11.7 [3.6, 19.8]	-9.6 [-19.9, 0.7]	
Week 9	1.2 [-5.3, 7.7]	10.3 [1.8, 18.9]	-9.2 [-19.9, 1.6]	
Week 12	4.2 [-2.5, 11.0]	11.4 [2.6, 20.2]	-7.1 [-18.2, 4.0]	
Week 15	-0.8 [-7.8, 6.2]	11.8 [2.1, 21.5]	-12.6 [-24.6, -0.6]	
Week 18	-1.1 [-8.5, 6.4]	13.1 [1.2, 25.0]	-14.2 [-28.2, -0.1]	
Week 21	0.4 [-7.5, 8.2]	8.8 [-3.5, 21.0]	-8.4 [-22.9, 6.1]	
Week 24	3.4 [-5.0, 11.8]	19.0 [5.9, 32.0]	-15.6 [-31.1, -0.1]	
Week 27	3.3 [-5.7, 12.3]	11.1 [-3.5, 25.6]	-7.8 [-24.9, 9.3]	
Week 30	1.7 [-7.4, 10.8]	5.1 [-9.4, 19.7]	-3.5 [-20.6, 13.7]	
Week 33	-2.4 [-11.6, 6.9]	6.4 [-10.7, 23.5]	-8.8 [-28.2, 10.6]	
Week 36	5.1 [-4.5, 14.6]	5.2 [-11.9, 22.2]	-0.1 [-19.6, 19.5]	
Week 39	5.7 [-4.1, 15.4]	4.6 [-13.6, 22.8]	1.1 [-19.6, 21.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Fatigue

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	3.8 [-8.4, 16.1]	8.3 [-10.4, 27.0]	-4.5 [-26.8, 17.9]	
Week 45	3.1 [-9.0, 15.2]	21.1 [0.2, 42.1]	-18.0 [-42.2, 6.2]	
Week 48	4.6 [-8.4, 17.6]	20.3 [-11.7, 52.4]	-15.7 [-50.3, 18.9]	
Week 54	7.0 [-7.5, 21.5]	-2.4 [-38.7, 33.8]	9.4 [-29.6, 48.5]	
Week 60	-4.9 [-20.1, 10.3]	19.4 [-18.7, 57.5]	-24.3 [-65.3, 16.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.9185
Dato-DXd	45	
ICC	32	
Time		0.8165
Treatment x Time		0.6108

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-2.7 [-4.9, -0.5]	-2.9 [-7.1, 1.3]	0.2 [-4.5, 5.0]	0.03 [-0.44, 0.49]
Treatment estimate by planned visit:				
Week 3	1.7 [-1.7, 5.2]	-2.3 [-6.6, 2.1]	4.0 [-1.6, 9.5]	
Week 6	-1.5 [-5.3, 2.3]	-1.3 [-6.3, 3.8]	-0.2 [-6.6, 6.1]	
Week 9	-1.9 [-5.8, 2.0]	-3.6 [-8.8, 1.7]	1.7 [-4.9, 8.2]	
Week 12	1.1 [-2.9, 5.2]	-4.2 [-9.5, 1.2]	5.3 [-1.4, 12.0]	
Week 15	-6.0 [-10.3, -1.8]	-0.5 [-6.5, 5.5]	-5.6 [-12.9, 1.7]	
Week 18	0.4 [-4.2, 5.0]	-0.8 [-8.4, 6.9]	1.2 [-7.7, 10.1]	
Week 21	-5.1 [-9.9, -0.3]	-4.3 [-11.9, 3.2]	-0.8 [-9.7, 8.2]	
Week 24	-4.5 [-9.6, 0.7]	-2.8 [-10.8, 5.2]	-1.7 [-11.2, 7.9]	
Week 27	-6.3 [-11.9, -0.8]	-4.8 [-13.8, 4.3]	-1.5 [-12.2, 9.1]	
Week 30	-1.0 [-6.5, 4.6]	-2.0 [-10.7, 6.8]	1.0 [-9.3, 11.3]	
Week 33	-5.4 [-11.0, 0.1]	-3.2 [-14.0, 7.6]	-2.2 [-14.4, 9.9]	
Week 36	0.3 [-5.5, 6.0]	-3.2 [-13.5, 7.1]	3.5 [-8.3, 15.3]	
Week 39	-2.8 [-8.6, 3.1]	-2.4 [-13.5, 8.8]	-0.4 [-13.0, 12.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Nausea and Vomiting

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-5.9 [-13.9, 2.1]	2.1 [-9.3, 13.4]	-8.0 [-21.8, 5.9]	
Week 45	1.7 [-5.8, 9.2]	-1.4 [-14.4, 11.6]	3.1 [-11.8, 18.1]	
Week 48	-4.3 [-12.2, 3.7]	-4.8 [-26.0, 16.5]	0.5 [-22.2, 23.2]	
Week 54	-2.7 [-11.7, 6.4]	-6.4 [-29.1, 16.4]	3.7 [-20.8, 28.2]	
Week 60	-6.2 [-15.5, 3.0]	-7.1 [-30.2, 15.9]	0.9 [-24.0, 25.8]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Pain

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.3436
Dato-DXd	45	
ICC	32	
Time		0.0492
Treatment x Time		0.3108

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Pain

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-5.4 [-10.4, -0.5]	-0.5 [-9.5, 8.5]	-4.9 [-15.2, 5.3]	-0.24 [-0.70, 0.23]
Treatment estimate by planned visit:				
Week 3	-3.5 [-10.0, 2.9]	0.6 [-7.3, 8.6]	-4.1 [-14.4, 6.1]	
Week 6	-7.7 [-14.6, -0.9]	-2.4 [-11.1, 6.4]	-5.4 [-16.5, 5.8]	
Week 9	-6.8 [-13.8, 0.3]	4.3 [-5.0, 13.5]	-11.1 [-22.7, 0.6]	
Week 12	-3.2 [-10.5, 4.1]	11.6 [2.1, 21.1]	-14.8 [-26.8, -2.8]	
Week 15	-7.1 [-14.7, 0.5]	2.7 [-7.8, 13.2]	-9.8 [-22.8, 3.1]	
Week 18	-8.7 [-16.8, -0.6]	2.9 [-10.0, 15.8]	-11.6 [-26.8, 3.6]	
Week 21	-6.2 [-14.7, 2.2]	3.9 [-9.3, 17.1]	-10.1 [-25.8, 5.6]	
Week 24	0.0 [-9.0, 9.1]	8.7 [-5.5, 22.8]	-8.6 [-25.4, 8.2]	
Week 27	-4.4 [-14.2, 5.3]	-3.8 [-19.5, 12.0]	-0.7 [-19.2, 17.8]	
Week 30	-4.2 [-14.0, 5.7]	3.7 [-12.0, 19.5]	-7.9 [-26.5, 10.7]	
Week 33	-5.8 [-15.8, 4.2]	-8.4 [-26.9, 10.1]	2.6 [-18.4, 23.6]	
Week 36	-3.1 [-13.5, 7.2]	0.8 [-17.7, 19.2]	-3.9 [-25.1, 17.2]	
Week 39	-6.0 [-16.6, 4.5]	-10.4 [-30.0, 9.3]	4.3 [-18.0, 26.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

Symptom Scales - Pain

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	4.0 [-9.2, 17.2]	-12.4 [-32.7, 7.9]	16.4 [-7.7, 40.6]	
Week 45	-8.4 [-21.5, 4.7]	12.5 [-10.2, 35.3]	-20.9 [-47.1, 5.3]	
Week 48	-7.2 [-21.3, 6.8]	-9.8 [-44.4, 24.8]	2.6 [-34.8, 39.9]	
Week 54	-8.9 [-24.6, 6.8]	-13.7 [-52.8, 25.4]	4.8 [-37.3, 47.0]	
Week 60	-10.4 [-26.8, 6.1]	0.2 [-40.9, 41.3]	-10.6 [-54.9, 33.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.8202
Dato-DXd	45	
ICC	32	
Time		0.0072
Treatment x Time		<0.0001

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	3.1 [-0.6, 6.8]	4.0 [-2.9, 10.9]	-0.9 [-8.8, 7.0]	-0.06 [-0.52, 0.40]
Treatment estimate by planned visit:				
Week 3	3.4 [-1.8, 8.5]	11.7 [5.3, 18.2]	-8.4 [-16.6, -0.1]	
Week 6	-0.2 [-5.8, 5.4]	6.0 [-1.3, 13.4]	-6.3 [-15.5, 2.9]	
Week 9	1.6 [-4.1, 7.4]	4.0 [-3.7, 11.7]	-2.3 [-11.9, 7.3]	
Week 12	2.1 [-3.9, 8.1]	4.1 [-3.7, 12.0]	-2.0 [-11.9, 7.9]	
Week 15	1.5 [-4.7, 7.7]	4.9 [-3.8, 13.6]	-3.4 [-14.1, 7.4]	
Week 18	1.8 [-4.9, 8.4]	-2.8 [-13.7, 8.0]	4.6 [-8.1, 17.4]	
Week 21	7.4 [0.4, 14.4]	-1.3 [-12.4, 9.7]	8.7 [-4.3, 21.8]	
Week 24	4.3 [-3.2, 11.8]	18.3 [6.6, 30.0]	-14.1 [-28.0, -0.2]	
Week 27	7.1 [-0.9, 15.2]	1.2 [-11.9, 14.3]	5.9 [-9.5, 21.4]	
Week 30	2.7 [-5.4, 10.8]	17.5 [4.6, 30.4]	-14.8 [-30.0, 0.5]	
Week 33	7.0 [-1.2, 15.2]	-5.1 [-20.6, 10.3]	12.1 [-5.4, 29.7]	
Week 36	5.7 [-2.8, 14.2]	13.7 [-1.5, 28.9]	-8.0 [-25.4, 9.5]	
Week 39	7.7 [-0.9, 16.4]	-3.2 [-19.4, 13.1]	10.9 [-7.5, 29.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Dyspnea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	4.6 [-6.6, 15.8]	19.5 [2.8, 36.2]	-14.9 [-35.0, 5.2]	
Week 45	4.2 [-6.7, 15.0]	-3.2 [-22.0, 15.7]	7.3 [-14.5, 29.1]	
Week 48	-1.5 [-13.1, 10.2]	-4.1 [-33.8, 25.6]	2.6 [-29.3, 34.5]	
Week 54	-2.0 [-15.1, 11.1]	-4.7 [-37.6, 28.2]	2.7 [-32.7, 38.1]	
Week 60	-2.1 [-15.7, 11.5]	-5.0 [-39.1, 29.0]	2.9 [-33.8, 39.5]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.0008
Dato-DXd	45	
ICC	32	
Time		0.5563
Treatment x Time		0.1509

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-11.6 [-16.5, -6.6]	7.3 [-2.2, 16.8]	-18.9 [-29.8, -8.0]	-0.87 [-1.36, -0.39]
Treatment estimate by planned visit:				
Week 3	-8.3 [-15.1, -1.6]	-0.4 [-8.8, 8.1]	-8.0 [-18.8, 2.9]	
Week 6	-8.8 [-16.2, -1.5]	-8.0 [-17.5, 1.5]	-0.8 [-12.9, 11.2]	
Week 9	-13.0 [-20.6, -5.4]	-2.5 [-12.5, 7.5]	-10.5 [-23.1, 2.1]	
Week 12	-3.9 [-11.8, 3.9]	-7.4 [-17.7, 2.9]	3.4 [-9.5, 16.4]	
Week 15	-13.6 [-21.8, -5.5]	-4.2 [-15.7, 7.2]	-9.4 [-23.5, 4.7]	
Week 18	-11.0 [-19.7, -2.3]	-2.9 [-17.2, 11.3]	-8.0 [-24.8, 8.7]	
Week 21	-12.9 [-22.1, -3.8]	2.9 [-11.5, 17.4]	-15.8 [-33.0, 1.3]	
Week 24	-9.8 [-19.6, 0.1]	9.2 [-6.3, 24.7]	-18.9 [-37.4, -0.5]	
Week 27	-13.5 [-24.0, -2.9]	-3.7 [-21.1, 13.6]	-9.7 [-30.1, 10.7]	
Week 30	-8.8 [-19.4, 1.9]	0.0 [-17.1, 17.1]	-8.8 [-29.1, 11.6]	
Week 33	-7.2 [-17.9, 3.6]	18.3 [-2.2, 38.7]	-25.5 [-48.7, -2.2]	
Week 36	-8.0 [-19.1, 3.2]	11.9 [-8.3, 32.1]	-19.9 [-43.1, 3.3]	
Week 39	-12.6 [-24.0, -1.2]	13.3 [-8.3, 34.9]	-25.9 [-50.5, -1.4]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Insomnia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-11.0 [-25.7, 3.6]	6.9 [-15.3, 29.1]	-17.9 [-44.7, 9.0]	
Week 45	-12.9 [-27.1, 1.4]	26.4 [1.5, 51.4]	-39.3 [-68.2, -10.4]	
Week 48	-15.9 [-31.2, -0.6]	24.8 [-14.1, 63.6]	-40.7 [-82.6, 1.2]	
Week 54	-11.9 [-29.0, 5.2]	23.7 [-19.4, 66.9]	-35.6 [-82.2, 10.9]	
Week 60	-25.5 [-43.3, -7.7]	23.1 [-21.6, 67.8]	-48.5 [-96.7, -0.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.6167
Dato-DXd	45	
ICC	32	
Time		0.8822
Treatment x Time		0.7559

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	2.9 [-2.8, 8.7]	5.9 [-4.5, 16.3]	-3.0 [-14.9, 8.9]	-0.12 [-0.59, 0.34]
Treatment estimate by planned visit:				
Week 3	2.4 [-4.9, 9.7]	8.4 [-0.6, 17.4]	-6.1 [-17.6, 5.5]	
Week 6	-1.6 [-9.3, 6.1]	5.2 [-4.7, 15.1]	-6.8 [-19.3, 5.7]	
Week 9	0.5 [-7.5, 8.5]	6.1 [-4.4, 16.5]	-5.5 [-18.7, 7.6]	
Week 12	0.5 [-7.8, 8.7]	8.2 [-2.6, 18.9]	-7.7 [-21.3, 5.8]	
Week 15	-3.1 [-11.7, 5.5]	16.3 [4.5, 28.2]	-19.4 [-34.0, -4.8]	
Week 18	-2.8 [-11.9, 6.3]	9.3 [-5.1, 23.8]	-12.1 [-29.2, 4.9]	
Week 21	-1.1 [-10.7, 8.4]	3.2 [-11.7, 18.1]	-4.3 [-22.0, 13.4]	
Week 24	8.4 [-1.8, 18.6]	8.5 [-7.5, 24.4]	-0.1 [-19.1, 18.8]	
Week 27	10.0 [-1.0, 21.0]	-3.1 [-20.8, 14.6]	13.1 [-7.7, 34.0]	
Week 30	-0.1 [-11.2, 11.0]	2.0 [-15.8, 19.8]	-2.0 [-23.0, 19.0]	
Week 33	5.6 [-5.7, 16.9]	1.8 [-19.0, 22.5]	3.9 [-19.8, 27.5]	
Week 36	6.2 [-5.5, 17.9]	10.0 [-10.8, 30.9]	-3.8 [-27.7, 20.1]	
Week 39	3.8 [-8.2, 15.7]	5.6 [-16.6, 27.8]	-1.9 [-27.1, 23.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Appetite Loss

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	4.6 [-10.2, 19.4]	13.3 [-9.6, 36.2]	-8.6 [-35.9, 18.6]	
Week 45	1.4 [-13.4, 16.1]	10.9 [-14.7, 36.5]	-9.6 [-39.1, 19.9]	
Week 48	9.2 [-6.7, 25.0]	4.5 [-34.1, 43.1]	4.7 [-37.0, 46.4]	
Week 54	5.8 [-11.9, 23.4]	-0.1 [-43.9, 43.7]	5.9 [-41.4, 53.1]	
Week 60	2.8 [-15.7, 21.4]	-3.4 [-49.7, 42.9]	6.3 [-43.6, 56.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.4468
Dato-DXd	45	
ICC	32	
Time		0.9242
Treatment x Time		0.8286

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	3.0 [-2.1, 8.1]	7.2 [-2.3, 16.7]	-4.2 [-15.0, 6.7]	-0.19 [-0.65, 0.27]
Treatment estimate by planned visit:				
Week 3	2.8 [-4.3, 10.0]	7.6 [-1.4, 16.5]	-4.7 [-16.1, 6.7]	
Week 6	-0.9 [-8.7, 6.8]	10.4 [0.4, 20.5]	-11.4 [-24.1, 1.3]	
Week 9	4.6 [-3.4, 12.6]	6.3 [-4.3, 16.8]	-1.7 [-14.9, 11.6]	
Week 12	10.4 [2.1, 18.6]	2.7 [-8.2, 13.5]	7.7 [-5.9, 21.3]	
Week 15	0.0 [-8.6, 8.6]	3.0 [-9.0, 15.1]	-3.0 [-17.9, 11.8]	
Week 18	8.5 [-0.7, 17.7]	6.0 [-9.0, 21.0]	2.5 [-15.1, 20.1]	
Week 21	6.2 [-3.5, 15.9]	8.8 [-6.4, 24.1]	-2.6 [-20.7, 15.4]	
Week 24	11.7 [1.3, 22.0]	11.9 [-4.3, 28.0]	-0.2 [-19.4, 19.0]	
Week 27	7.3 [-3.8, 18.5]	7.0 [-11.1, 25.1]	0.3 [-21.0, 21.6]	
Week 30	4.6 [-6.6, 15.8]	13.1 [-4.8, 31.0]	-8.5 [-29.6, 12.6]	
Week 33	-2.7 [-14.0, 8.6]	15.7 [-5.7, 37.1]	-18.5 [-42.7, 5.7]	
Week 36	1.3 [-10.4, 13.0]	9.7 [-11.3, 30.7]	-8.4 [-32.4, 15.7]	
Week 39	0.1 [-11.8, 12.1]	2.4 [-20.1, 24.9]	-2.3 [-27.7, 23.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Constipation

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-0.8 [-16.2, 14.7]	6.0 [-17.0, 29.0]	-6.8 [-34.5, 21.0]	
Week 45	2.3 [-12.7, 17.3]	5.4 [-20.7, 31.4]	-3.1 [-33.2, 27.0]	
Week 48	0.9 [-15.2, 17.0]	12.0 [-29.0, 53.0]	-11.2 [-55.2, 32.9]	
Week 54	3.2 [-14.9, 21.2]	16.2 [-29.3, 61.6]	-13.0 [-61.9, 35.9]	
Week 60	-4.9 [-23.7, 13.8]	-14.6 [-61.7, 32.4]	9.7 [-41.0, 60.4]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.0080
Dato-DXd	45	
ICC	32	
Time		0.1101
Treatment x Time		0.3448

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-1.5 [-4.0, 0.9]	5.8 [1.0, 10.5]	-7.3 [-12.6, -1.9]	-0.68 [-1.15, -0.20]
Treatment estimate by planned visit:				
Week 3	0.7 [-3.1, 4.5]	5.2 [0.4, 10.0]	-4.5 [-10.6, 1.6]	
Week 6	-2.7 [-6.8, 1.5]	2.2 [-3.3, 7.8]	-4.9 [-11.8, 2.0]	
Week 9	-2.3 [-6.6, 2.1]	5.1 [-0.6, 10.9]	-7.4 [-14.6, -0.2]	
Week 12	-0.5 [-5.0, 3.9]	7.6 [1.7, 13.4]	-8.1 [-15.5, -0.7]	
Week 15	-2.4 [-7.1, 2.2]	3.7 [-2.9, 10.2]	-6.1 [-14.1, 2.0]	
Week 18	-2.9 [-7.9, 2.1]	15.3 [7.0, 23.7]	-18.2 [-28.0, -8.4]	
Week 21	-2.2 [-7.5, 3.1]	13.7 [5.4, 22.0]	-15.9 [-25.8, -6.0]	
Week 24	1.3 [-4.3, 7.0]	14.9 [6.1, 23.7]	-13.6 [-24.1, -3.1]	
Week 27	-3.0 [-9.1, 3.1]	-0.4 [-10.3, 9.5]	-2.6 [-14.3, 9.1]	
Week 30	-2.3 [-8.4, 3.7]	5.6 [-4.1, 15.2]	-7.9 [-19.3, 3.5]	
Week 33	-5.4 [-11.5, 0.7]	7.2 [-4.7, 19.0]	-12.6 [-25.9, 0.8]	
Week 36	-6.3 [-12.6, 0.1]	1.8 [-9.6, 13.1]	-8.0 [-21.1, 5.0]	
Week 39	3.5 [-3.0, 9.9]	0.0 [-12.2, 12.2]	3.4 [-10.4, 17.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Diarrhea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-1.6 [-10.3, 7.1]	11.9 [-0.5, 24.4]	-13.5 [-28.7, 1.6]	
Week 45	-4.2 [-12.4, 4.0]	9.6 [-4.6, 23.8]	-13.8 [-30.2, 2.6]	
Week 48	2.3 [-6.4, 11.1]	3.0 [-20.2, 26.1]	-0.6 [-25.4, 24.2]	
Week 54	4.2 [-5.7, 14.1]	-0.4 [-25.4, 24.5]	4.6 [-22.2, 31.5]	
Week 60	-3.7 [-13.9, 6.5]	-2.1 [-27.5, 23.3]	-1.6 [-28.9, 25.8]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.9276
Dato-DXd	45	
ICC	32	
Time		0.7504
Treatment x Time		0.5120

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-0.1 [-4.8, 4.6]	-0.5 [-9.1, 8.1]	0.5 [-9.3, 10.2]	0.02 [-0.44, 0.48]
Treatment estimate by planned visit:				
Week 3	-5.4 [-11.5, 0.8]	-1.2 [-8.9, 6.5]	-4.1 [-14.0, 5.7]	
Week 6	-3.8 [-10.4, 2.9]	-4.1 [-12.7, 4.5]	0.3 [-10.5, 11.2]	
Week 9	1.3 [-5.5, 8.2]	-7.6 [-16.7, 1.4]	9.0 [-2.4, 20.3]	
Week 12	1.4 [-5.7, 8.5]	-3.8 [-13.1, 5.4]	5.2 [-6.5, 16.9]	
Week 15	0.2 [-7.1, 7.6]	-5.7 [-16.0, 4.5]	6.0 [-6.7, 18.6]	
Week 18	-3.0 [-10.8, 4.9]	-6.1 [-18.6, 6.5]	3.1 [-11.7, 17.9]	
Week 21	-8.1 [-16.3, 0.1]	5.2 [-7.7, 18.1]	-13.3 [-28.6, 2.0]	
Week 24	4.5 [-4.4, 13.3]	4.6 [-9.2, 18.3]	-0.1 [-16.4, 16.2]	
Week 27	0.4 [-9.1, 9.8]	-5.7 [-21.0, 9.6]	6.0 [-12.0, 24.0]	
Week 30	3.0 [-6.6, 12.5]	0.7 [-14.6, 16.0]	2.3 [-15.7, 20.3]	
Week 33	2.9 [-6.8, 12.5]	-5.9 [-24.0, 12.1]	8.8 [-11.6, 29.3]	
Week 36	5.0 [-5.0, 15.0]	-4.7 [-22.7, 13.2]	9.7 [-10.8, 30.3]	
Week 39	5.2 [-5.1, 15.4]	4.1 [-15.0, 23.2]	1.1 [-20.6, 22.8]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

Table 3.41.1 EORTC QLQ-C30 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Common Symptoms - Financial Difficulties

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-1.8 [-14.7, 11.1]	-5.0 [-24.6, 14.7]	3.2 [-20.4, 26.7]	
Week 45	1.6 [-11.1, 14.3]	-3.2 [-25.3, 18.9]	4.8 [-20.7, 30.2]	
Week 48	2.5 [-11.2, 16.2]	4.8 [-29.1, 38.7]	-2.3 [-38.9, 34.3]	
Week 54	-6.9 [-22.2, 8.4]	10.2 [-28.0, 48.4]	-17.1 [-58.3, 24.0]	
Week 60	-0.4 [-16.5, 15.6]	13.9 [-26.1, 54.0]	-14.4 [-57.5, 28.8]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQC30_MMRM_mFASA.rtf

EORTC QLQ-C30 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Verlaufskurve

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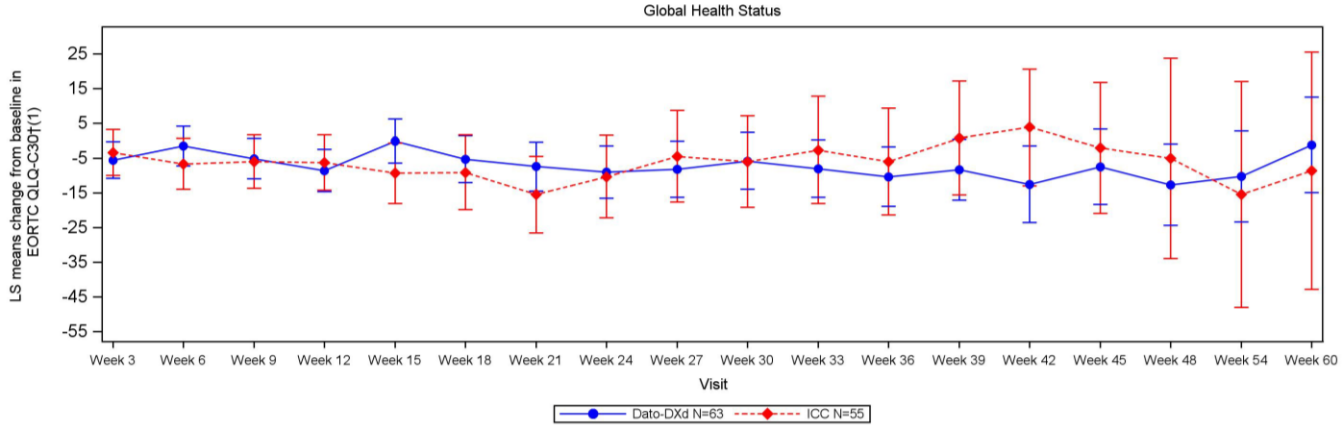
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

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Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A

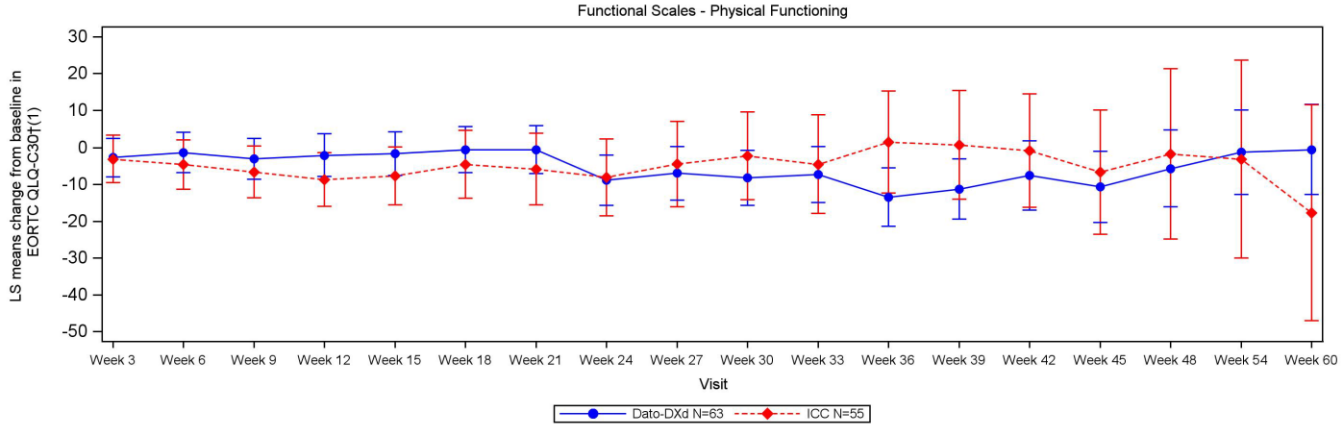

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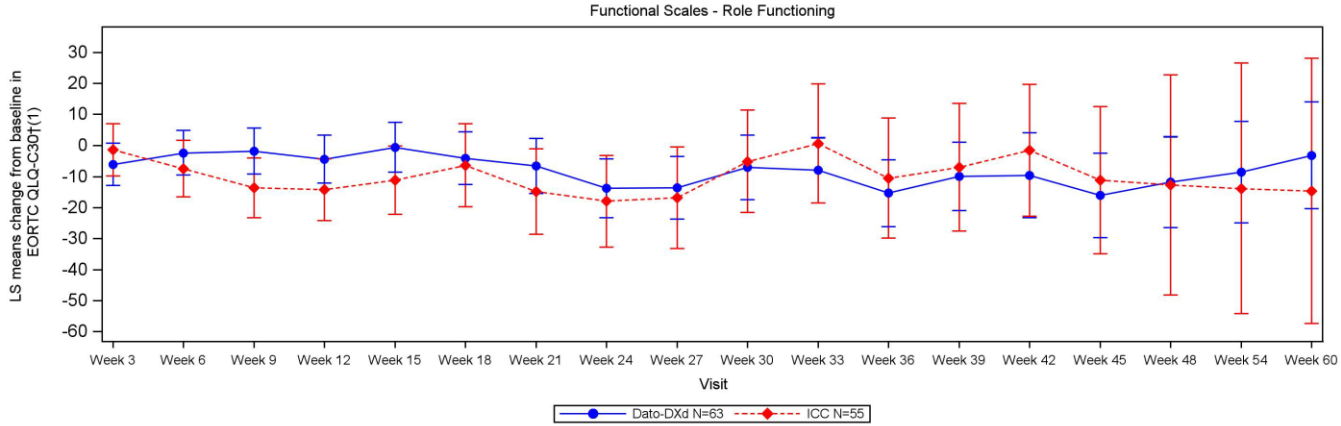
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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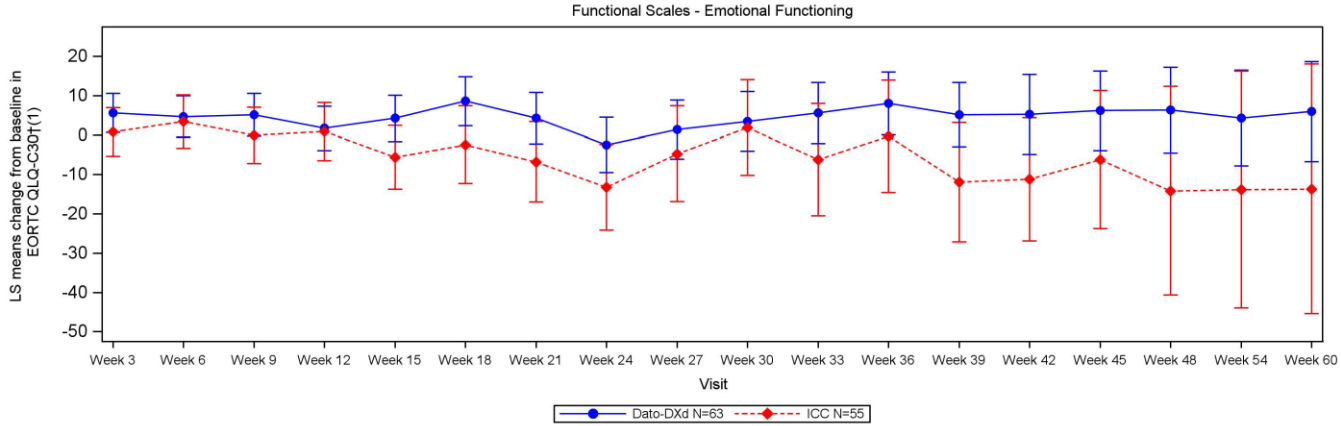
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

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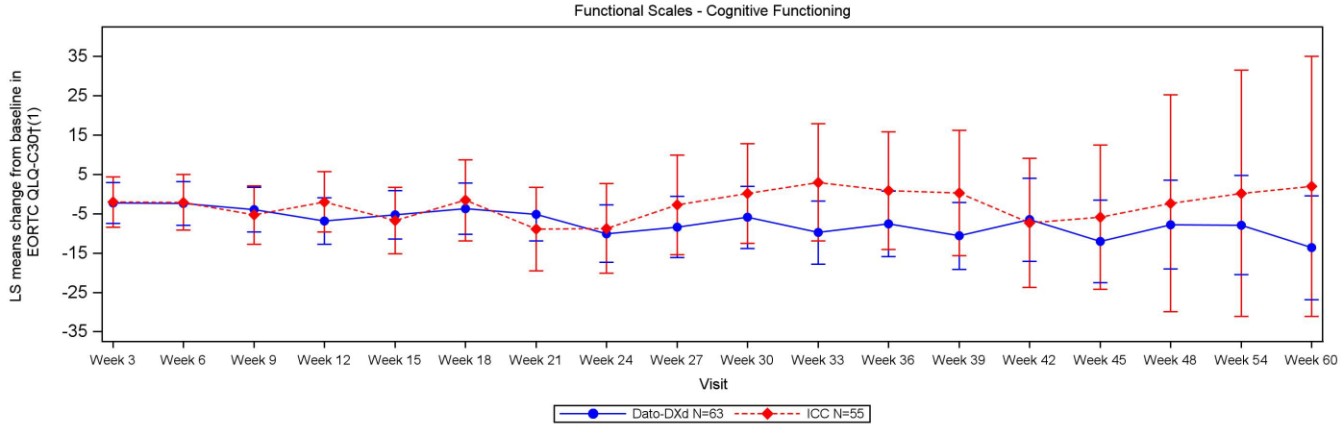
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

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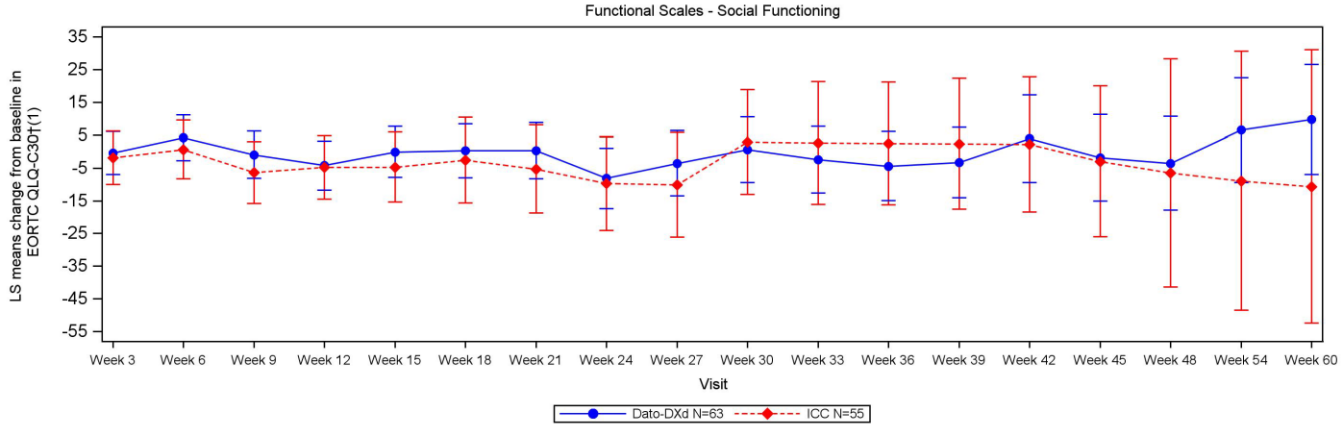
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

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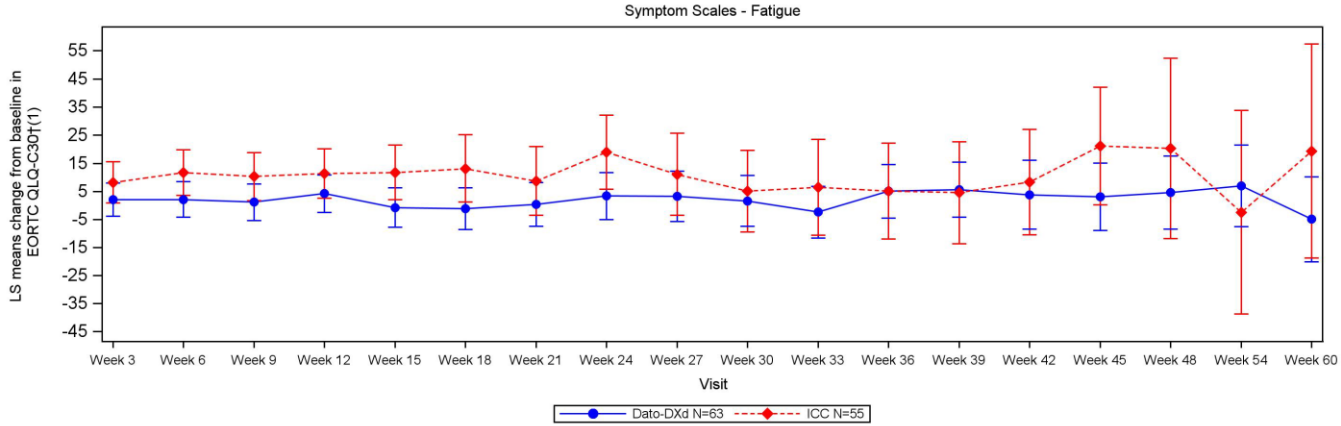
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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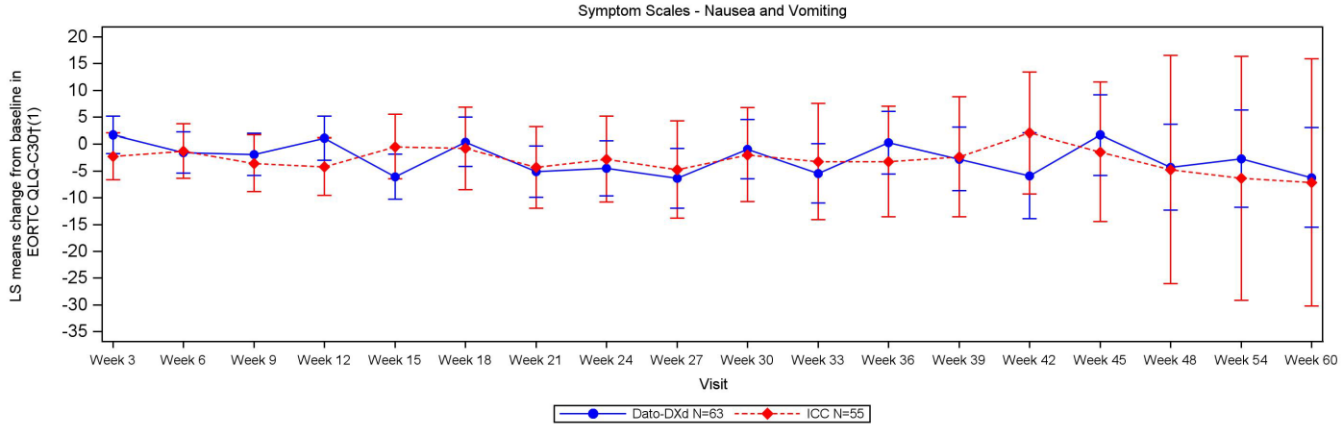

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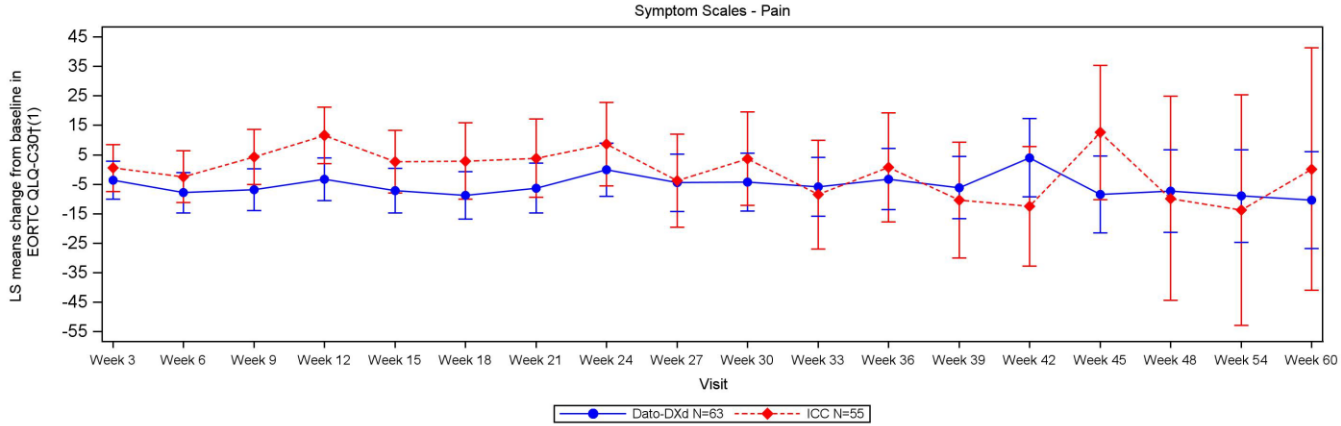
Statistical analyses for AMNOG (HTA Germany)

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Statistical analyses for AMNOG (HTA Germany)

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A

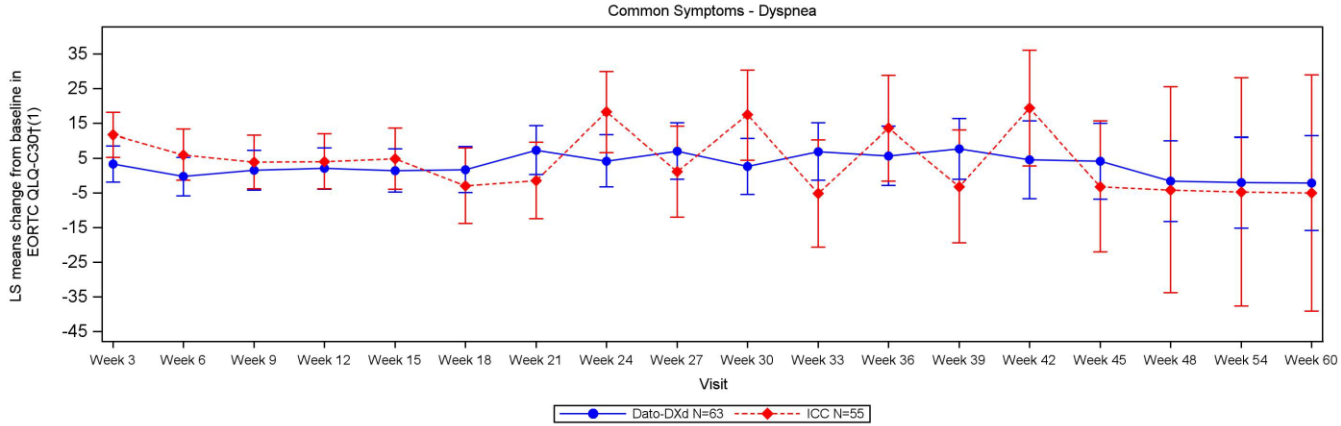

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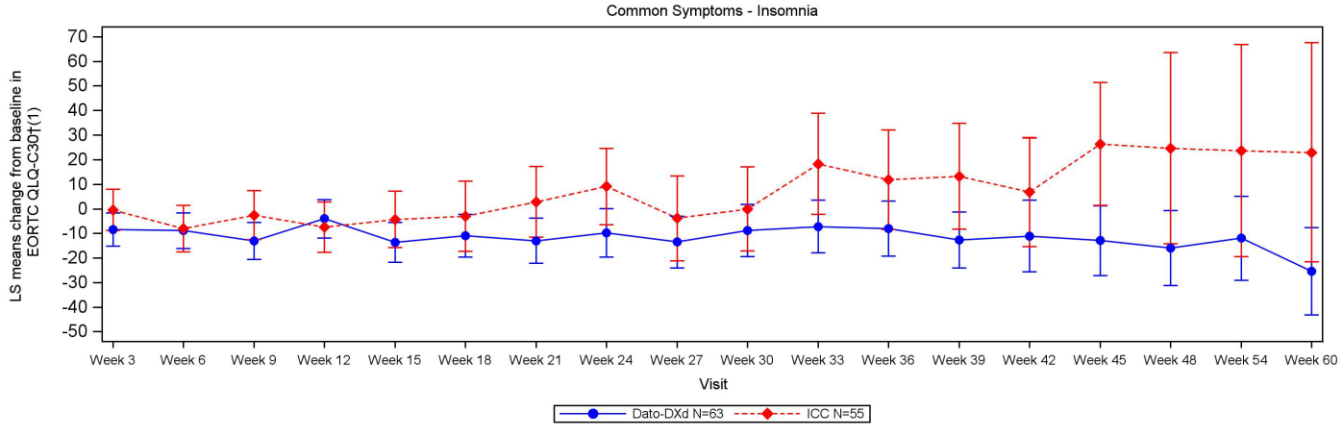
Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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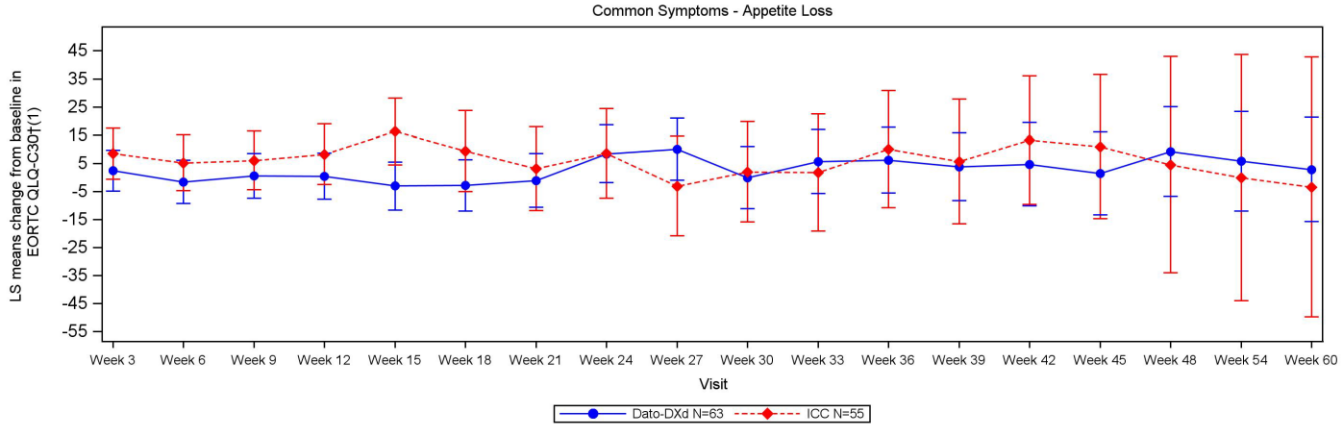

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Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

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Data Intelligence – Evidence Generation
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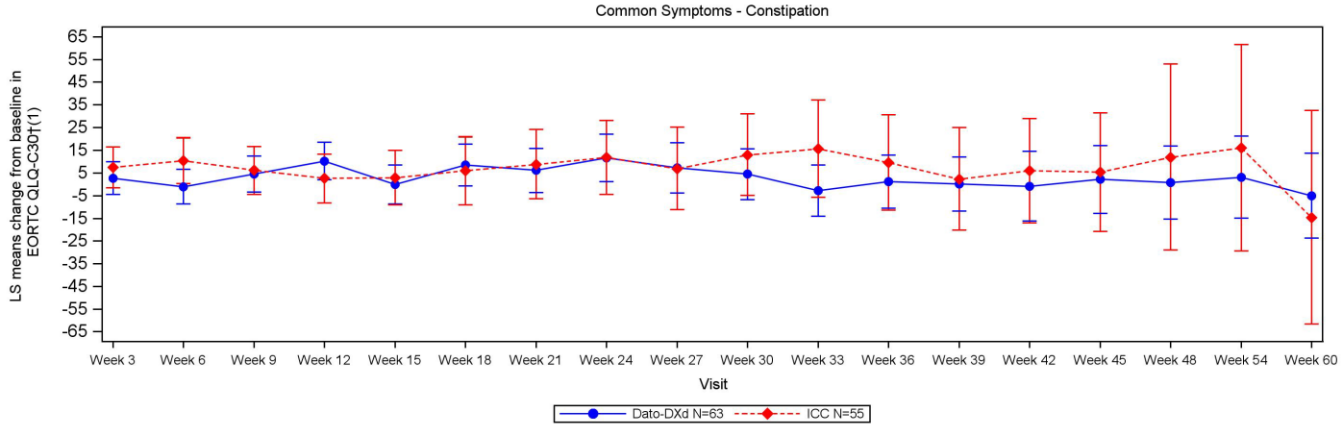
Statistical analyses for AMNOG (HTA Germany)

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Visits with zero patients in Dato-DXd or ICC group are removed.

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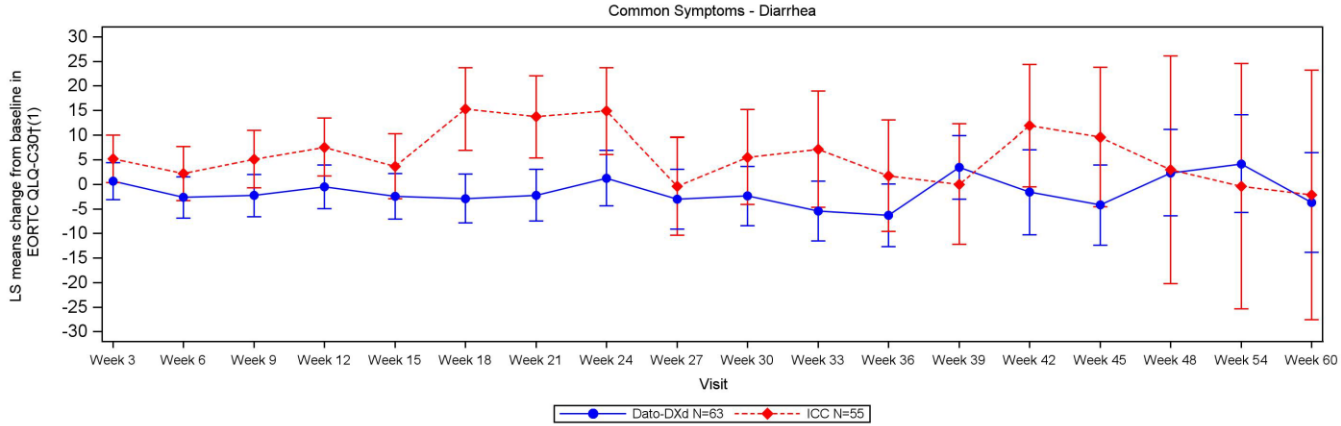
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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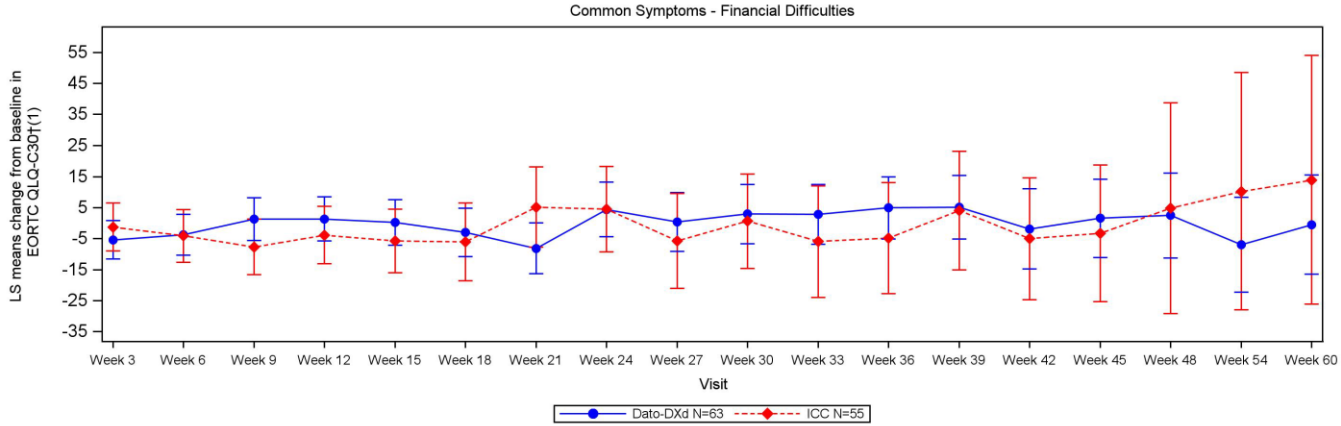
Statistical analyses for AMNOG (HTA Germany)

Figure 3.42.1 EORTC QLQ-C30 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



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Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQC30_MMRM_mFASA.rtf

EORTC QLQ-BR45/IL116

EORTC QLQ-BR45/IL116 – Zeit bis zur ersten Verschlechterung

EORTC QLQ-BR45/IL116 – Zeit bis zur ersten Verschlechterung – Prüfung der Kriterien der Anhebungsregel

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Table 3.29.6 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - increased significance level -DCO 24-Jul-2024 - DCO 29-Apr-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_6.sas; Output name: DE.T_QLQBR45_FD_INC_mFASA_Add.rtf

Table 3.29.6 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - increased significance level -DCO 24-Jul-2024 - DCO 29-Apr-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with PRO baseline measurement, n (%)	44 (69.8)	35 (63.6)	
Number of subjects with at least one PRO post-baseline measurement, n (%)	44 (69.8)	33 (60.0)	
Number of subjects with events, n (%)	19 (30.2)	19 (34.5)	
Number of subjects censored, n (%)	44 (69.8)	36 (65.5)	
Median time to first event (months) [a]	10.3	1.4	
85% Confidence Interval	(5.5 , NE)	(0.8 , 11.1)	
Cox proportional hazards model [b]			
Hazard Ratio			0.54
85% Confidence Interval			(0.33, 0.88)
Stratified log-rank p-value [c]			0.0730

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_6.sas; Output name: DE.T_QLQBR45_FD_INC_mFASA_Add.rtf

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Statistical analyses for AMNOG (HTA Germany)

Table 3.29.4 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Symptom Scales - Breast Symptoms

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.5113
mFASA	63	12 (19.0)	51 (81.0)	NE (4.2 , NE)	55	9 (16.4)	46 (83.6)	13.8 (5.6 , NE)	0.88 (0.37, 2.09)	0.7697	
non-mFASA	269	62 (23.0)	207 (77.0)	NE (13.9 , NE)	279	47 (16.8)	232 (83.2)	NE (NE, NE)	1.15 (0.79, 1.68)	0.4745	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-BR45/IL116 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.29.4 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA
Symptom Scales - Arm Symptoms

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.1318
mFASA	63	19 (30.2)	44 (69.8)	10.3 (2.8 , NE)	55	19 (34.5)	36 (65.5)	1.4 (0.7 , 11.1)	0.48 (0.25, 0.93)	0.0284	
non-mFASA	269	97 (36.1)	172 (63.9)	6.3 (4.9 , 9.7)	279	100 (35.8)	179 (64.2)	2.9 (2.8 , 5.6)	0.75 (0.57, 1.00)	0.0471	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC QLQ-BR45/IL116 is considered in this table.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.2878
Region 1 [US, Canada, Europe]	33	6 (18.2)	27 (81.8)	NE (2.8, NE)	28	3 (10.7)	25 (89.3)	13.8 (3.5, NE)	2.17 (0.44, 10.74)	0.3323	
Region 2 [Rest of World]	30	6 (20.0)	24 (80.0)	NE (4.2, NE)	27	6 (22.2)	21 (77.8)	7.0 (3.4, NE)	0.61 (0.20, 1.91)	0.4004	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.7216
Yes	52	10 (19.2)	42 (80.8)	NE (4.2, NE)	45	8 (17.8)	37 (82.2)	13.8 (5.6, NE)	1.02 (0.40, 2.59)	0.9746	
No	11	2 (18.2)	9 (81.8)	NE (1.4, NE)	10	1 (10.0)	9 (90.0)	NE (0.7, NE)	0.90 (0.08, 10.15)	0.9302	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	17 (89.5)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	8 (25.0)	24 (75.0)	-	30	3 (10.0)	27 (90.0)	-	-	-	
Neither taxanes nor anthracyclines	11	2 (18.2)	9 (81.8)	-	9	3 (33.3)	6 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.3900
<65 years	52	9 (17.3)	43 (82.7)	NE (4.2, NE)	41	4 (9.8)	37 (90.2)	13.8 (NE, NE)	1.31 (0.40, 4.28)	0.6406	
≥65 years	11	3 (27.3)	8 (72.7)	NE (2.8, NE)	14	5 (35.7)	9 (64.3)	5.6 (0.7, NE)	0.61 (0.14, 2.56)	0.4952	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9650
Asian	21	4 (19.0)	17 (81.0)	NE (2.8, NE)	21	4 (19.0)	17 (81.0)	7.0 (5.6, NE)	0.72 (0.18, 2.90)	0.6382	
Non-Asian	32	6 (18.8)	26 (81.3)	NE (4.2, NE)	26	5 (19.2)	21 (80.8)	13.8 (3.4, NE)	0.72 (0.22, 2.38)	0.5922	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9675
Capecitabine	21	5 (23.8)	16 (76.2)	NE (2.8, NE)	9	3 (33.3)	6 (66.7)	13.8 (0.7, NE)	0.99 (0.23, 4.21)	0.9947	
Eribulin mesylate	31	7 (22.6)	24 (77.4)	NE (2.8, NE)	41	6 (14.6)	35 (85.4)	NE (3.5, NE)	1.25 (0.42, 3.73)	0.6822	
Vinorelbine	11	0	11 (100)	NE (NE, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											>0.9999
Yes	6	0	6 (100)	NE (NE, NE)	6	0	6 (100)	NE (NE, NE)	NE (NE, NE)	NE	
No	57	12 (21.1)	45 (78.9)	NE (4.2, NE)	49	9 (18.4)	40 (81.6)	13.8 (5.6, NE)	0.95 (0.40, 2.25)	0.9082	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	12 (19.4)	50 (80.6)	-	54	9 (16.7)	45 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	6 (19.4)	25 (80.6)	-	24	4 (16.7)	20 (83.3)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.1829
0	35	5 (14.3)	30 (85.7)	NE (NE, NE)	33	6 (18.2)	27 (81.8)	13.8 (3.4, NE)	0.53 (0.16, 1.74)	0.2940	
≥1	28	7 (25.0)	21 (75.0)	NE (2.8, NE)	22	3 (13.6)	19 (86.4)	NE (3.5, NE)	1.85 (0.48, 7.18)	0.3715	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	10 (20.4)	39 (79.6)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.8553
≤12 months	22	3 (13.6)	19 (86.4)	NE (2.8, NE)	19	3 (15.8)	16 (84.2)	NE (3.4, NE)	0.90 (0.18, 4.47)	0.8967	
>12 months	29	6 (20.7)	23 (79.3)	NE (1.5, NE)	27	5 (18.5)	22 (81.5)	13.8 (3.5, NE)	1.01 (0.30, 3.34)	0.9963	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	10 (16.9)	49 (83.1)	-	55	9 (16.4)	46 (83.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.8393
Region 1 [US, Canada, Europe]	33	7 (21.2)	26 (78.8)	NE (2.1, NE)	28	8 (28.6)	20 (71.4)	1.4 (0.7, NE)	0.39 (0.14, 1.09)	0.0633	
Region 2 [Rest of World]	30	12 (40.0)	18 (60.0)	10.3 (2.8, NE)	27	11 (40.7)	16 (59.3)	1.4 (0.7, NE)	0.54 (0.23, 1.25)	0.1651	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5176
Yes	52	15 (28.8)	37 (71.2)	10.3 (2.8, NE)	45	16 (35.6)	29 (64.4)	1.4 (0.7, 11.1)	0.56 (0.27, 1.15)	0.1146	
No	11	4 (36.4)	7 (63.6)	13.8 (0.7, NE)	10	3 (30.0)	7 (70.0)	NE (0.7, NE)	0.45 (0.09, 2.35)	0.3318	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	6 (31.6)	13 (68.4)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	7 (23.3)	23 (76.7)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.1612
<65 years	52	14 (26.9)	38 (73.1)	10.3 (5.5, NE)	41	15 (36.6)	26 (63.4)	1.4 (0.7, 3.5)	0.38 (0.18, 0.80)	0.0091	
≥65 years	11	5 (45.5)	6 (54.5)	2.8 (0.7, NE)	14	4 (28.6)	10 (71.4)	11.1 (0.7, NE)	0.96 (0.24, 3.85)	0.9539	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.4282
Asian	21	9 (42.9)	12 (57.1)	10.3 (0.8, NE)	21	10 (47.6)	11 (52.4)	1.4 (0.7, NE)	0.69 (0.27, 1.76)	0.4641	
Non-Asian	32	9 (28.1)	23 (71.9)	13.8 (5.5, NE)	26	9 (34.6)	17 (65.4)	1.5 (0.7, NE)	0.37 (0.14, 0.97)	0.0395	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.2631
Capecitabine	21	10 (47.6)	11 (52.4)	2.1 (0.7, 6.9)	9	6 (66.7)	3 (33.3)	0.7 (0.7, 11.1)	1.03 (0.34, 3.13)	0.8895	
Eribulin mesylate	31	8 (25.8)	23 (74.2)	13.8 (2.8, NE)	41	11 (26.8)	30 (73.2)	1.5 (0.7, NE)	0.44 (0.17, 1.14)	0.0820	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (1.3, NE)	5	2 (40.0)	3 (60.0)	1.4 (1.4, NE)	0.16 (0.01, 1.74)	0.0838	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.5892
Yes	6	2 (33.3)	4 (66.7)	13.8 (0.8, NE)	6	1 (16.7)	5 (83.3)	NE (1.4, NE)	0.55 (0.03, 8.78)	0.6660	
No	57	17 (29.8)	40 (70.2)	10.3 (2.8, NE)	49	18 (36.7)	31 (63.3)	1.4 (0.7, 11.1)	0.49 (0.25, 0.95)	0.0360	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	18 (29.0)	44 (71.0)	-	54	19 (35.2)	35 (64.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	9 (29.0)	22 (71.0)	-	24	8 (33.3)	16 (66.7)	-	-	-	
Asian	21	9 (42.9)	12 (57.1)	-	21	10 (47.6)	11 (52.4)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.0895
0	35	9 (25.7)	26 (74.3)	13.8 (2.8, NE)	33	12 (36.4)	21 (63.6)	0.8 (0.7, NE)	0.29 (0.12, 0.74)	0.0071	
≥1	28	10 (35.7)	18 (64.3)	6.9 (1.3, NE)	22	7 (31.8)	15 (68.2)	3.5 (0.8, NE)	0.90 (0.34, 2.38)	0.8375	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	15 (30.6)	34 (69.4)	-	42	15 (35.7)	27 (64.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.2331
≤12 months	22	5 (22.7)	17 (77.3)	NE (1.4, NE)	19	5 (26.3)	14 (73.7)	11.1 (0.7, NE)	0.93 (0.25, 3.48)	0.9220	
>12 months	29	9 (31.0)	20 (69.0)	10.3 (1.3, NE)	27	12 (44.4)	15 (55.6)	0.8 (0.7, 1.5)	0.31 (0.12, 0.75)	0.0081	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

Table 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	18 (30.5)	41 (69.5)	-	55	19 (34.5)	36 (65.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQBR45_FD_SUB_mFASA_FA.rtf

EORTC QLQ-BR45/IL116 – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 3.29.2 EORTC QLQ-BR45/IL116 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQBR45_FD_SUB_mFASA_FA.rtf

EORTC QLQ-BR45/IL116 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert

EORTC QLQ-BR45/IL116 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.1261
Dato-DXd	44	
ICC	31	
Time		0.0237
Treatment x Time		0.7735

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-4.2 [-6.4, -2.0]	-0.7 [-4.7, 3.3]	-3.6 [-8.1, 1.0]	-0.39 [-0.86, 0.08]
Treatment estimate by planned visit:				
Week 3	-1.2 [-4.2, 1.8]	-0.2 [-4.0, 3.5]	-0.9 [-5.7, 3.8]	
Week 6	-4.2 [-7.5, -1.0]	-6.5 [-10.7, -2.4]	2.3 [-2.9, 7.5]	
Week 9	-5.4 [-8.7, -2.1]	-5.9 [-10.2, -1.5]	0.4 [-5.0, 5.9]	
Week 12	-1.6 [-5.1, 1.9]	-0.5 [-4.9, 4.0]	-1.1 [-6.7, 4.5]	
Week 15	-4.7 [-8.3, -1.1]	0.0 [-5.0, 4.9]	-4.6 [-10.7, 1.5]	
Week 18	-2.9 [-6.7, 1.0]	0.2 [-6.1, 6.6]	-3.1 [-10.5, 4.3]	
Week 21	-4.6 [-8.7, -0.6]	-2.4 [-8.6, 3.8]	-2.2 [-9.7, 5.2]	
Week 24	-3.5 [-7.8, 0.9]	-1.7 [-8.3, 4.9]	-1.8 [-9.7, 6.1]	
Week 27	-3.9 [-8.5, 0.7]	0.2 [-7.2, 7.6]	-4.0 [-12.8, 4.7]	
Week 30	-4.1 [-8.7, 0.5]	4.3 [-3.0, 11.6]	-8.4 [-17.1, 0.3]	
Week 33	-3.9 [-8.6, 0.7]	0.8 [-7.9, 9.5]	-4.7 [-14.6, 5.2]	
Week 36	-6.4 [-11.3, -1.6]	3.8 [-4.8, 12.4]	-10.2 [-20.1, -0.4]	
Week 39	-5.2 [-10.2, -0.2]	-2.2 [-11.4, 7.0]	-3.0 [-13.5, 7.5]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Breast Symptoms

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-4.4 [-10.8, 1.9]	2.1 [-7.3, 11.6]	-6.6 [-18.0, 4.9]	
Week 45	-4.5 [-10.7, 1.6]	5.4 [-5.3, 16.1]	-9.9 [-22.3, 2.4]	
Week 48	-5.5 [-12.1, 1.2]	0.0 [-16.6, 16.6]	-5.5 [-23.4, 12.5]	
Week 54	-5.4 [-12.8, 2.0]	-3.5 [-22.0, 15.1]	-1.9 [-21.9, 18.1]	
Week 60	-4.3 [-12.0, 3.5]	-5.7 [-25.0, 13.6]	1.4 [-19.3, 22.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.4158
Dato-DXd	44	
ICC	31	
Time		0.9669
Treatment x Time		0.5282

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-1.0 [-4.2, 2.3]	1.8 [-4.1, 7.6]	-2.8 [-9.5, 3.9]	-0.21 [-0.67, 0.26]
Treatment estimate by planned visit:				
Week 3	-1.9 [-6.0, 2.3]	6.4 [1.2, 11.5]	-8.2 [-14.8, -1.6]	
Week 6	-3.5 [-8.0, 0.9]	4.8 [-0.8, 10.4]	-8.3 [-15.4, -1.2]	
Week 9	-4.9 [-9.4, -0.3]	4.0 [-1.8, 9.9]	-8.9 [-16.3, -1.5]	
Week 12	0.1 [-4.6, 4.9]	2.4 [-3.6, 8.5]	-2.3 [-10.0, 5.4]	
Week 15	-2.9 [-7.8, 2.0]	4.2 [-2.5, 10.8]	-7.0 [-15.3, 1.2]	
Week 18	-0.2 [-5.4, 5.1]	2.8 [-5.6, 11.1]	-2.9 [-12.8, 6.9]	
Week 21	-4.0 [-9.6, 1.5]	3.8 [-4.6, 12.1]	-7.8 [-17.8, 2.2]	
Week 24	-3.2 [-9.1, 2.7]	2.5 [-6.4, 11.5]	-5.7 [-16.5, 5.0]	
Week 27	-4.0 [-10.2, 2.3]	2.4 [-7.5, 12.3]	-6.4 [-18.1, 5.4]	
Week 30	0.9 [-5.4, 7.1]	0.4 [-9.6, 10.4]	0.4 [-11.4, 12.3]	
Week 33	-1.2 [-7.5, 5.2]	-1.8 [-13.5, 9.9]	0.6 [-12.7, 13.9]	
Week 36	3.5 [-3.1, 10.0]	-3.4 [-15.1, 8.3]	6.9 [-6.6, 20.3]	
Week 39	0.0 [-6.9, 6.8]	-2.1 [-14.6, 10.3]	2.1 [-12.1, 16.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

Table 3.43.1 EORTC QLQ-BR45/IL116 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A
Symptom Scales - Arm Symptoms

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	1.0 [-7.4, 9.3]	8.0 [-4.9, 20.9]	-7.1 [-22.5, 8.3]	
Week 45	4.8 [-3.5, 13.1]	1.7 [-12.7, 16.1]	3.1 [-13.6, 19.7]	
Week 48	3.3 [-5.6, 12.3]	-0.2 [-21.8, 21.5]	3.5 [-20.0, 27.0]	
Week 54	0.1 [-9.9, 10.0]	-1.5 [-26.1, 23.1]	1.6 [-25.0, 28.1]	
Week 60	-5.7 [-16.2, 4.7]	-2.4 [-28.4, 23.6]	-3.3 [-31.3, 24.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: T_3_32_1.sas; Output name: DE.T_QLQBR45_MMRM_mFASA.rtf

EORTC QLQ-BR45/IL116 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Verlaufskurve

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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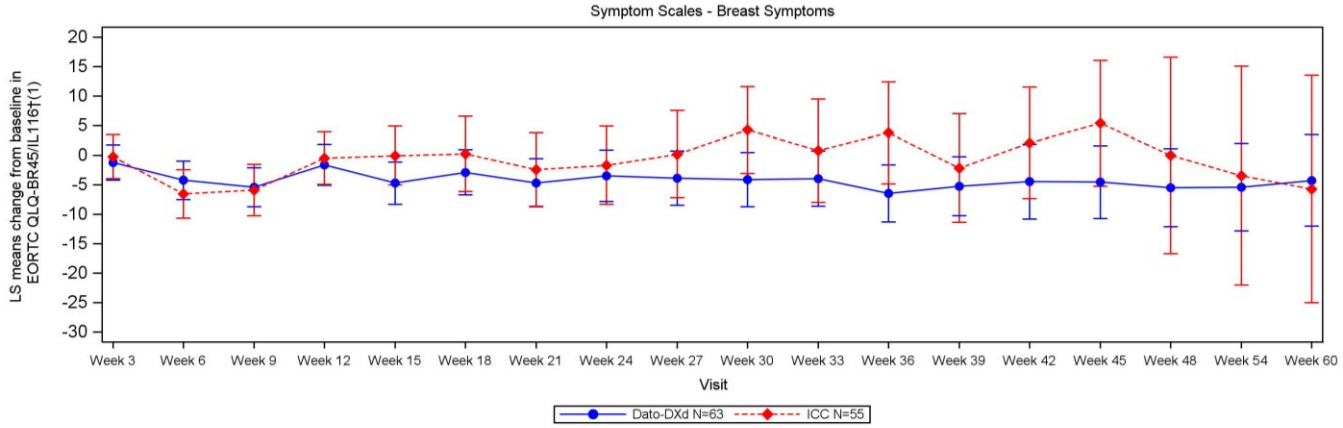
Figure 3.44.1 EORTC QLQ-BR45/IL116 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQBR45_MMRM_mFASA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
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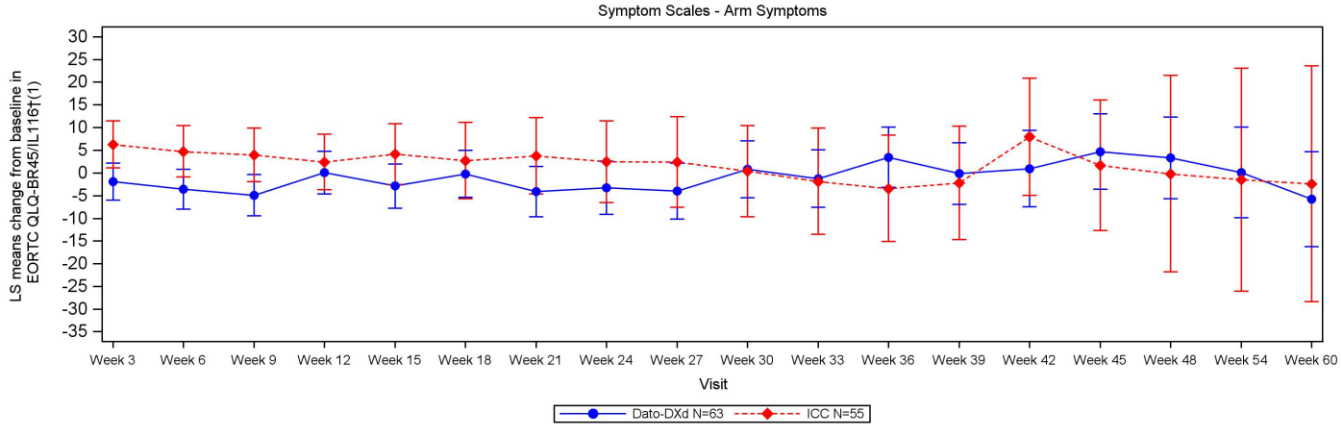
Statistical analyses for AMNOG (HTA Germany)

Figure 3.44.1 EORTC QLQ-BR45/IL116 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:30; Program name: F_3_32_1.sas; Output name: DE.F_QLQBR45_MMRM_mFASA.rtf

EORTC IL117

EORTC IL117 – Rücklauf

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
EORTC IL117 - Dry eyes	Baseline	45	35 (77.8)	41	25 (61.0)
	Week 1	45	24 (53.3)	40	23 (57.5)
	Week 2	46	28 (60.9)	39	24 (61.5)
	Week 3	43	33 (76.7)	39	28 (71.8)
	Week 4	38	23 (60.5)	39	27 (69.2)
	Week 5	38	20 (52.6)	31	22 (71.0)
	Week 6	38	30 (78.9)	28	19 (67.9)
	Week 7	35	23 (65.7)	27	21 (77.8)
	Week 8	36	25 (69.4)	25	20 (80.0)
	Week 9	36	30 (83.3)	26	18 (69.2)
	Week 10	36	21 (58.3)	27	19 (70.4)
	Week 11	37	23 (62.2)	25	17 (68.0)
	Week 12	37	31 (83.8)	25	20 (80.0)
	Week 15	36	29 (80.6)	20	15 (75.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	32	25 (78.1)	15	8 (53.3)
	Week 21	31	22 (71.0)	15	11 (73.3)
	Week 24	27	22 (81.5)	12	8 (66.7)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	20 (80.0)	10	7 (70.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	5 (83.3)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	50	13 (26.0)	42	16 (38.1)
	Baseline and at least one post baseline [c]		35 (55.6)		24 (43.6)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
EORTC IL117 - Mouth pain	Baseline	45	35 (77.8)	41	25 (61.0)
	Week 1	45	24 (53.3)	40	23 (57.5)
	Week 2	46	28 (60.9)	39	24 (61.5)
	Week 3	43	33 (76.7)	39	28 (71.8)
	Week 4	38	23 (60.5)	39	27 (69.2)
	Week 5	38	20 (52.6)	31	22 (71.0)
	Week 6	38	30 (78.9)	28	19 (67.9)
	Week 7	35	23 (65.7)	27	21 (77.8)
	Week 8	36	25 (69.4)	25	20 (80.0)
	Week 9	36	30 (83.3)	26	18 (69.2)
	Week 10	36	21 (58.3)	27	19 (70.4)
	Week 11	37	23 (62.2)	25	17 (68.0)
	Week 12	37	31 (83.8)	25	20 (80.0)
	Week 15	36	29 (80.6)	20	15 (75.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	32	25 (78.1)	15	8 (53.3)
	Week 21	31	22 (71.0)	15	11 (73.3)
	Week 24	27	22 (81.5)	12	8 (66.7)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	20 (80.0)	10	7 (70.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	5 (83.3)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	50	13 (26.0)	42	16 (38.1)
	Baseline and at least one post baseline [c]		35 (55.6)		24 (43.6)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
EORTC IL117 - Sore mouth	Baseline	45	35 (77.8)	41	25 (61.0)
	Week 1	45	24 (53.3)	40	23 (57.5)
	Week 2	46	28 (60.9)	39	24 (61.5)
	Week 3	43	33 (76.7)	39	28 (71.8)
	Week 4	38	23 (60.5)	39	27 (69.2)
	Week 5	38	20 (52.6)	31	22 (71.0)
	Week 6	38	30 (78.9)	28	19 (67.9)
	Week 7	35	23 (65.7)	27	21 (77.8)
	Week 8	36	25 (69.4)	25	20 (80.0)
	Week 9	36	30 (83.3)	26	18 (69.2)
	Week 10	36	21 (58.3)	27	19 (70.4)
	Week 11	37	23 (62.2)	25	17 (68.0)
	Week 12	37	31 (83.8)	25	20 (80.0)
	Week 15	36	29 (80.6)	20	15 (75.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	32	25 (78.1)	15	8 (53.3)
	Week 21	31	22 (71.0)	15	11 (73.3)
	Week 24	27	22 (81.5)	12	8 (66.7)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	20 (80.0)	10	7 (70.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	5 (83.3)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

Table 3.61.1 EORTC IL117 - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	50	13 (26.0)	42	16 (38.1)
	Baseline and at least one post baseline [c]		35 (55.6)		24 (43.6)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:36; Program name: T_3_13_1.sas; Output name: DE.T_QLQIL117_COMP_mSASA.rtf

EORTC IL117 – Zeit bis zur ersten Verschlechterung

EORTC IL117 – Zeit bis zur ersten Verschlechterung – Hauptanalyse – Kaplan-Meier—Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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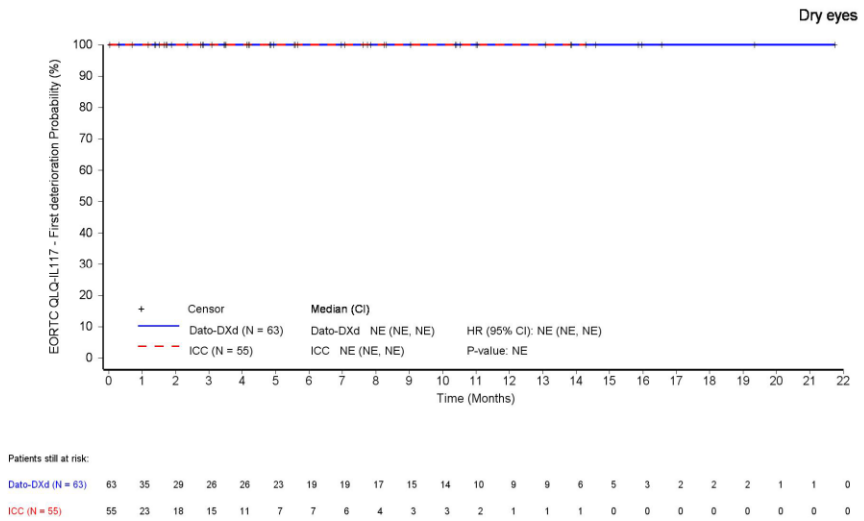
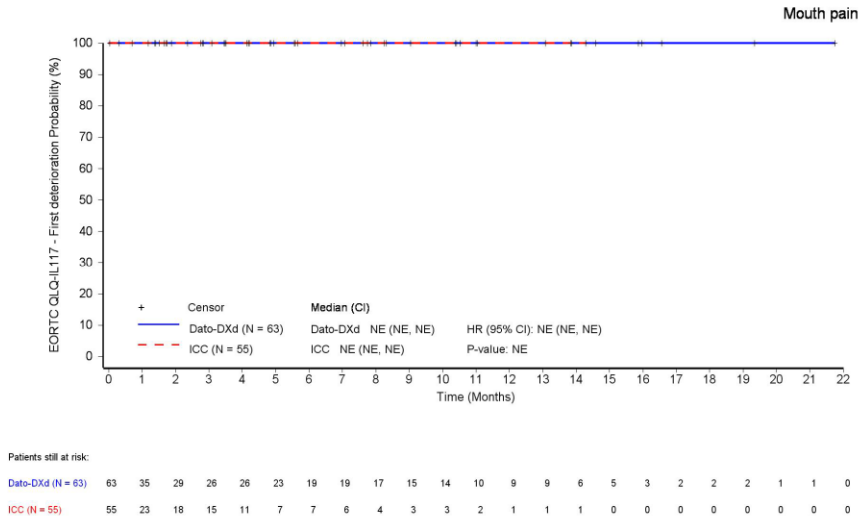
Figure 3.33.1 EORTC IL117 - First deterioration - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC IL117 is considered in this table.

Data source: ADAM.ADQS, ADAM.ADQSTTE
Run date: 21FEB2025 - 11:29; Program name: F_2_3_1.sas; Output name: DE.F_QLQIL117_FD_mSASA.rtf

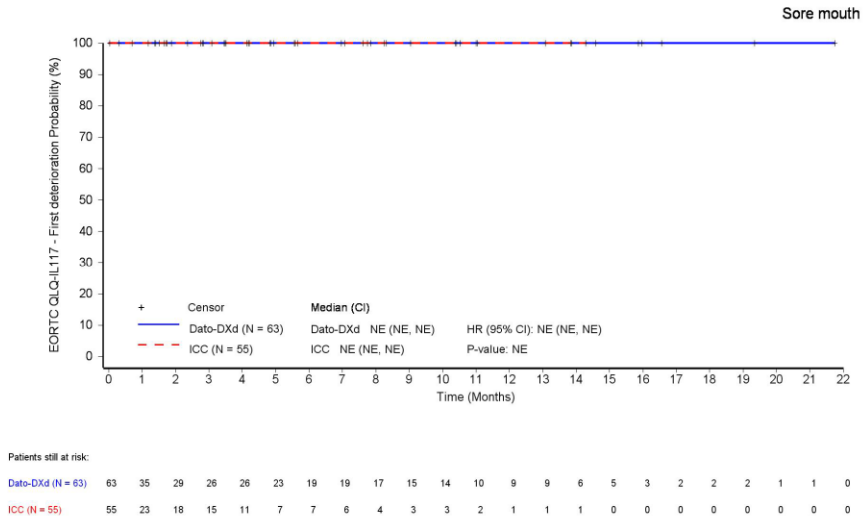
Figure 3.33.1 EORTC IL117 - First deterioration - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC IL117 is considered in this table.

Data source: ADAM.ADQS, ADAM.ADQSTTE
Run date: 21FEB2025 - 11:29; Program name: F_2_3_1.sas; Output name: DE.F_QLQIL117_FD_mSASA.rtf

Figure 3.33.1 EORTC IL117 - First deterioration - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.
A Minimal Clinically Important Difference of 10 for endpoints derived from EORTC IL117 is considered in this table.

Data source: ADAM.ADQS, ADAM.ADQSTTE
Run date: 21FEB2025 - 11:29; Program name: F_2_3_1.sas; Output name: DE.F_QLQIL117_FD_mSASA.rtf

EORTC IL117 – Prüfung der Kriterien der Anhebungsregel

Table 3.33.3 EORTC IL117 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Dry eyes

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_6.sas; Output name: DE.T_QLQIL117_FD_INC_mSASA_Add.rtf

Table 3.33.3 EORTC IL117 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Mouth pain

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_6.sas; Output name: DE.T_QLQIL117_FD_INC_mSASA_Add.rtf

Table 3.33.3 EORTC IL117 - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Sore mouth

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_6.sas; Output name: DE.T_QLQIL117_FD_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.33.5 EORTC IL117 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Dry eyes

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											NE
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; ICC: Investigator's Choice of Chemotherapy; CI: confidence interval;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:18; Program name: t_4_52_4.sas; Output name: DE.T_QLQIL117_FD_SUB_mSASA_Add.rtf

Table 3.33.5 EORTC IL117 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Mouth pain

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											NE
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; ICC: Investigator's Choice of Chemotherapy; CI: confidence interval;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:18; Program name: t_4_52_4.sas; Output name: DE.T_QLQIL117_FD_SUB_mSASA_Add.rtf

Table 3.33.5 EORTC IL117 - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Sore mouth

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											NE
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; ICC: Investigator's Choice of Chemotherapy; CI: confidence interval;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:18; Program name: t_4_52_4.sas; Output name: DE.T_QLQIL117_FD_SUB_mSASA_Add.rtf

EORTC IL117 – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Dry eyes

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Mouth pain

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

Table 3.33.2 EORTC IL117 - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

Sore mouth

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_QLQIL117_FD_SUB_mFASA_FA.rtf

EORTC IL117 – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 3.33.2 EORTC IL117 - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_QLQIL117_FD_SUB_mFASA_FA.rtf

EORTC IL117 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert

EORTC IL117 – Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Dry eyes

	Model †(1)	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.8392
Dato-DXd	35	
ICC	24	
Time		0.0837
Treatment x Time		0.3019

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Dry eyes

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	0.5 [0.3, 0.6]	0.5 [0.2, 0.8]	0.0 [-0.3, 0.3]	-0.06 [-0.59, 0.47]
Treatment estimate by planned visit:				
Week 1	0.0 [-0.3, 0.3]	0.1 [-0.2, 0.5]	-0.1 [-0.6, 0.3]	
Week 2	0.3 [0.0, 0.5]	0.2 [-0.1, 0.5]	0.1 [-0.3, 0.5]	
Week 3	0.3 [0.0, 0.5]	0.3 [0.0, 0.6]	0.0 [-0.4, 0.4]	
Week 4	0.4 [0.2, 0.7]	0.3 [0.0, 0.6]	0.2 [-0.2, 0.6]	
Week 5	0.2 [-0.1, 0.5]	0.1 [-0.2, 0.4]	0.1 [-0.3, 0.6]	
Week 6	0.3 [0.1, 0.6]	0.1 [-0.3, 0.4]	0.3 [-0.2, 0.7]	
Week 7	0.4 [0.1, 0.6]	0.3 [-0.1, 0.6]	0.1 [-0.3, 0.5]	
Week 8	0.3 [0.0, 0.6]	0.5 [0.1, 0.8]	-0.2 [-0.6, 0.3]	
Week 9	0.5 [0.2, 0.7]	0.4 [0.0, 0.7]	0.1 [-0.3, 0.6]	
Week 10	0.4 [0.1, 0.7]	0.5 [0.2, 0.9]	-0.2 [-0.6, 0.3]	
Week 11	0.4 [0.1, 0.7]	0.4 [0.0, 0.8]	0.0 [-0.5, 0.4]	
Week 12	0.6 [0.3, 0.9]	0.4 [0.0, 0.7]	0.2 [-0.2, 0.7]	
Week 15	0.4 [0.1, 0.7]	0.1 [-0.3, 0.5]	0.3 [-0.2, 0.7]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Dry eyes

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 18	0.4 [0.1, 0.6]	0.4 [-0.1, 1.0]	-0.1 [-0.7, 0.6]	
Week 21	0.6 [0.3, 0.9]	0.4 [-0.1, 1.0]	0.1 [-0.5, 0.8]	
Week 24	0.6 [0.2, 0.9]	0.8 [0.2, 1.3]	-0.2 [-0.8, 0.4]	
Week 27	0.5 [0.2, 0.8]	1.1 [0.5, 1.7]	-0.6 [-1.3, 0.1]	
Week 30	0.5 [0.2, 0.9]	0.6 [0.0, 1.3]	-0.1 [-0.9, 0.6]	
Week 33	0.5 [0.1, 0.8]	0.8 [0.0, 1.5]	-0.3 [-1.1, 0.5]	
Week 36	0.8 [0.4, 1.1]	0.8 [0.1, 1.5]	0.0 [-0.8, 0.7]	
Week 39	0.7 [0.4, 1.1]	0.9 [0.1, 1.7]	-0.2 [-1.0, 0.7]	
Week 42	0.7 [0.3, 1.1]	1.0 [0.2, 1.7]	-0.3 [-1.2, 0.6]	
Week 45	0.4 [0.0, 0.9]	1.7 [0.9, 2.5]	-1.2 [-2.1, -0.3]	
Week 48	0.4 [-0.1, 0.9]	0.9 [-0.3, 2.0]	-0.5 [-1.7, 0.8]	
Week 51	0.6 [0.1, 1.1]	1.0 [-0.3, 2.3]	-0.4 [-1.8, 1.0]	
Week 54	0.8 [0.3, 1.3]	0.1 [-1.3, 1.4]	0.7 [-0.8, 2.1]	
Week 57	0.8 [0.3, 1.3]	0.1 [-1.2, 1.5]	0.6 [-0.8, 2.1]	
Week 60	0.8 [0.2, 1.3]	0.2 [-1.2, 1.6]	0.6 [-0.9, 2.1]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Mouth pain

	Model †(1)	
	n [a]	p-value[b]
Baseline		0.0063
Treatment		0.0429
Dato-DXd	35	
ICC	24	
Time		0.3215
Treatment x Time		0.7415

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Mouth pain

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	0.6 [0.4, 0.7]	0.3 [0.0, 0.5]	0.3 [0.0, 0.6]	0.61 [0.07, 1.15]
Treatment estimate by planned visit:				
Week 1	0.5 [0.3, 0.8]	0.3 [-0.1, 0.6]	0.3 [-0.1, 0.7]	
Week 2	0.6 [0.4, 0.9]	0.4 [0.1, 0.7]	0.2 [-0.2, 0.7]	
Week 3	0.3 [0.1, 0.6]	0.3 [0.0, 0.6]	0.0 [-0.4, 0.4]	
Week 4	0.3 [0.1, 0.6]	0.3 [0.0, 0.6]	0.0 [-0.4, 0.4]	
Week 5	0.8 [0.5, 1.1]	0.3 [0.0, 0.6]	0.5 [0.1, 0.9]	
Week 6	0.4 [0.1, 0.7]	0.2 [-0.1, 0.5]	0.2 [-0.2, 0.6]	
Week 7	0.6 [0.3, 0.9]	0.0 [-0.3, 0.4]	0.5 [0.1, 1.0]	
Week 8	1.0 [0.7, 1.3]	0.1 [-0.2, 0.5]	0.9 [0.4, 1.3]	
Week 9	0.6 [0.3, 0.8]	0.1 [-0.3, 0.4]	0.5 [0.0, 1.0]	
Week 10	0.7 [0.4, 1.0]	0.2 [-0.2, 0.5]	0.5 [0.1, 1.0]	
Week 11	0.7 [0.5, 1.0]	0.3 [-0.1, 0.6]	0.5 [0.0, 1.0]	
Week 12	0.7 [0.4, 0.9]	0.2 [-0.1, 0.6]	0.4 [0.0, 0.9]	
Week 15	0.7 [0.4, 1.0]	0.2 [-0.2, 0.6]	0.5 [0.0, 1.0]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Mouth pain

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 18	0.7 [0.4, 1.0]	0.5 [-0.1, 1.0]	0.2 [-0.4, 0.9]	
Week 21	0.7 [0.4, 1.0]	0.3 [-0.2, 0.9]	0.4 [-0.2, 1.0]	
Week 24	0.8 [0.5, 1.1]	0.1 [-0.5, 0.6]	0.7 [0.1, 1.4]	
Week 27	0.7 [0.3, 1.0]	0.2 [-0.3, 0.8]	0.4 [-0.3, 1.1]	
Week 30	0.5 [0.2, 0.9]	0.2 [-0.4, 0.9]	0.3 [-0.4, 1.0]	
Week 33	0.6 [0.3, 0.9]	0.2 [-0.5, 1.0]	0.3 [-0.5, 1.2]	
Week 36	0.6 [0.2, 0.9]	0.3 [-0.4, 1.0]	0.3 [-0.5, 1.1]	
Week 39	0.6 [0.2, 1.0]	0.6 [-0.2, 1.4]	0.0 [-0.9, 0.9]	
Week 42	0.5 [0.1, 1.0]	0.6 [-0.2, 1.4]	0.0 [-1.0, 0.9]	
Week 45	0.4 [0.0, 0.8]	0.2 [-0.6, 1.0]	0.1 [-0.8, 1.1]	
Week 48	0.5 [0.1, 1.0]	-0.1 [-1.3, 1.1]	0.6 [-0.7, 1.9]	
Week 51	0.2 [-0.3, 0.7]	-0.3 [-1.6, 1.1]	0.5 [-0.9, 1.9]	
Week 54	0.5 [0.0, 1.1]	0.6 [-0.8, 2.0]	-0.1 [-1.5, 1.4]	
Week 57	0.6 [0.0, 1.1]	0.5 [-0.9, 1.9]	0.0 [-1.5, 1.5]	
Week 60	0.1 [-0.4, 0.7]	0.5 [-0.9, 1.9]	-0.3 [-1.8, 1.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Sore mouth

	Model †[1]	
	n [a]	p-value[b]
Baseline		0.0003
Treatment		0.0068
Dato-DXd	35	
ICC	24	
Time		0.0961
Treatment x Time		0.7582

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Sore mouth

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	0.7 [0.5, 0.8]	0.2 [0.0, 0.5]	0.4 [0.1, 0.7]	0.81 [0.26, 1.36]
Treatment estimate by planned visit:				
Week 1	0.4 [0.1, 0.7]	0.3 [0.0, 0.7]	0.1 [-0.3, 0.5]	
Week 2	0.7 [0.4, 0.9]	0.3 [0.0, 0.6]	0.4 [0.0, 0.8]	
Week 3	0.4 [0.1, 0.6]	0.3 [0.0, 0.6]	0.1 [-0.3, 0.5]	
Week 4	0.3 [0.0, 0.6]	0.3 [-0.1, 0.6]	0.1 [-0.4, 0.5]	
Week 5	0.7 [0.4, 1.0]	0.3 [0.0, 0.6]	0.5 [0.0, 0.9]	
Week 6	0.4 [0.1, 0.7]	0.2 [-0.1, 0.5]	0.2 [-0.2, 0.6]	
Week 7	0.7 [0.4, 1.0]	0.2 [-0.2, 0.5]	0.5 [0.1, 1.0]	
Week 8	0.9 [0.6, 1.2]	0.4 [0.0, 0.7]	0.5 [0.1, 1.0]	
Week 9	0.7 [0.4, 1.0]	0.3 [-0.1, 0.6]	0.4 [0.0, 0.9]	
Week 10	0.7 [0.4, 1.0]	0.3 [-0.1, 0.6]	0.4 [0.0, 0.9]	
Week 11	0.9 [0.6, 1.2]	0.3 [-0.1, 0.6]	0.6 [0.1, 1.1]	
Week 12	0.7 [0.4, 1.0]	0.2 [-0.1, 0.6]	0.4 [0.0, 0.9]	
Week 15	0.7 [0.4, 1.0]	0.3 [-0.1, 0.7]	0.4 [0.0, 0.9]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

Table 3.62.1 EORTC IL117 - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Sore mouth

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 18	1.0 [0.7, 1.3]	0.4 [-0.2, 0.9]	0.6 [0.0, 1.2]	
Week 21	0.9 [0.6, 1.2]	0.5 [0.0, 1.0]	0.4 [-0.2, 1.0]	
Week 24	1.0 [0.7, 1.3]	0.5 [0.0, 1.0]	0.5 [-0.1, 1.1]	
Week 27	0.8 [0.4, 1.1]	0.1 [-0.4, 0.7]	0.6 [0.0, 1.3]	
Week 30	0.8 [0.4, 1.1]	0.0 [-0.6, 0.6]	0.8 [0.0, 1.5]	
Week 33	0.7 [0.3, 1.0]	0.1 [-0.6, 0.8]	0.5 [-0.2, 1.3]	
Week 36	0.8 [0.4, 1.1]	0.3 [-0.4, 1.0]	0.5 [-0.3, 1.3]	
Week 39	1.0 [0.7, 1.4]	0.2 [-0.5, 1.0]	0.8 [-0.1, 1.6]	
Week 42	0.5 [0.1, 1.0]	0.2 [-0.6, 1.0]	0.3 [-0.6, 1.2]	
Week 45	0.5 [0.1, 1.0]	0.2 [-0.6, 1.0]	0.3 [-0.6, 1.2]	
Week 48	0.6 [0.1, 1.1]	0.0 [-1.1, 1.2]	0.5 [-0.7, 1.8]	
Week 51	0.4 [-0.1, 0.9]	-0.1 [-1.4, 1.2]	0.5 [-0.9, 1.9]	
Week 54	0.7 [0.2, 1.2]	0.9 [-0.5, 2.2]	-0.1 [-1.6, 1.3]	
Week 57	0.6 [0.1, 1.1]	-0.2 [-1.6, 1.2]	0.8 [-0.7, 2.2]	
Week 60	0.3 [-0.2, 0.8]	-0.2 [-1.6, 1.2]	0.5 [-1.0, 2.0]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_QLQIL117_MMRM_mSASA.rtf

EORTC IL117– Verschlechterung um ≥ 10 Punkte gegenüber dem Baseline-Wert – Verlaufskurve

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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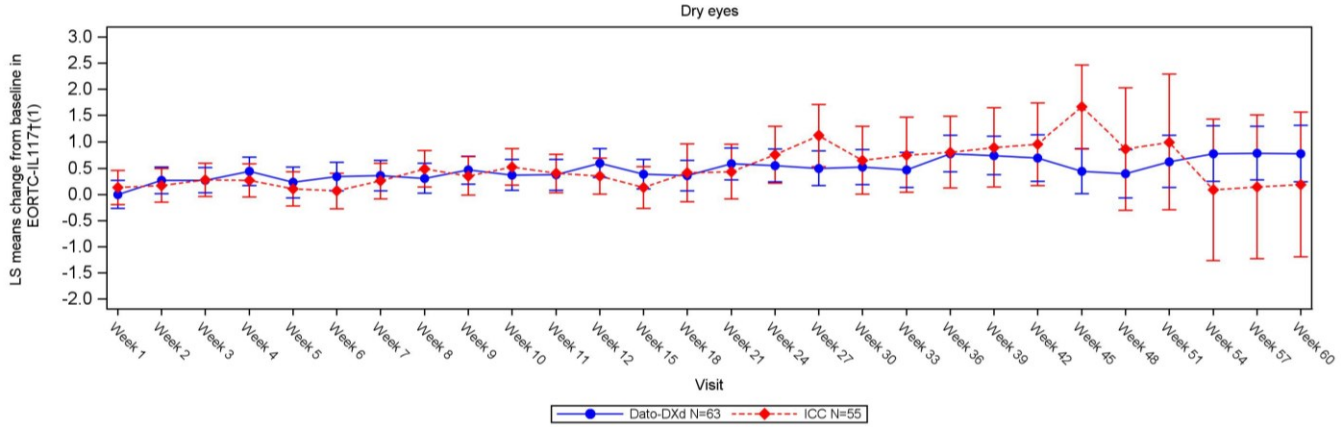
Figure 3.63.1 EORTC IL117 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Safety Analysis Set A

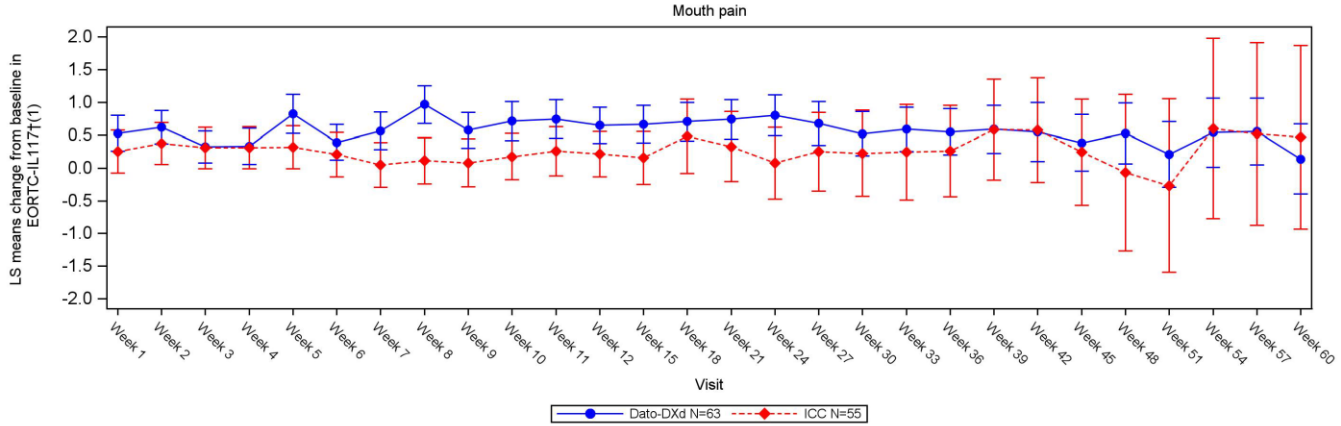


Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: F_3_32_1.sas; Output name: DE.F_QLQIL117_MMRM_mSASA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Figure 3.63.1 EORTC IL117 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: F_3_32_1.sas; Output name: DE.F_QLQIL117_MMRM_mSASA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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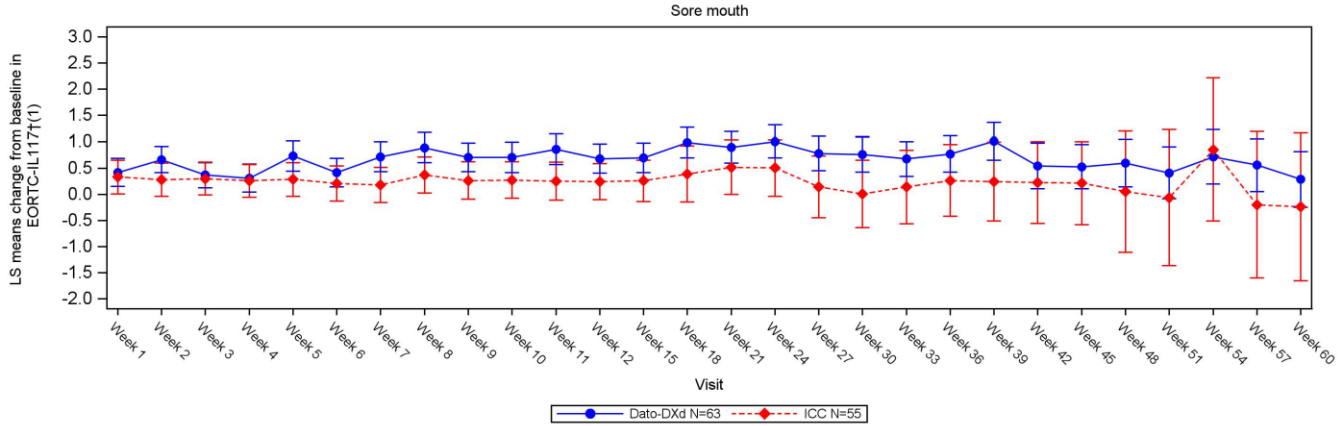
Figure 3.63.1 EORTC IL117 - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: F_3_32_1.sas; Output name: DE.F_QLQIL117_MMRM_mSASA.rtf

EQ-5D VAS

EQ-5D VAS – Zeit bis zur ersten Verschlechterung

EQ-5D VAS – Zeit bis zur ersten Verschlechterung – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Table 3.25.6 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, PRO: Patient Reported Outcome.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_EQ-5D-5L-VAS_FD_INC_mFASA_Add.rtf

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Statistical analyses for AMNOG (HTA Germany)

Table 3.25.4 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.3477
mFASA	63	21 (33.3)	42 (66.7)	5.6 (2.1 , NE)	55	10 (18.2)	45 (81.8)	NE (2.8 , NE)	1.40 (0.66, 2.97)	0.3750	
non-mFASA	269	86 (32.0)	183 (68.0)	8.3 (4.2 , 12.5)	279	90 (32.3)	189 (67.7)	5.6 (4.2 , 7.7)	0.92 (0.69, 1.24)	0.6084	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_4.sas; Output name: DE.T_EQ-5D-5L-VAS_FD_SUB_mFASA_Add.rtf

EQ-5D VAS – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.3458
Region 1 [US, Canada, Europe]	33	11 (33.3)	22 (66.7)	5.6 (1.6, 9.0)	28	2 (7.1)	26 (92.9)	NE (1.4, NE)	2.30 (0.51, 10.42)	0.2593	
Region 2 [Rest of World]	30	10 (33.3)	20 (66.7)	NE (1.4, NE)	27	8 (29.6)	19 (70.4)	6.9 (1.5, NE)	1.08 (0.42, 2.73)	0.8791	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.1433
Yes	52	18 (34.6)	34 (65.4)	5.6 (1.4, NE)	45	7 (15.6)	38 (84.4)	NE (2.8, NE)	1.90 (0.79, 4.55)	0.1401	
No	11	3 (27.3)	8 (72.7)	NE (1.4, NE)	10	3 (30.0)	7 (70.0)	3.4 (0.7, NE)	0.48 (0.09, 2.39)	0.3569	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	9 (28.1)	23 (71.9)	-	30	3 (10.0)	27 (90.0)	-	-	-	
Neither taxanes nor anthracyclines	11	7 (63.6)	4 (36.4)	-	9	4 (44.4)	5 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.0922
<65 years	52	16 (30.8)	36 (69.2)	5.6 (2.8, NE)	41	8 (19.5)	33 (80.5)	NE (1.4, NE)	0.95 (0.40, 2.24)	0.9244	
≥65 years	11	5 (45.5)	6 (54.5)	1.4 (0.7, NE)	14	2 (14.3)	12 (85.7)	NE (3.4, NE)	4.75 (0.89, 25.34)	0.0483	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9896
Asian	21	9 (42.9)	12 (57.1)	4.1 (0.8, NE)	21	6 (28.6)	15 (71.4)	6.9 (1.4, NE)	1.37 (0.49, 3.87)	0.5534	
Non-Asian	32	10 (31.3)	22 (68.8)	9.0 (2.1, NE)	26	4 (15.4)	22 (84.6)	NE (1.4, NE)	1.33 (0.41, 4.27)	0.6275	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3370
Capecitabine	21	4 (19.0)	17 (81.0)	NE (0.8, NE)	9	3 (33.3)	6 (66.7)	6.9 (0.7, NE)	0.73 (0.16, 3.26)	0.6295	
Eribulin mesylate	31	12 (38.7)	19 (61.3)	5.6 (1.6, NE)	41	6 (14.6)	35 (85.4)	NE (2.8, NE)	2.15 (0.81, 5.75)	0.1175	
Vinorelbine	11	5 (45.5)	6 (54.5)	9.0 (0.7, NE)	5	1 (20.0)	4 (80.0)	NE (1.4, NE)	0.50 (0.05, 5.57)	0.5683	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:47; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.8020
Yes	6	2 (33.3)	4 (66.7)	NE (1.4, NE)	6	1 (16.7)	5 (83.3)	NE (2.8, NE)	1.10 (0.10, 12.24)	0.9358	
No	57	19 (33.3)	38 (66.7)	5.6 (1.9, NE)	49	9 (18.4)	40 (81.6)	NE (1.5, NE)	1.44 (0.65, 3.19)	0.3591	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	21 (33.9)	41 (66.1)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	10 (32.3)	21 (67.7)	-	24	4 (16.7)	20 (83.3)	-	-	-	
Asian	21	9 (42.9)	12 (57.1)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.3235
0	35	13 (37.1)	22 (62.9)	5.6 (1.6, NE)	33	7 (21.2)	26 (78.8)	6.9 (1.4, NE)	0.99 (0.40, 2.50)	0.9871	
≥1	28	8 (28.6)	20 (71.4)	5.6 (0.8, NE)	22	3 (13.6)	19 (86.4)	NE (1.4, NE)	2.30 (0.61, 8.68)	0.2086	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	19 (38.8)	30 (61.2)	-	42	6 (14.3)	36 (85.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7981
≤12 months	22	6 (27.3)	16 (72.7)	9.0 (2.1, NE)	19	3 (15.8)	16 (84.2)	NE (1.4, NE)	1.90 (0.47, 7.64)	0.3532	
>12 months	29	11 (37.9)	18 (62.1)	1.9 (0.7, NE)	27	5 (18.5)	22 (81.5)	6.9 (1.4, NE)	1.45 (0.50, 4.21)	0.4839	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

Table 3.25.2 EQ-5D-5L VAS - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	20 (33.9)	39 (66.1)	-	55	10 (18.2)	45 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: t_2_11_2.sas; Output name: DE.T_EQ5D_FD_SUB_mFASA_FA.rtf

EQ-5D VAS – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 3.25.2 EQ-5D-5L VAS - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:48; Program name: f_2_11_2.sas; Output name: DE.F_EQ5D_FD_SUB_mFASA_FA.rtf

EQ-5D VAS – Veränderung um ≥ 15 Punkte gegenüber dem Baseline-Wert

EQ-5D VAS – Veränderung um ≥ 15 Punkte gegenüber dem Baseline-Wert – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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Table 3.39.1 EQ-5D-5L VAS - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.2228
Dato-DXd	42	
ICC	27	
Time		0.7523
Treatment x Time		0.3433

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 24FEB2025 - 16:34; Program name: T_3_32_1.sas; Output name: DE.T_EQ5DVAS_MMRM_mFASA.rtf

Table 3.39.1 EQ-5D-5L VAS - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-2.3 [-6.2, 1.6]	3.1 [-4.5, 10.7]	-5.4 [-14.0, 3.3]	-0.34 [-0.83, 0.16]
Treatment estimate by planned visit:				
Week 3	-1.3 [-6.2, 3.6]	-0.5 [-6.9, 6.0]	-0.9 [-9.0, 7.3]	
Week 6	2.1 [-3.2, 7.3]	-1.2 [-8.4, 5.9]	3.3 [-5.6, 12.2]	
Week 9	-1.4 [-6.8, 4.1]	-2.7 [-10.0, 4.5]	1.4 [-7.7, 10.5]	
Week 12	-2.9 [-8.5, 2.7]	-2.8 [-10.4, 4.7]	-0.1 [-9.6, 9.4]	
Week 15	1.3 [-4.5, 7.1]	-2.0 [-10.4, 6.4]	3.3 [-7.0, 13.6]	
Week 18	-1.1 [-7.4, 5.1]	-2.7 [-13.2, 7.9]	1.5 [-10.7, 13.8]	
Week 21	-2.5 [-9.2, 4.1]	-8.8 [-19.3, 1.7]	6.3 [-6.2, 18.8]	
Week 24	-4.1 [-11.2, 3.0]	5.0 [-6.3, 16.4]	-9.2 [-22.6, 4.3]	
Week 27	-2.8 [-10.2, 4.5]	7.7 [-4.9, 20.4]	-10.6 [-25.3, 4.2]	
Week 30	0.1 [-7.5, 7.7]	5.3 [-8.0, 18.6]	-5.2 [-20.6, 10.2]	
Week 33	-5.2 [-12.8, 2.5]	11.3 [-4.7, 27.3]	-16.5 [-34.3, 1.3]	
Week 36	-4.3 [-12.2, 3.6]	8.6 [-8.6, 25.8]	-12.9 [-31.9, 6.1]	
Week 39	-3.5 [-11.7, 4.7]	16.5 [-1.4, 34.3]	-20.0 [-39.6, -0.3]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 24FEB2025 - 16:34; Program name: T_3_32_1.sas; Output name: DE.T_EQ5DVAS_MMRM_mFASA.rtf

Daiichi Sankyo
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Table 3.39.1 EQ-5D-5L VAS - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	-9.4 [-19.3, 0.4]	15.6 [-2.5, 33.7]	-25.0 [-45.7, -4.3]	
Week 45	-2.6 [-12.6, 7.5]	8.4 [-9.9, 26.6]	-10.9 [-31.9, 10.0]	
Week 48	-4.1 [-14.6, 6.5]	4.7 [-21.0, 30.4]	-8.8 [-36.5, 19.0]	
Week 54	1.5 [-10.1, 13.1]	-3.0 [-31.8, 25.8]	4.5 [-26.6, 35.5]	
Week 60	-0.5 [-12.7, 11.6]	-3.9 [-34.2, 26.4]	3.4 [-29.3, 36.0]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 24FEB2025 - 16:34; Program name: T_3_32_1.sas; Output name: DE.T_EQ5DVAS_MMRM_mFASA.rtf

EQ-5D VAS – Veränderung um ≥ 15 Punkte gegenüber dem Baseline-Wert – Verlaufskurve

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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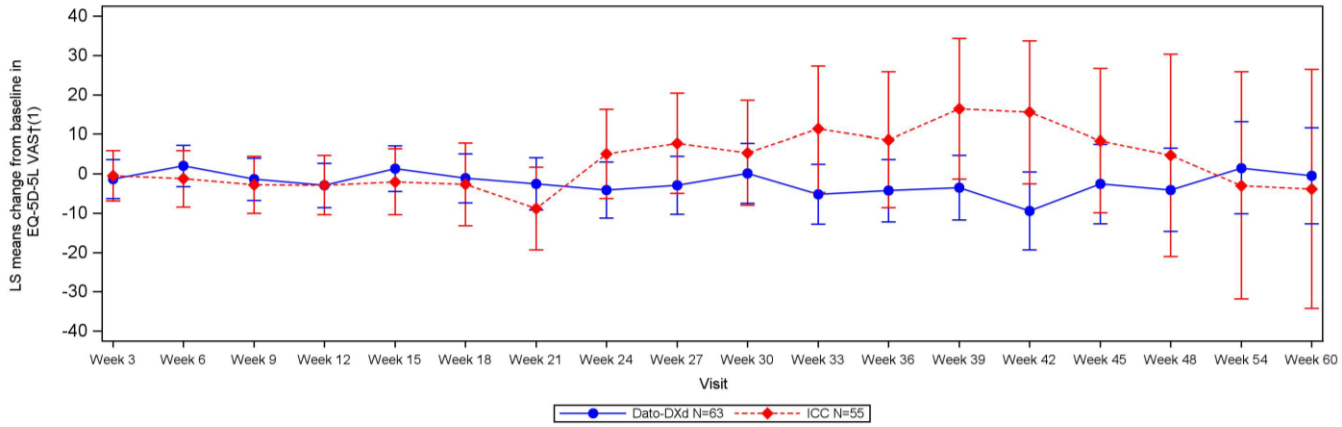
Figure 3.40.1 EQ-5D-5L VAS - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:29; Program name: F_3_32_1.sas; Output name: DE.F_EQ5DVAS_MMRM_mFASA.rtf

PGI-S

PGI-S – Zeit bis zur ersten Verschlechterung

PGI-S – Zeit bis zur ersten Verschlechterung – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 3.35.3 PGI-S - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_6.sas; Output name: DE.T_PGIS_FD_INC_mFASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.35.5 PGI-S - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.6600
mFASA	63	21 (33.3)	42 (66.7)	6.2 (2.1 , NE)	55	15 (27.3)	40 (72.7)	1.4 (1.4 , NE)	0.75 (0.39, 1.47)	0.4144	
non-mFASA	269	100 (37.2)	169 (62.8)	4.2 (2.8 , 7.6)	279	98 (35.1)	181 (64.9)	2.8 (1.5 , 5.7)	0.91 (0.69, 1.21)	0.5274	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; ICC: Investigator's Choice of Chemotherapy; CI: confidence interval;
[a] Exact confidence interval based on Clopper-Pearson method for single proportion.
[b] Confidence interval is the Wald asymptotic confidence interval. In case of zero cells a correction value of 0.5 is added to each cell frequency of the corresponding 2x2 table.
[c] Risk difference is presented on percentage point scale. The confidence interval for risk differences is derived using the Miettinen-Nurminen method.
[d] Two-sided p-value based on the Cochran-Mantel-Haenszel test
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 20MAR2025 - 7:19; Program name: t_4_52_4.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_Add.rtf

PGI-S – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.7054
Region 1 [US, Canada, Europe]	33	9 (27.3)	24 (72.7)	6.3 (0.8, NE)	28	5 (17.9)	23 (82.1)	1.4 (0.7, NE)	0.86 (0.29, 2.56)	0.7822	
Region 2 [Rest of World]	30	12 (40.0)	18 (60.0)	6.2 (2.1, NE)	27	10 (37.0)	17 (63.0)	1.4 (1.4, NE)	0.64 (0.27, 1.52)	0.3124	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.2664
Yes	52	17 (32.7)	35 (67.3)	6.2 (1.5, NE)	45	11 (24.4)	34 (75.6)	7.9 (1.4, NE)	0.90 (0.42, 1.92)	0.7889	
No	11	4 (36.4)	7 (63.6)	NE (0.7, NE)	10	4 (40.0)	6 (60.0)	1.4 (0.7, NE)	0.46 (0.11, 1.96)	0.2940	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	6 (31.6)	13 (68.4)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	7 (23.3)	23 (76.7)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.4346
<65 years	52	15 (28.8)	37 (71.2)	NE (2.1, NE)	41	11 (26.8)	30 (73.2)	1.4 (1.4, NE)	0.68 (0.31, 1.48)	0.3332	
≥65 years	11	6 (54.5)	5 (45.5)	2.8 (0.7, NE)	14	4 (28.6)	10 (71.4)	4.6 (0.7, NE)	1.11 (0.29, 4.16)	0.8783	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.6750
Asian	21	8 (38.1)	13 (61.9)	12.5 (1.4, NE)	21	9 (42.9)	12 (57.1)	1.4 (1.4, NE)	0.54 (0.20, 1.47)	0.2289	
Non-Asian	32	11 (34.4)	21 (65.6)	2.8 (1.5, NE)	26	6 (23.1)	20 (76.9)	NE (0.7, NE)	0.89 (0.33, 2.40)	0.8257	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3932
Capecitabine	21	7 (33.3)	14 (66.7)	6.2 (0.7, NE)	9	6 (66.7)	3 (33.3)	1.4 (0.7, 7.9)	0.51 (0.17, 1.54)	0.2248	
Eribulin mesylate	31	11 (35.5)	20 (64.5)	2.8 (1.5, NE)	41	7 (17.1)	34 (82.9)	NE (0.7, NE)	1.22 (0.47, 3.16)	0.6705	
Vinorelbine	11	3 (27.3)	8 (72.7)	NE (0.7, NE)	5	2 (40.0)	3 (60.0)	1.4 (1.4, NE)	0.52 (0.09, 3.14)	0.4709	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9023
Yes	6	3 (50.0)	3 (50.0)	1.4 (0.7, NE)	6	2 (33.3)	4 (66.7)	1.4 (0.7, NE)	1.26 (0.21, 7.56)	0.8195	
No	57	18 (31.6)	39 (68.4)	6.3 (2.1, NE)	49	13 (26.5)	36 (73.5)	1.4 (1.4, NE)	0.74 (0.36, 1.52)	0.4198	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	20 (32.3)	42 (67.7)	-	54	15 (27.8)	39 (72.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	11 (35.5)	20 (64.5)	-	24	6 (25.0)	18 (75.0)	-	-	-	
Asian	21	8 (38.1)	13 (61.9)	-	21	9 (42.9)	12 (57.1)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.6612
0	35	13 (37.1)	22 (62.9)	6.2 (1.4, NE)	33	8 (24.2)	25 (75.8)	1.4 (0.7, NE)	0.84 (0.35, 2.02)	0.7160	
≥1	28	8 (28.6)	20 (71.4)	12.5 (1.4, NE)	22	7 (31.8)	15 (68.2)	1.4 (0.8, NE)	0.55 (0.19, 1.59)	0.2725	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	18 (36.7)	31 (63.3)	-	42	11 (26.2)	31 (73.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.9076
≤12 months	22	7 (31.8)	15 (68.2)	2.8 (0.8, NE)	19	6 (31.6)	13 (68.4)	4.6 (0.7, NE)	0.77 (0.25, 2.40)	0.6569	
>12 months	29	9 (31.0)	20 (69.0)	6.3 (1.5, NE)	27	6 (22.2)	21 (77.8)	1.4 (0.7, NE)	0.74 (0.26, 2.09)	0.5497	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

Table 3.35.2 PGI-S - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	20 (33.9)	39 (66.1)	-	55	15 (27.3)	40 (72.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_PGIS_FD_SUB_mFASA_FA.rtf

PGI-S – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 3.35.2 PGI-S - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 10:50; Program name: f_2_11_2.sas; Output name: DE.F_PGIS_FD_SUB_mFASA_FA.rtf

PGI-S – Verschlechterung um ≥ 1 Punkt gegenüber dem Baseline-Wert

PGI-S – Verschlechterung um ≥ 1 Punkt gegenüber dem Baseline-Wert – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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Table 3.66.1 EORTC PGI-S - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Model †[1]	
	n [a]	p-value[b]
Baseline		<0.0001
Treatment		0.3322
Dato-DXd	42	
ICC	28	
Time		0.6950
Treatment x Time		0.3043

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_PGIS_MMRM_mFASA.rtf

Table 3.66.1 EORTC PGI-S - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Overall treatment estimate	-0.1 [-0.2, 0.1]	0.1 [-0.2, 0.4]	-0.2 [-0.5, 0.2]	-0.26 [-0.75, 0.23]
Treatment estimate by planned visit:				
Week 3	0.0 [-0.3, 0.2]	0.1 [-0.2, 0.4]	-0.2 [-0.5, 0.2]	
Week 6	0.0 [-0.3, 0.2]	0.1 [-0.2, 0.4]	-0.1 [-0.5, 0.3]	
Week 9	0.1 [-0.2, 0.3]	0.1 [-0.2, 0.5]	-0.1 [-0.5, 0.4]	
Week 12	0.1 [-0.2, 0.3]	0.3 [-0.1, 0.6]	-0.2 [-0.6, 0.2]	
Week 15	-0.1 [-0.4, 0.2]	0.4 [0.0, 0.8]	-0.5 [-1.0, 0.0]	
Week 18	-0.1 [-0.4, 0.2]	0.2 [-0.3, 0.7]	-0.3 [-0.9, 0.3]	
Week 21	0.0 [-0.4, 0.3]	0.3 [-0.2, 0.8]	-0.4 [-0.9, 0.2]	
Week 24	0.0 [-0.3, 0.4]	0.3 [-0.2, 0.8]	-0.2 [-0.9, 0.4]	
Week 27	0.0 [-0.3, 0.4]	0.0 [-0.7, 0.6]	0.1 [-0.6, 0.8]	
Week 30	0.0 [-0.3, 0.4]	0.0 [-0.6, 0.7]	0.0 [-0.7, 0.7]	
Week 33	-0.2 [-0.6, 0.1]	0.0 [-0.7, 0.7]	-0.2 [-1.1, 0.6]	
Week 36	-0.3 [-0.6, 0.1]	0.3 [-0.4, 1.0]	-0.6 [-1.4, 0.3]	
Week 39	0.0 [-0.4, 0.3]	-0.7 [-1.5, 0.1]	0.7 [-0.2, 1.6]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_PGIS_MMRM_mFASA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Table 3.66.1 EORTC PGI-S - Mixed model for repeated measurements - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC	
	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Estimate [95% CI] [c]	Hedges' g [95% CI]
Week 42	0.0 [-0.4, 0.5]	-0.4 [-1.3, 0.4]	0.5 [-0.5, 1.4]	
Week 45	0.0 [-0.4, 0.5]	-0.1 [-1.0, 0.7]	0.2 [-0.8, 1.1]	
Week 48	-0.2 [-0.7, 0.3]	0.0 [-1.2, 1.3]	-0.2 [-1.6, 1.1]	
Week 54	-0.2 [-0.8, 0.3]	1.1 [-0.3, 2.5]	-1.3 [-2.8, 0.2]	
Week 60	-0.2 [-0.8, 0.4]	0.2 [-1.3, 1.6]	-0.3 [-1.9, 1.2]	

CI: Confidence Interval, PRO: Patient Reported Outcome; ICC: Investigator's Choice of Chemotherapy.
[a] n is the number of subjects included in the model in each treatment group.
[b] p-value from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
[c] Least Squares Means and associated Confidence Interval from Mixed Model for Repeated Measures
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: T_3_32_1.sas; Output name: DE.T_PGIS_MMRM_mFASA.rtf

PGI-S – Verschlechterung um ≥ 1 Punkt gegenüber dem Baseline-Wert – Verlaufskurve

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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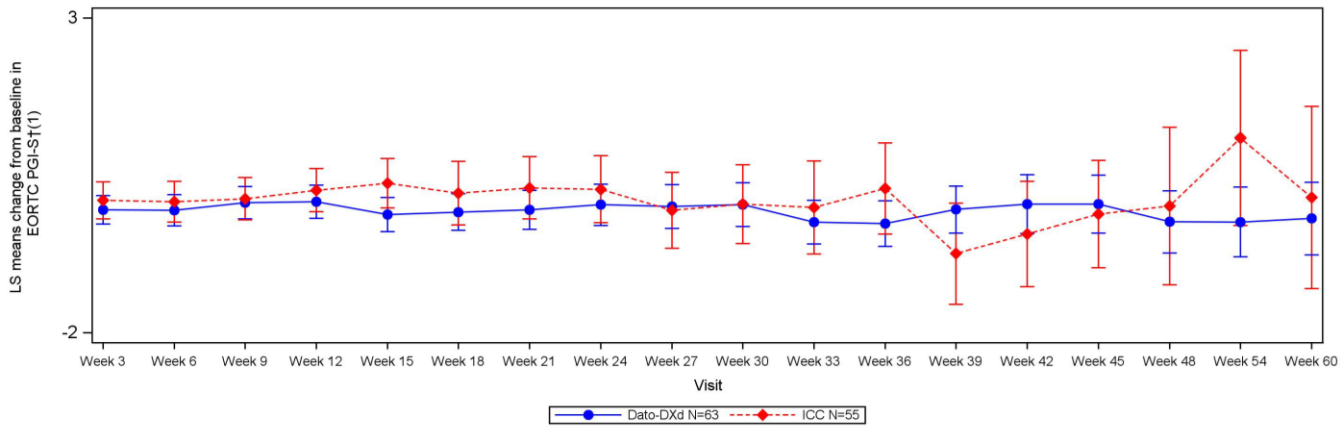
Figure 3.67.1 EORTC PGI-S - Plot of Least Squares Means estimate by treatment across time - DCO 24-Jul-2024 - Modified Full Analysis Set A



Estimation method is (1) restricted maximum likelihood or (2) maximum likelihood.
Least Squares Means and associated confidence interval from MMRM used to model change from baseline in QoL scores with treatment, time and a treatment by time interaction as covariates in the model with an * Unstructured / † AR(1) / ‡ Compound symmetry covariance matrix structure for residuals. ICC: Investigator's Choice of Chemotherapy.
Visits with zero patients in Dato-DXd or ICC group are removed.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:31; Program name: F_3_32_1.sas; Output name: DE.F_PGIS_MMRM_mFASA.rtf

PGI-C

PGI-C – Zeit bis zur ersten Verschlechterung

PGI-C – Zeit bis zur ersten Verschlechterung – Hauptanalyse – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
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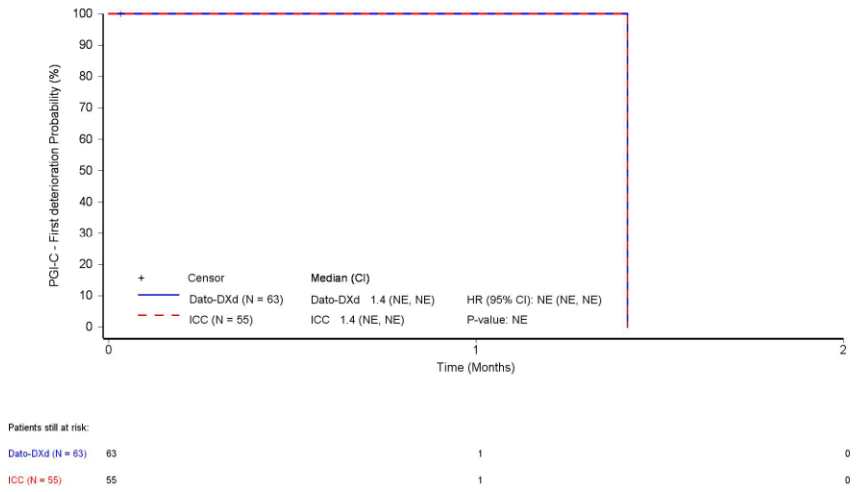
Figure 3.37.1 PGI-C - First deterioration - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Full Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADQS, ADAM.ADQSTTE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_PGIC_FD_mFASA.rtf

PGI-C – Zeit bis zur ersten Verschlechterung – Prüfung der Kriterien der Anhebungsregel

Table 2.79.1 PGI-C - First deterioration - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Full Analysis Set A

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 11:11; Program name: t_4_52_6.sas; Output name: DE.T_PGICINC_mFASA_FA.rtf

Daiichi Sankyo
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Table 2.80.2 PGI-C - First deterioration - Time-to-event analysis - DCO 24-Jul-2024 - mFASA vs non-mFASA

	Dato-DXd (N=332)				ICC (N=334)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mFASA vs non-mFASA											0.5250
mFASA	63	1 (1.6)	62 (98.4)	1.4 (NE, NE)	55	1 (1.8)	54 (98.2)	1.4 (NE, NE)	1.00 (0.06, 15.99)	NE	
non-mFASA	269	10 (3.7)	259 (96.3)	1.4 (1.4 , 1.7)	279	5 (1.8)	274 (98.2)	1.5 (1.4 , NE)	2.66 (0.72, 9.81)	0.1153	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mFASA consists of all patients in mFAS not included into mFASA

Data source: ADAM.ADQSTTE
Run date: 06MAY2025 - 11:11; Program name: t_4_52_4.sas; Output name: DE.T_PGIC_SUB_mFASA_nonmFASA_FA.rtf

PGI-C – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	-	27	1 (3.7)	26 (96.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	1 (1.9)	51 (98.1)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	1 (10.0)	9 (90.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	1 (2.4)	40 (97.6)	-	-	-	
≥65 years	11	1 (9.1)	10 (90.9)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	1 (4.8)	20 (95.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	1 (11.1)	8 (88.9)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	1 (9.1)	10 (90.9)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	1 (1.8)	56 (98.2)	-	49	1 (2.0)	48 (98.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	1 (1.6)	61 (98.4)	-	54	1 (1.9)	53 (98.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	1 (4.8)	20 (95.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	1 (2.9)	34 (97.1)	-	33	1 (3.0)	32 (97.0)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	1 (2.0)	48 (98.0)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	1 (3.4)	28 (96.6)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

Table 3.37.2 PGI-C - First deterioration - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	1 (1.7)	58 (98.3)	-	55	1 (1.8)	54 (98.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: t_2_11_2.sas; Output name: DE.T_PGIC_FD_SUB_mFASA_FA.rtf

PGI-C – Zeit bis zur ersten Verschlechterung – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 3.37.2 PGI-C - First deterioration - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Full Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADQSTTE
Run date: 07MAY2025 - 8:57; Program name: f_2_11_2.sas; Output name: DE.F_PGIC_FD_SUB_mFASA_FA.rtf

Unerwünschte Ereignisse

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Jegliche UE – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 4.48.6 Treatment-emergent adverse events - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_TEAE_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.48.4 Treatment-emergent adverse events - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7740
mSASA	63	61 (96.8)	2 (3.2)	0.2 (0.1 , 0.3)	55	53 (96.4)	2 (3.6)	0.3 (0.2 , 0.5)	1.08 (0.74, 1.57)	0.6651	
non-mSASA	265	261 (98.5)	4 (1.5)	0.1 (0.1 , 0.1)	265	258 (97.4)	7 (2.6)	0.2 (0.2 , 0.3)	1.20 (1.01, 1.43)	0.0452	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_TEAE_SUB_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9379
Region 1 [US, Canada, Europe]	33	31 (93.9)	2 (6.1)	0.1 (0.1, 0.7)	28	27 (96.4)	1 (3.6)	0.2 (0.1, 0.5)	1.07 (0.63, 1.82)	0.8219	
Region 2 [Rest of World]	30	30 (100)	0	0.2 (0.1, 0.7)	27	26 (96.3)	1 (3.7)	0.4 (0.2, 0.7)	1.00 (0.58, 1.71)	0.9950	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9195
Yes	52	50 (96.2)	2 (3.8)	0.2 (0.1, 0.7)	45	43 (95.6)	2 (4.4)	0.3 (0.1, 0.7)	1.06 (0.70, 1.60)	0.7896	
No	11	11 (100)	0	0.1 (0.0, 0.2)	10	10 (100)	0	0.3 (0.0, 0.5)	1.42 (0.58, 3.46)	0.4569	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	19 (100)	0	-	13	12 (92.3)	1 (7.7)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	3 (100)	0	-	-	-	
Both taxanes and anthracyclines	32	30 (93.8)	2 (6.3)	-	30	29 (96.7)	1 (3.3)	-	-	-	
Neither taxanes nor anthracyclines	11	11 (100)	0	-	9	9 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7885
<65 years	52	50 (96.2)	2 (3.8)	0.2 (0.1, 0.7)	41	39 (95.1)	2 (4.9)	0.3 (0.1, 0.5)	1.04 (0.68, 1.60)	0.8361	
≥65 years	11	11 (100)	0	0.1 (0.0, 0.8)	14	14 (100)	0	0.5 (0.0, 1.4)	1.10 (0.48, 2.50)	0.8383	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5257
Asian	21	21 (100)	0	0.2 (0.0, 0.7)	21	20 (95.2)	1 (4.8)	0.7 (0.3, 0.7)	0.90 (0.46, 1.73)	0.7178	
Non-Asian	32	31 (96.9)	1 (3.1)	0.2 (0.1, 0.3)	26	25 (96.2)	1 (3.8)	0.2 (0.1, 0.5)	1.23 (0.71, 2.13)	0.4512	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1347
Capecitabine	21	20 (95.2)	1 (4.8)	0.2 (0.0, 0.7)	9	8 (88.9)	1 (11.1)	0.8 (0.7, 1.4)	2.26 (0.94, 5.40)	0.0578	
Eribulin mesylate	31	30 (96.8)	1 (3.2)	0.2 (0.1, 0.2)	41	41 (100)	0	0.2 (0.1, 0.3)	0.98 (0.61, 1.58)	0.9611	
Vinorelbine	11	11 (100)	0	0.7 (0.1, 1.2)	5	4 (80.0)	1 (20.0)	0.4 (0.0, NE)	0.81 (0.25, 2.65)	0.7295	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.2047
Yes	6	6 (100)	0	0.4 (0.1, NE)	6	6 (100)	0	0.2 (0.0, NE)	0.48 (0.13, 1.73)	0.2608	
No	57	55 (96.5)	2 (3.5)	0.2 (0.1, 0.3)	49	47 (95.9)	2 (4.1)	0.3 (0.2, 0.5)	1.17 (0.79, 1.74)	0.4127	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	1 (100)	0	-	-	-	
Female	62	60 (96.8)	2 (3.2)	-	54	52 (96.3)	2 (3.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	30 (96.8)	1 (3.2)	-	24	23 (95.8)	1 (4.2)	-	-	-	
Asian	21	21 (100)	0	-	21	20 (95.2)	1 (4.8)	-	-	-	
Other*	1	1 (100)	0	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9657
0	35	34 (97.1)	1 (2.9)	0.2 (0.1, 0.7)	33	31 (93.9)	2 (6.1)	0.5 (0.1, 0.7)	1.08 (0.66, 1.78)	0.7608	
≥1	28	27 (96.4)	1 (3.6)	0.2 (0.1, 0.3)	22	22 (100)	0	0.3 (0.0, 0.4)	1.02 (0.58, 1.82)	0.9091	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	6 (100)	0	-	-	-	
≥6 months	49	48 (98.0)	1 (2.0)	-	42	40 (95.2)	2 (4.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7235
≤12 months	22	20 (90.9)	2 (9.1)	0.2 (0.1, 0.7)	19	19 (100)	0	0.3 (0.0, 0.7)	0.95 (0.50, 1.81)	0.8948	
>12 months	29	29 (100)	0	0.3 (0.1, 0.7)	27	25 (92.6)	2 (7.4)	0.3 (0.1, 0.7)	1.07 (0.62, 1.85)	0.8066	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Table 4.48.2 Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	3 (75.0)	1 (25.0)	-	0	0	0	-	-	-	
No	59	58 (98.3)	1 (1.7)	-	55	53 (96.4)	2 (3.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAE_SUB_mSASA_FA.rtf

Jegliche UE – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 4.48.2 Treatment-emergent adverse events - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: f_2_11_2.sas; Output name: DE.F_TEAE_SUB_mSASA_FA.rtf

Schwerwiegende UE

Schwerwiegende UE – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 4.49.6 Serious Treatment-emergent adverse events - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	7 (11.1)	9 (16.4)	
Number of subjects censored, n (%)	56 (88.9)	46 (83.6)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(12.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.51
85% Confidence Interval			(0.24, 1.05)
Stratified log-rank p-value [c]			0.1732

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_6.sas; Output name: DE.T_TEAESER_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.49.4 Serious Treatment-emergent adverse events - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.5972
mSASA	63	7 (11.1)	56 (88.9)	NE (NE, NE)	55	9 (16.4)	46 (83.6)	NE (12.2 , NE)	0.50 (0.18, 1.35)	0.1617	
non-mSASA	265	51 (19.2)	214 (80.8)	NE (22.5 , NE)	265	54 (20.4)	211 (79.6)	NE (20.8 , NE)	0.71 (0.48, 1.05)	0.0842	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:30; Program name: t_4_52_4.sas; Output name: DE.T_TEAESER_SUB_mSASA_Add.rtf

Schwerwiegende UE – Subgruppenanalysen

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	6 (18.2)	27 (81.8)	-	28	2 (7.1)	26 (92.9)	-	-	-	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	-	27	7 (25.9)	20 (74.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9915
Yes	52	7 (13.5)	45 (86.5)	NE (12.3, NE)	45	6 (13.3)	39 (86.7)	NE (12.2, NE)	0.77 (0.26, 2.32)	0.6452	
No	11	0	11 (100)	NE (NE, NE)	10	3 (30.0)	7 (70.0)	NE (1.4, NE)	0.00 (0.00, NE)	0.0286	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	4 (12.5)	28 (87.5)	-	30	4 (13.3)	26 (86.7)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.8271
<65 years	52	5 (9.6)	47 (90.4)	NE (12.3, NE)	41	5 (12.2)	36 (87.8)	NE (NE, NE)	0.54 (0.15, 1.91)	0.3358	
≥65 years	11	2 (18.2)	9 (81.8)	NE (1.3, NE)	14	4 (28.6)	10 (71.4)	12.2 (3.9, NE)	0.51 (0.09, 2.85)	0.4386	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	1 (4.8)	20 (95.2)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Non-Asian	32	4 (12.5)	28 (87.5)	-	26	3 (11.5)	23 (88.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9999
Capecitabine	21	3 (14.3)	18 (85.7)	NE (9.1, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	0.2628	
Eribulin mesylate	31	3 (9.7)	28 (90.3)	NE (12.3, NE)	41	9 (22.0)	32 (78.0)	NE (12.2, NE)	0.35 (0.09, 1.30)	0.1007	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (NE, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.5465	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9935
Yes	6	0	6 (100)	NE (NE, NE)	6	3 (50.0)	3 (50.0)	3.9 (0.9, NE)	0.00 (0.00, NE)	0.0436	
No	57	7 (12.3)	50 (87.7)	NE (NE, NE)	49	6 (12.2)	43 (87.8)	NE (12.2, NE)	0.75 (0.25, 2.24)	0.5998	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	6 (9.7)	56 (90.3)	-	54	9 (16.7)	45 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	4 (12.9)	27 (87.1)	-	24	3 (12.5)	21 (87.5)	-	-	-	
Asian	21	1 (4.8)	20 (95.2)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	4 (11.4)	31 (88.6)	-	33	3 (9.1)	30 (90.9)	-	-	-	
≥1	28	3 (10.7)	25 (89.3)	-	22	6 (27.3)	16 (72.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	6 (12.2)	43 (87.8)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	3 (13.6)	19 (86.4)	-	19	4 (21.1)	15 (78.9)	-	-	-	
>12 months	29	4 (13.8)	25 (86.2)	-	27	2 (7.4)	25 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Table 4.49.2 Serious Treatment-emergent adverse events - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	7 (11.9)	52 (88.1)	-	55	9 (16.4)	46 (83.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESER_SUB_mSASA_FA.rtf

Schwerwiegende UE – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 4.49.2 Serious Treatment-emergent adverse events - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: f_2_11_2.sas; Output name: DE.F_TEAESER_SUB_mSASA_FA.rtf

Schwere UE (CTCAE-Grad ≥3)

Schwere UE (CTCAE-Grad ≥3) – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 4.50.6 Severe Treatment-emergent adverse events (CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_TEAESEV_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.50.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4132
mSASA	63	17 (27.0)	46 (73.0)	NE (7.6 , NE)	55	31 (56.4)	24 (43.6)	2.8 (0.9 , 11.7)	0.31 (0.17, 0.57)	<0.0001	
non-mSASA	265	97 (36.6)	168 (63.4)	20.9 (12.1 , NE)	265	152 (57.4)	113 (42.6)	2.1 (1.2 , 5.6)	0.41 (0.32, 0.54)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_TEAESEV_SUB_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.0274
Region 1 [US, Canada, Europe]	33	12 (36.4)	21 (63.6)	7.6 (5.0, NE)	28	13 (46.4)	15 (53.6)	4.1 (0.8, NE)	0.58 (0.26, 1.28)	0.1718	
Region 2 [Rest of World]	30	5 (16.7)	25 (83.3)	NE (NE, NE)	27	18 (66.7)	9 (33.3)	1.4 (0.7, 7.4)	0.15 (0.05, 0.41)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9852
Yes	52	17 (32.7)	35 (67.3)	NE (6.2, NE)	45	23 (51.1)	22 (48.9)	4.1 (1.1, NE)	0.47 (0.25, 0.88)	0.0160	
No	11	0	11 (100)	NE (NE, NE)	10	8 (80.0)	2 (20.0)	1.1 (0.0, 2.8)	0.00 (0.00, NE)	0.0002	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	8 (61.5)	5 (38.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	7 (21.9)	25 (78.1)	-	30	15 (50.0)	15 (50.0)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	6 (66.7)	3 (33.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.0883
<65 years	52	11 (21.2)	41 (78.8)	NE (NE, NE)	41	23 (56.1)	18 (43.9)	2.8 (0.7, NE)	0.24 (0.12, 0.50)	<0.0001	
≥65 years	11	6 (54.5)	5 (45.5)	7.6 (0.3, NE)	14	8 (57.1)	6 (42.9)	2.0 (0.7, NE)	0.73 (0.25, 2.16)	0.5797	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.2384
Asian	21	4 (19.0)	17 (81.0)	NE (6.2, NE)	21	13 (61.9)	8 (38.1)	1.4 (0.7, NE)	0.20 (0.07, 0.62)	0.0021	
Non-Asian	32	9 (28.1)	23 (71.9)	NE (5.6, NE)	26	12 (46.2)	14 (53.8)	4.1 (1.3, NE)	0.50 (0.21, 1.20)	0.1152	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1153
Capecitabine	21	7 (33.3)	14 (66.7)	NE (5.6, NE)	9	3 (33.3)	6 (66.7)	NE (0.7, NE)	0.97 (0.25, 3.78)	0.9818	
Eribulin mesylate	31	6 (19.4)	25 (80.6)	NE (NE, NE)	41	26 (63.4)	15 (36.6)	1.4 (0.7, NE)	0.20 (0.08, 0.50)	0.0001	
Vinorelbine	11	4 (36.4)	7 (63.6)	NE (0.3, NE)	5	2 (40.0)	3 (60.0)	4.1 (0.0, NE)	0.69 (0.12, 3.78)	0.6639	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9892
Yes	6	0	6 (100)	NE (NE, NE)	6	4 (66.7)	2 (33.3)	4.3 (0.0, NE)	0.00 (0.00, NE)	0.0183	
No	57	17 (29.8)	40 (70.2)	NE (6.9, NE)	49	27 (55.1)	22 (44.9)	2.8 (0.8, NE)	0.36 (0.20, 0.67)	0.0008	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	1 (100)	0	-	-	-	
Female	62	16 (25.8)	46 (74.2)	-	54	30 (55.6)	24 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	9 (29.0)	22 (71.0)	-	24	10 (41.7)	14 (58.3)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	13 (61.9)	8 (38.1)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.3092
0	35	9 (25.7)	26 (74.3)	NE (6.9, NE)	33	17 (51.5)	16 (48.5)	3.4 (1.4, NE)	0.37 (0.16, 0.83)	0.0124	
≥1	28	8 (28.6)	20 (71.4)	NE (6.2, NE)	22	14 (63.6)	8 (36.4)	0.8 (0.3, NE)	0.24 (0.10, 0.60)	0.0010	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	4 (66.7)	2 (33.3)	-	-	-	
≥6 months	49	14 (28.6)	35 (71.4)	-	42	23 (54.8)	19 (45.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3415
≤12 months	22	4 (18.2)	18 (81.8)	NE (5.6, NE)	19	9 (47.4)	10 (52.6)	11.7 (0.3, NE)	0.32 (0.10, 1.06)	0.0506	
>12 months	29	12 (41.4)	17 (58.6)	7.6 (4.6, NE)	27	14 (51.9)	13 (48.1)	2.0 (0.8, NE)	0.56 (0.26, 1.22)	0.1392	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Table 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

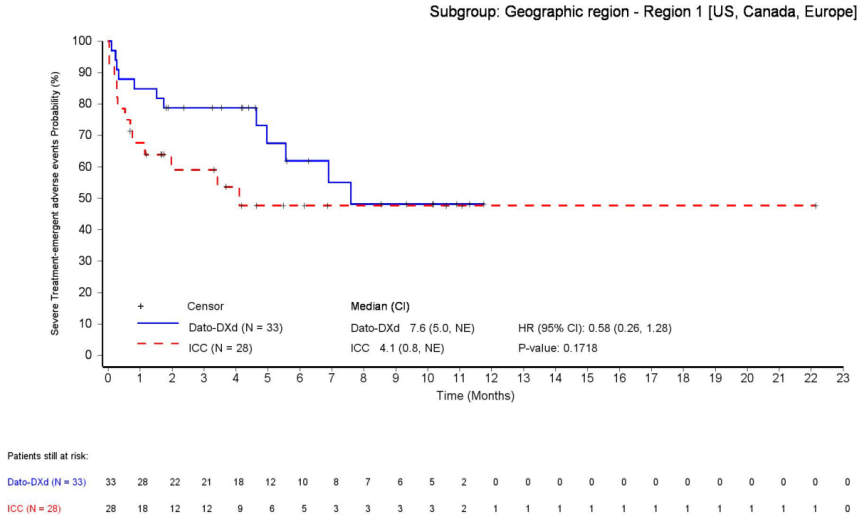
	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	17 (28.8)	42 (71.2)	-	55	31 (56.4)	24 (43.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_TEAESEV_SUB_mSASA_FA.rtf

Schwere UE (CTCAE-Grad ≥3) – Subgruppenanalysen – Kaplan-Meier-Kurven

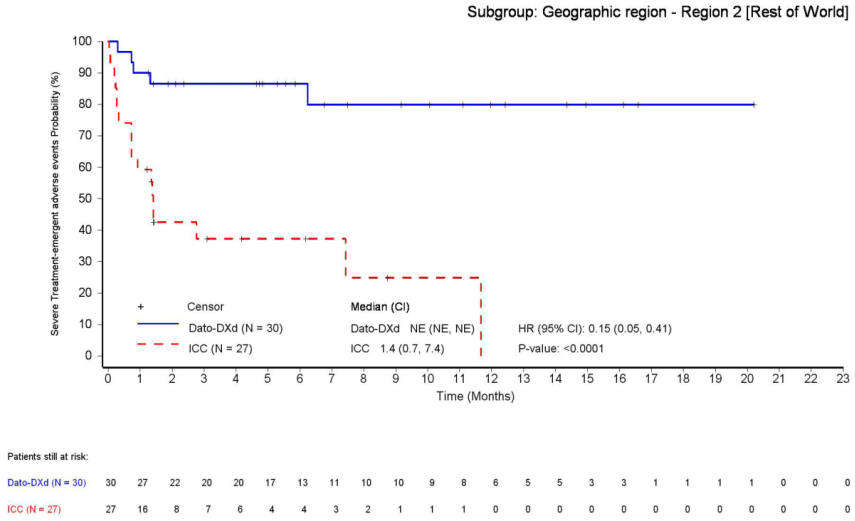
Figure 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: f_2_11_2.sas; Output name: DE.F_TEAESEV_SUB_mSASA_FA.rtf

Figure 4.50.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: f_2_11_2.sas; Output name: DE.F_TEAESEV_SUB_mSASA_FA.rtf

Therapieabbruch aufgrund von UE

Therapieabbruch aufgrund von UE – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 4.51.6 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:32; Program name: t_4_52_6.sas; Output name: DE.T_TEAEDISC_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.51.4 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.1833
mSASA	63	2 (3.2)	61 (96.8)	NE (NE, NE)	55	4 (7.3)	51 (92.7)	NE (12.2 , NE)	0.24 (0.04, 1.31)	0.0733	
non-mSASA	265	11 (4.2)	254 (95.8)	NE (NE, NE)	265	7 (2.6)	258 (97.4)	NE (NE, NE)	1.22 (0.47, 3.16)	0.6884	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:32; Program name: t_4_52_4.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	1 (3.0)	32 (97.0)	-	28	2 (7.1)	26 (92.9)	-	-	-	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	-	27	2 (7.4)	25 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	1 (1.9)	51 (98.1)	-	45	4 (8.9)	41 (91.1)	-	-	-	
No	11	1 (9.1)	10 (90.9)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	1 (5.3)	18 (94.7)	-	13	2 (15.4)	11 (84.6)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	1 (3.1)	31 (96.9)	-	30	1 (3.3)	29 (96.7)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	2 (3.8)	50 (96.2)	-	41	1 (2.4)	40 (97.6)	-	-	-	
≥65 years	11	0	11 (100)	-	14	3 (21.4)	11 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	2 (9.5)	19 (90.5)	-	-	-	
Non-Asian	32	2 (6.3)	30 (93.8)	-	26	1 (3.8)	25 (96.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	1 (4.8)	20 (95.2)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	1 (3.2)	30 (96.8)	-	41	4 (9.8)	37 (90.2)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	2 (3.5)	55 (96.5)	-	49	4 (8.2)	45 (91.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	2 (3.2)	60 (96.8)	-	54	4 (7.4)	50 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	2 (6.5)	29 (93.5)	-	24	1 (4.2)	23 (95.8)	-	-	-	
Asian	21	0	21 (100)	-	21	2 (9.5)	19 (90.5)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	2 (5.7)	33 (94.3)	-	33	4 (12.1)	29 (87.9)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	2 (4.1)	47 (95.9)	-	42	3 (7.1)	39 (92.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	2 (10.5)	17 (89.5)	-	-	-	
>12 months	29	1 (3.4)	28 (96.6)	-	27	2 (7.4)	25 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Table 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	2 (3.4)	57 (96.6)	-	55	4 (7.3)	51 (92.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:50; Program name: t_2_11_2.sas; Output name: DE.T_TEAEDISC_SUB_mSASA_FA.rtf

Therapieabbruch aufgrund von UE – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 4.51.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

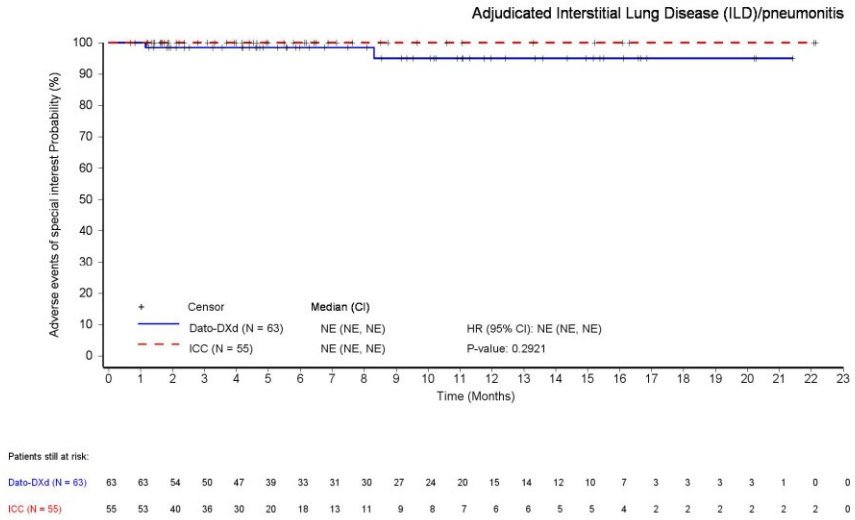
Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:51; Program name: f_2_11_2.sas; Output name: DE.F_TEAEDISC_SUB_mSASA_FA.rtf

Unerwünschte Ereignisse von besonderem Interesse

Jegliche UESI

Jegliche UESI– Hauptanalyse – Kaplan-Meier-Kurven

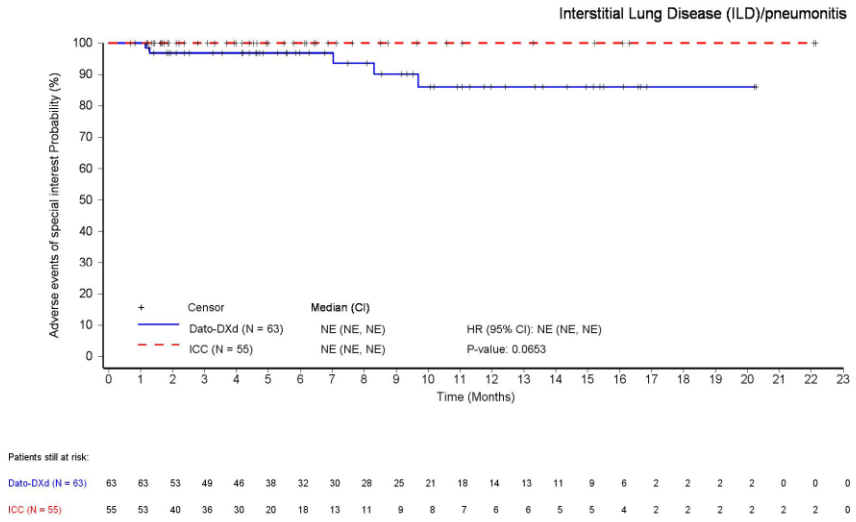
Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

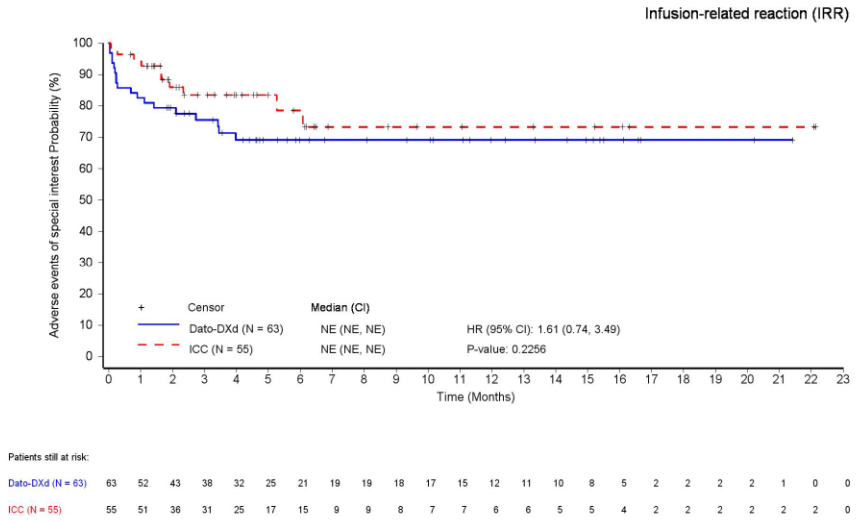
Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

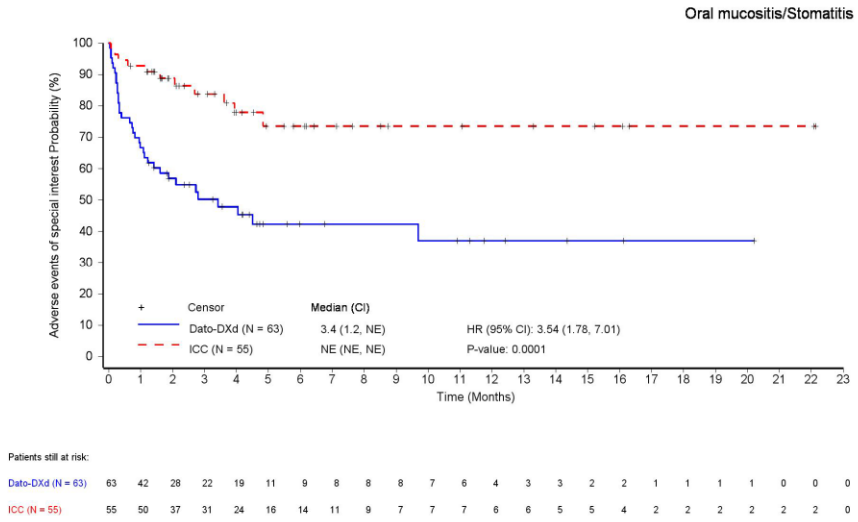
Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

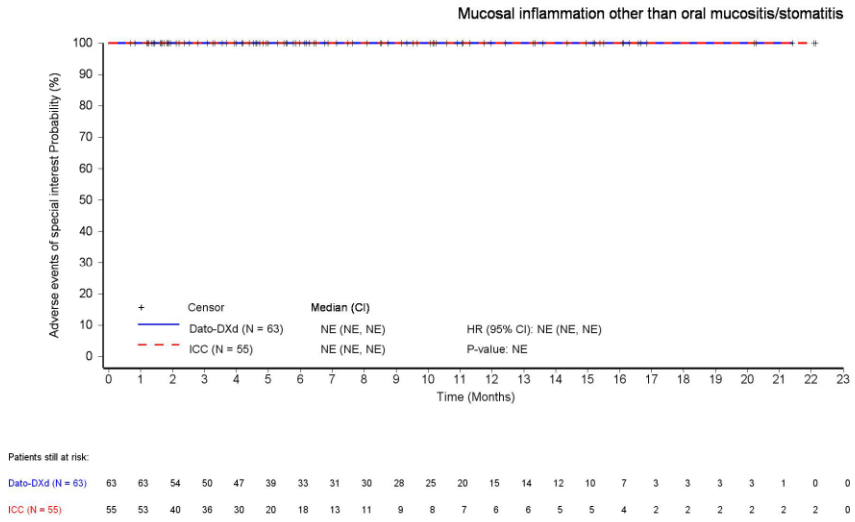
Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

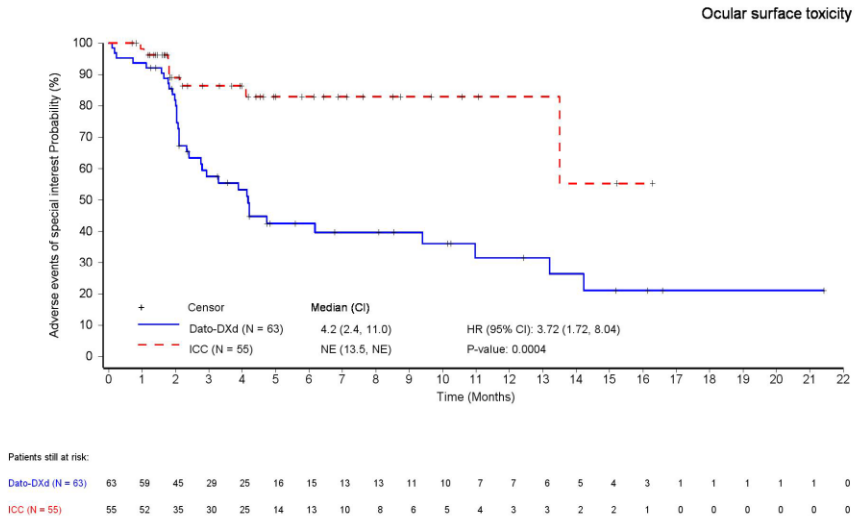
Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

Figure 4.52.1 Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:30; Program name: F_2_3_1.sas; Output name: DE.F_AESI_mSASA.rtf

Jegliche UESI – Prüfung der Kriterien der Anhebungsregel

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	2 (3.2)	0 (0.0)	
Number of subjects censored, n (%)	61 (96.8)	55 (100.0)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			NE
85% Confidence Interval			(NE, NE)
Stratified log-rank p-value [c]			0.2921

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	5 (7.9)	0 (0.0)	
Number of subjects censored, n (%)	58 (92.1)	55 (100.0)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			NE
85% Confidence Interval			(NE, NE)
Stratified log-rank p-value [c]			0.0653

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	18 (28.6)	10 (18.2)	
Number of subjects censored, n (%)	45 (71.4)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.61
85% Confidence Interval			(0.91, 2.84)
Stratified log-rank p-value [c]			0.2256

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Table 4.52.6 Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Ocular surface toxicity

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_3_75_1.sas; Output name: DE.T_AESI_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											>0.9999
mSASA	63	2 (3.2)	61 (96.8)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	0.2739	
non-mSASA	265	12 (4.5)	253 (95.5)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.0021	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9906
mSASA	63	5 (7.9)	58 (92.1)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	0.0926	
non-mSASA	265	12 (4.5)	253 (95.5)	NE (NE, NE)	265	2 (0.8)	263 (99.2)	NE (NE, NE)	4.50 (1.00, 20.16)	0.0315	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Infusion-related reaction (IRR)

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.8094
mSASA	63	18 (28.6)	45 (71.4)	NE (NE, NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	1.59 (0.73, 3.45)	0.2350	
non-mSASA	265	89 (33.6)	176 (66.4)	NE (20.0 , NE)	265	53 (20.0)	212 (80.0)	NE (NE, NE)	1.69 (1.20, 2.38)	0.0024	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Oral mucositis/Stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4203
mSASA	63	34 (54.0)	29 (46.0)	3.4 (1.2 , NE)	55	11 (20.0)	44 (80.0)	NE (NE, NE)	3.44 (1.74, 6.81)	0.0002	
non-mSASA	265	170 (64.2)	95 (35.8)	2.4 (1.8 , 3.0)	265	48 (18.1)	217 (81.9)	NE (NE, NE)	4.65 (3.37, 6.41)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9998
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	4 (1.5)	261 (98.5)	NE (NE, NE)	265	1 (0.4)	264 (99.6)	NE (NE, NE)	3.10 (0.35, 27.81)	0.2872	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.4 Adverse events of special interest - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Ocular surface toxicity

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.1409
mSASA	63	36 (57.1)	27 (42.9)	4.2 (2.4 , 11.0)	55	8 (14.5)	47 (85.5)	NE (13.5 , NE)	3.71 (1.72, 7.99)	0.0003	
non-mSASA	265	141 (53.2)	124 (46.8)	5.9 (4.1 , 7.5)	265	70 (26.4)	195 (73.6)	NE (NE, NE)	2.05 (1.54, 2.73)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable. ICC: Investigator's Choice of Chemotherapy
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:29; Program name: t_4_52_4.sas; Output name: DE.T_AESI_SUB_mSASA_Add.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	1 (3.0)	32 (97.0)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	2 (3.8)	50 (96.2)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	2 (6.3)	30 (93.8)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	2 (3.8)	50 (96.2)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	1 (4.8)	20 (95.2)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	1 (3.1)	31 (96.9)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	1 (4.8)	20 (95.2)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	1 (3.2)	30 (96.8)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	2 (3.5)	55 (96.5)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	2 (3.2)	60 (96.8)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	1 (3.2)	30 (96.8)	-	24	0	24 (100)	-	-	-	
Asian	21	1 (4.8)	20 (95.2)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	2 (5.7)	33 (94.3)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	2 (4.1)	47 (95.9)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	2 (6.9)	27 (93.1)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	2 (3.4)	57 (96.6)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	1 (3.0)	32 (97.0)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	4 (13.3)	26 (86.7)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	5 (9.6)	47 (90.4)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	17 (89.5)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	3 (9.4)	29 (90.6)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	3 (5.8)	49 (94.2)	-	41	0	41 (100)	-	-	-	
≥65 years	11	2 (18.2)	9 (81.8)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	3 (14.3)	18 (85.7)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	2 (6.3)	30 (93.8)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	3 (14.3)	18 (85.7)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	2 (6.5)	29 (93.5)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	5 (8.8)	52 (91.2)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	5 (8.1)	57 (91.9)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	2 (6.5)	29 (93.5)	-	24	0	24 (100)	-	-	-	
Asian	21	3 (14.3)	18 (85.7)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	2 (5.7)	33 (94.3)	-	33	0	33 (100)	-	-	-	
≥1	28	3 (10.7)	25 (89.3)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	5 (10.2)	44 (89.8)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	2 (9.1)	20 (90.9)	-	19	0	19 (100)	-	-	-	
>12 months	29	2 (6.9)	27 (93.1)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	5 (8.5)	54 (91.5)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.8941
Region 1 [US, Canada, Europe]	33	11 (33.3)	22 (66.7)	NE (2.7, NE)	28	6 (21.4)	22 (78.6)	NE (5.3, NE)	1.65 (0.61, 4.46)	0.3232	
Region 2 [Rest of World]	30	7 (23.3)	23 (76.7)	NE (NE, NE)	27	4 (14.8)	23 (85.2)	NE (NE, NE)	1.54 (0.45, 5.26)	0.4922	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9903
Yes	52	16 (30.8)	36 (69.2)	NE (NE, NE)	45	10 (22.2)	35 (77.8)	NE (6.1, NE)	1.43 (0.65, 3.15)	0.3721	
No	11	2 (18.2)	9 (81.8)	NE (4.0, NE)	10	0	10 (100)	NE (NE, NE)	NE (NE, NE)	0.1981	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	17 (89.5)	-	13	2 (15.4)	11 (84.6)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	12 (37.5)	20 (62.5)	-	30	7 (23.3)	23 (76.7)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.4732
<65 years	52	14 (26.9)	38 (73.1)	NE (NE, NE)	41	8 (19.5)	33 (80.5)	NE (5.3, NE)	1.35 (0.57, 3.22)	0.4979	
≥65 years	11	4 (36.4)	7 (63.6)	NE (0.2, NE)	14	2 (14.3)	12 (85.7)	NE (6.1, NE)	2.66 (0.48, 14.63)	0.2439	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9166
Asian	21	7 (33.3)	14 (66.7)	NE (3.4, NE)	21	4 (19.0)	17 (81.0)	NE (NE, NE)	1.67 (0.49, 5.75)	0.4049	
Non-Asian	32	9 (28.1)	23 (71.9)	NE (3.4, NE)	26	5 (19.2)	21 (80.8)	NE (5.3, NE)	1.50 (0.50, 4.49)	0.4668	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.6975
Capecitabine	21	7 (33.3)	14 (66.7)	NE (2.1, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	0.0723	
Eribulin mesylate	31	8 (25.8)	23 (74.2)	NE (3.4, NE)	41	8 (19.5)	33 (80.5)	NE (6.1, NE)	1.38 (0.52, 3.69)	0.5181	
Vinorelbine	11	3 (27.3)	8 (72.7)	NE (0.3, NE)	5	2 (40.0)	3 (60.0)	5.3 (1.6, NE)	0.53 (0.09, 3.25)	0.4853	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9912
Yes	6	0	6 (100)	NE (NE, NE)	6	2 (33.3)	4 (66.7)	NE (1.6, NE)	0.00 (0.00, NE)	0.0662	
No	57	18 (31.6)	39 (68.4)	NE (NE, NE)	49	8 (16.3)	41 (83.7)	NE (NE, NE)	2.03 (0.88, 4.66)	0.0903	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	17 (27.4)	45 (72.6)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	9 (29.0)	22 (71.0)	-	24	4 (16.7)	20 (83.3)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.8632
0	35	10 (28.6)	25 (71.4)	NE (NE, NE)	33	6 (18.2)	27 (81.8)	NE (6.1, NE)	1.70 (0.62, 4.69)	0.2991	
≥1	28	8 (28.6)	20 (71.4)	NE (4.0, NE)	22	4 (18.2)	18 (81.8)	NE (NE, NE)	1.53 (0.46, 5.08)	0.4836	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	14 (28.6)	35 (71.4)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.9321
≤12 months	22	9 (40.9)	13 (59.1)	NE (1.1, NE)	19	6 (31.6)	13 (68.4)	NE (1.6, NE)	1.47 (0.52, 4.13)	0.4686	
>12 months	29	7 (24.1)	22 (75.9)	NE (NE, NE)	27	4 (14.8)	23 (85.2)	NE (6.1, NE)	1.57 (0.46, 5.36)	0.4719	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	18 (30.5)	41 (69.5)	-	55	10 (18.2)	45 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.4777
Region 1 [US, Canada, Europe]	33	16 (48.5)	17 (51.5)	4.5 (1.4, NE)	28	6 (21.4)	22 (78.6)	NE (4.8, NE)	2.70 (1.05, 6.91)	0.0312	
Region 2 [Rest of World]	30	18 (60.0)	12 (40.0)	1.9 (1.0, NE)	27	5 (18.5)	22 (81.5)	NE (NE, NE)	4.38 (1.62, 11.84)	0.0015	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.6724
Yes	52	29 (55.8)	23 (44.2)	2.8 (1.1, NE)	45	10 (22.2)	35 (77.8)	NE (NE, NE)	3.29 (1.60, 6.76)	0.0006	
No	11	5 (45.5)	6 (54.5)	4.0 (0.2, NE)	10	1 (10.0)	9 (90.0)	NE (0.3, NE)	5.12 (0.60, 43.82)	0.0969	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	15 (78.9)	4 (21.1)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	13 (40.6)	19 (59.4)	-	30	6 (20.0)	24 (80.0)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.1924
<65 years	52	25 (48.1)	27 (51.9)	4.0 (1.4, NE)	41	9 (22.0)	32 (78.0)	NE (4.8, NE)	2.71 (1.26, 5.82)	0.0077	
≥65 years	11	9 (81.8)	2 (18.2)	1.0 (0.3, 4.5)	14	2 (14.3)	12 (85.7)	NE (NE, NE)	7.56 (1.62, 35.21)	0.0025	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.8397
Asian	21	12 (57.1)	9 (42.9)	2.1 (0.7, NE)	21	4 (19.0)	17 (81.0)	NE (3.6, NE)	3.53 (1.14, 10.97)	0.0197	
Non-Asian	32	15 (46.9)	17 (53.1)	9.7 (1.0, NE)	26	5 (19.2)	21 (80.8)	NE (4.8, NE)	2.98 (1.08, 8.23)	0.0268	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.7452
Capecitabine	21	12 (57.1)	9 (42.9)	3.4 (1.1, NE)	9	1 (11.1)	8 (88.9)	NE (3.9, NE)	7.32 (0.95, 56.55)	0.0256	
Eribulin mesylate	31	16 (51.6)	15 (48.4)	2.7 (0.7, NE)	41	10 (24.4)	31 (75.6)	NE (4.8, NE)	2.84 (1.28, 6.29)	0.0071	
Vinorelbine	11	6 (54.5)	5 (45.5)	4.0 (0.2, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.0856	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9884
Yes	6	0	6 (100)	NE (NE, NE)	6	3 (50.0)	3 (50.0)	3.9 (0.3, NE)	0.00 (0.00, NE)	0.0436	
No	57	34 (59.6)	23 (40.4)	2.7 (1.0, 4.5)	49	8 (16.3)	41 (83.7)	NE (NE, NE)	5.07 (2.34, 10.99)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	33 (53.2)	29 (46.8)	-	54	11 (20.4)	43 (79.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	15 (48.4)	16 (51.6)	-	24	5 (20.8)	19 (79.2)	-	-	-	
Asian	21	12 (57.1)	9 (42.9)	-	21	4 (19.0)	17 (81.0)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9101
0	35	17 (48.6)	18 (51.4)	9.7 (1.9, NE)	33	6 (18.2)	27 (81.8)	NE (NE, NE)	3.26 (1.28, 8.28)	0.0086	
≥1	28	17 (60.7)	11 (39.3)	1.4 (0.8, NE)	22	5 (22.7)	17 (77.3)	NE (3.6, NE)	3.65 (1.34, 9.92)	0.0065	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	25 (51.0)	24 (49.0)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3293
≤12 months	22	12 (54.5)	10 (45.5)	1.9 (0.8, NE)	19	6 (31.6)	13 (68.4)	NE (2.7, NE)	2.23 (0.83, 5.98)	0.1023	
>12 months	29	16 (55.2)	13 (44.8)	2.8 (0.4, NE)	27	4 (14.8)	23 (85.2)	NE (4.8, NE)	4.83 (1.61, 14.48)	0.0019	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	32 (54.2)	27 (45.8)	-	55	11 (20.0)	44 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.6712
Region 1 [US, Canada, Europe]	33	21 (63.6)	12 (36.4)	3.9 (2.1, 11.0)	28	4 (14.3)	24 (85.7)	NE (NE, NE)	4.12 (1.40, 12.08)	0.0051	
Region 2 [Rest of World]	30	15 (50.0)	15 (50.0)	4.7 (2.0, NE)	27	4 (14.8)	23 (85.2)	NE (13.5, NE)	3.09 (1.02, 9.36)	0.0357	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.8401
Yes	52	30 (57.7)	22 (42.3)	4.2 (2.8, 9.4)	45	7 (15.6)	38 (84.4)	NE (13.5, NE)	3.61 (1.58, 8.22)	0.0011	
No	11	6 (54.5)	5 (45.5)	2.4 (2.0, NE)	10	1 (10.0)	9 (90.0)	NE (1.1, NE)	4.79 (0.56, 41.07)	0.1168	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	12 (63.2)	7 (36.8)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	13 (40.6)	19 (59.4)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	10 (90.9)	1 (9.1)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.6863
<65 years	52	29 (55.8)	23 (44.2)	4.1 (2.4, 9.4)	41	6 (14.6)	35 (85.4)	NE (NE, NE)	3.38 (1.39, 8.18)	0.0042	
≥65 years	11	7 (63.6)	4 (36.4)	4.7 (1.6, NE)	14	2 (14.3)	12 (85.7)	NE (13.5, NE)	5.09 (1.04, 24.84)	0.0260	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5552
Asian	21	10 (47.6)	11 (52.4)	4.2 (2.0, NE)	21	2 (9.5)	19 (90.5)	NE (13.5, NE)	5.06 (1.11, 23.16)	0.0204	
Non-Asian	32	17 (53.1)	15 (46.9)	9.4 (2.1, 14.2)	26	4 (15.4)	22 (84.6)	NE (NE, NE)	2.81 (0.93, 8.48)	0.0569	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.5960
Capecitabine	21	10 (47.6)	11 (52.4)	6.2 (2.0, NE)	9	1 (11.1)	8 (88.9)	NE (1.0, NE)	4.35 (0.55, 34.08)	0.1271	
Eribulin mesylate	31	18 (58.1)	13 (41.9)	3.9 (2.1, 9.4)	41	6 (14.6)	35 (85.4)	13.5 (13.5, NE)	4.38 (1.73, 11.09)	0.0007	
Vinorelbine	11	8 (72.7)	3 (27.3)	4.7 (2.1, NE)	5	1 (20.0)	4 (80.0)	NE (1.8, NE)	0.70 (0.08, 6.36)	0.7481	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9883
Yes	6	2 (33.3)	4 (66.7)	NE (0.2, NE)	6	0	6 (100)	NE (NE, NE)	NE (NE, NE)	0.1573	
No	57	34 (59.6)	23 (40.4)	4.2 (2.3, 9.4)	49	8 (16.3)	41 (83.7)	NE (13.5, NE)	3.52 (1.62, 7.61)	0.0007	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	35 (56.5)	27 (43.5)	-	54	8 (14.8)	46 (85.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	17 (54.8)	14 (45.2)	-	24	4 (16.7)	20 (83.3)	-	-	-	
Asian	21	10 (47.6)	11 (52.4)	-	21	2 (9.5)	19 (90.5)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.3952
0	35	18 (51.4)	17 (48.6)	6.2 (2.9, NE)	33	6 (18.2)	27 (81.8)	NE (13.5, NE)	2.97 (1.17, 7.56)	0.0167	
≥1	28	18 (64.3)	10 (35.7)	2.8 (2.1, 9.4)	22	2 (9.1)	20 (90.9)	NE (4.1, NE)	7.02 (1.61, 30.57)	0.0025	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	0	6 (100)	-	-	-	
≥6 months	49	27 (55.1)	22 (44.9)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7125
≤12 months	22	15 (68.2)	7 (31.8)	2.3 (2.0, 4.2)	19	5 (26.3)	14 (73.7)	13.5 (4.1, NE)	4.43 (1.46, 13.43)	0.0042	
>12 months	29	15 (51.7)	14 (48.3)	6.2 (2.9, 13.2)	27	2 (7.4)	25 (92.6)	NE (NE, NE)	5.61 (1.28, 24.57)	0.0099	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.52.2 Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	35 (59.3)	24 (40.7)	-	55	8 (14.5)	47 (85.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:52; Program name: t_2_11_2.sas; Output name: DE.T_AESI_SUB_mSASA_FA.rtf

Jegliche UESI– Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Final

Figure 4.52.2 Adverse events of special interest - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

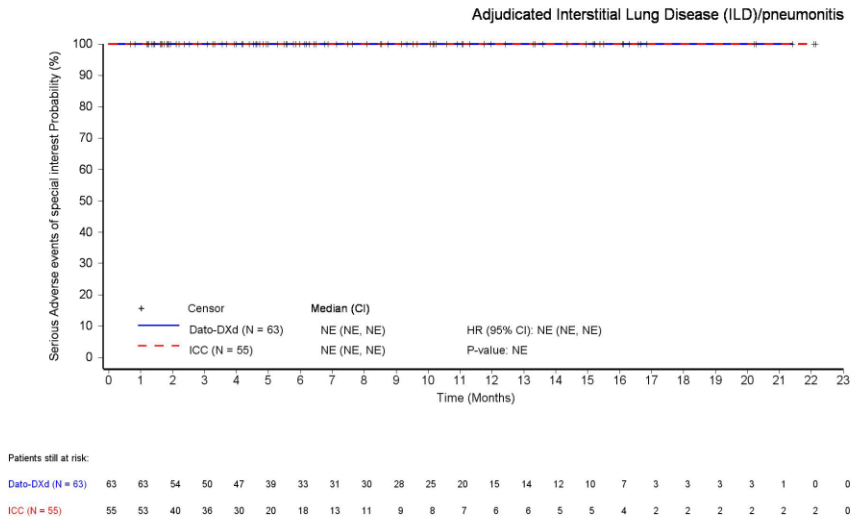
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:52; Program name: f_2_11_2.sas; Output name: DE.F_AESI_SUB_mSASA_FA.rtf

Schwerwiegende UESI

Schwerwiegende UESI – Hauptanalyse – Kaplan-Meier-Kurven

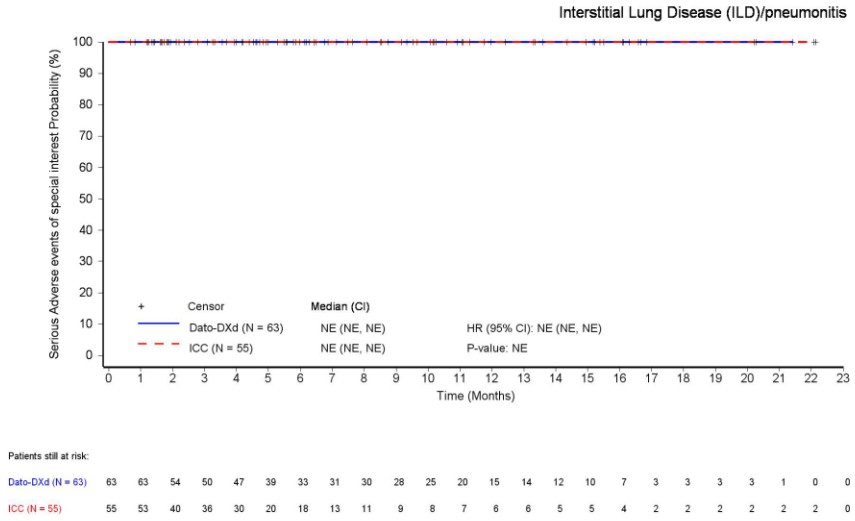
Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

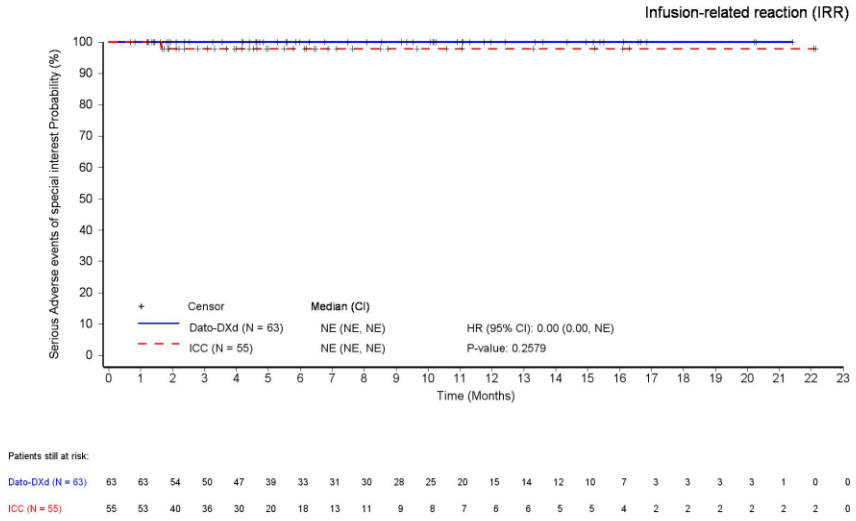
Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
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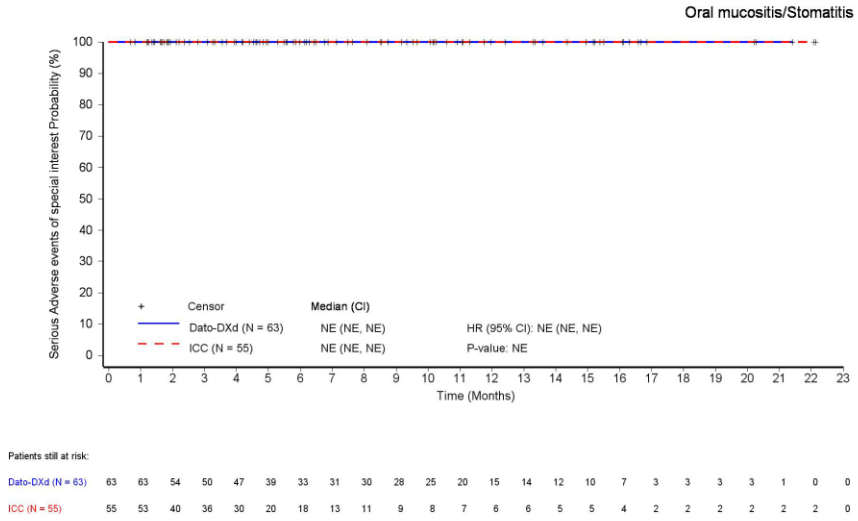
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

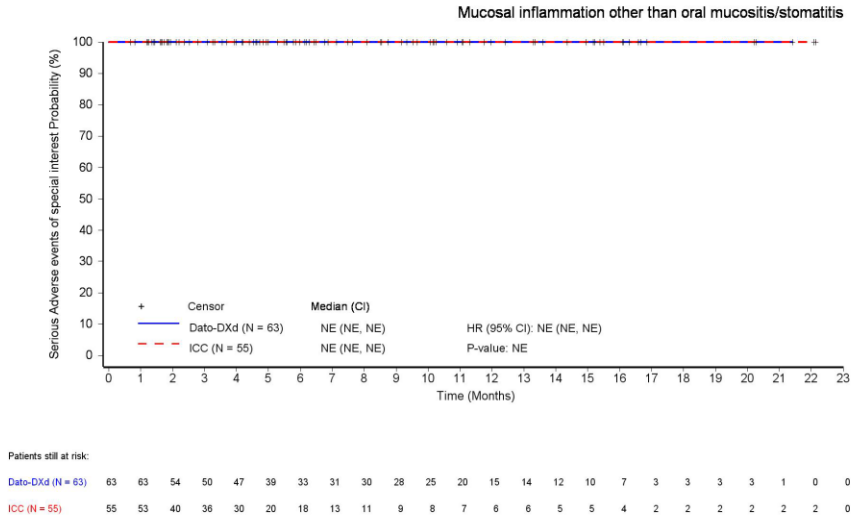
Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

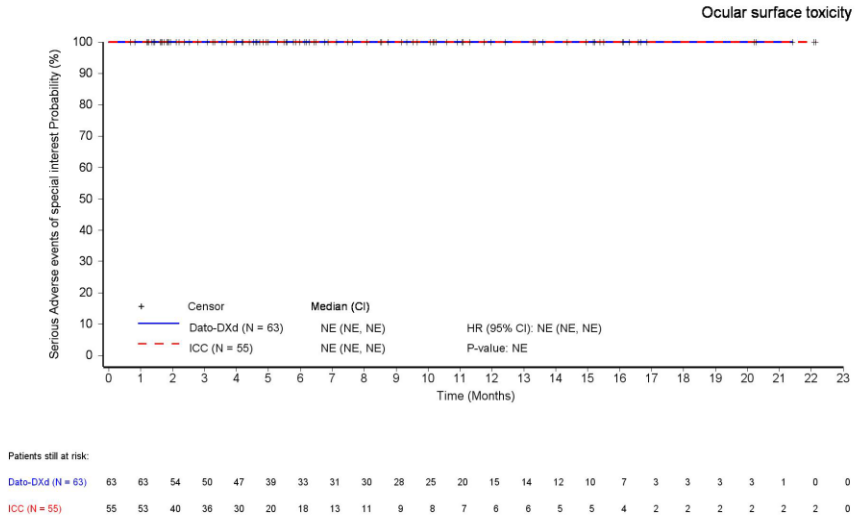
Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

Figure 4.53.1 Serious Adverse events of special interest - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:31; Program name: F_2_3_1.sas; Output name: DE.F_AESISER_mSASA.rtf

Schwerwiegende UESI – Prüfung der Kriterien der Anhebungsregel

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Table 4.53.6 Serious Adverse events of special interest - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISER_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9989
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	3 (1.1)	262 (98.9)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.0936	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9989
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	3 (1.1)	262 (98.9)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.0996	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Infusion-related reaction (IRR)

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9955
mSASA	63	0	63 (100)	NE (NE, NE)	55	1 (1.8)	54 (98.2)	NE (NE, NE)	0.00 (0.00, NE)	0.2495	
non-mSASA	265	2 (0.8)	263 (99.2)	NE (NE, NE)	265	2 (0.8)	263 (99.2)	NE (NE, NE)	0.76 (0.10, 5.45)	0.7799	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Oral mucositis/Stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											>0.9999
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	1 (0.4)	264 (99.6)	NE (NE, NE)	265	1 (0.4)	264 (99.6)	NE (NE, NE)	0.95 (0.06, 15.13)	0.9684	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											NE
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.53.4 Serious Adverse events of special interest- Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

Ocular surface toxicity

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9993
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	1 (0.4)	264 (99.6)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.3432	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISER_SUB_mSASA_Add.rtf

Schwerwiegende UESI – Subgruppenanalysen

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
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Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	1 (3.6)	27 (96.4)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	1 (2.2)	44 (97.8)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	1 (3.3)	29 (96.7)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	1 (2.4)	40 (97.6)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	1 (20.0)	4 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	1 (1.9)	53 (98.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	1 (4.5)	21 (95.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	1 (2.4)	41 (97.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	1 (3.7)	26 (96.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	1 (1.8)	54 (98.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.53.2 Serious Adverse events of special interest - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISER_SUB_mSASA_FA.rtf

Schwerwiegende UESI – Subgruppenanalysen – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 4.53.2 Serious Adverse events of special interest - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: f_2_11_2.sas; Output name: DE.F_AESISER_SUB_mSASA_FA.rtf

Schwere UESI (CTCAE-Grad ≥3)

Schwere UESI (CTCAE-Grad ≥3) – Hauptanalyse – Kaplan-Meier-Kurven

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
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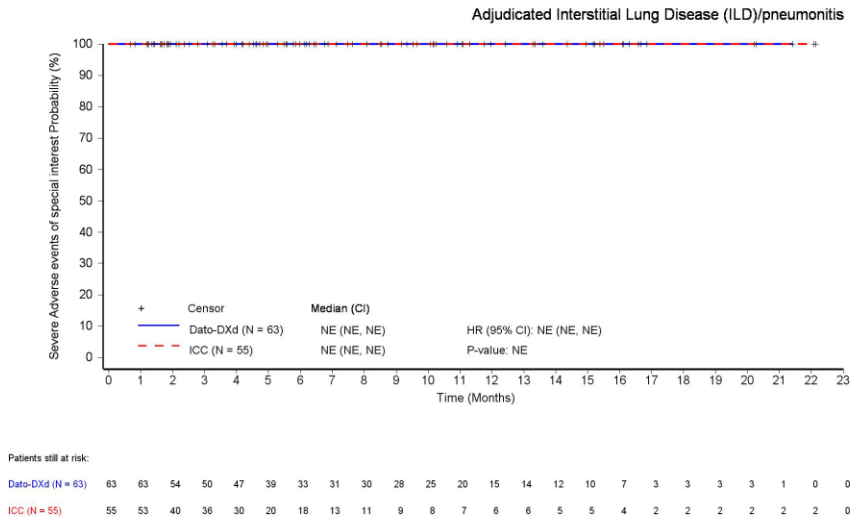
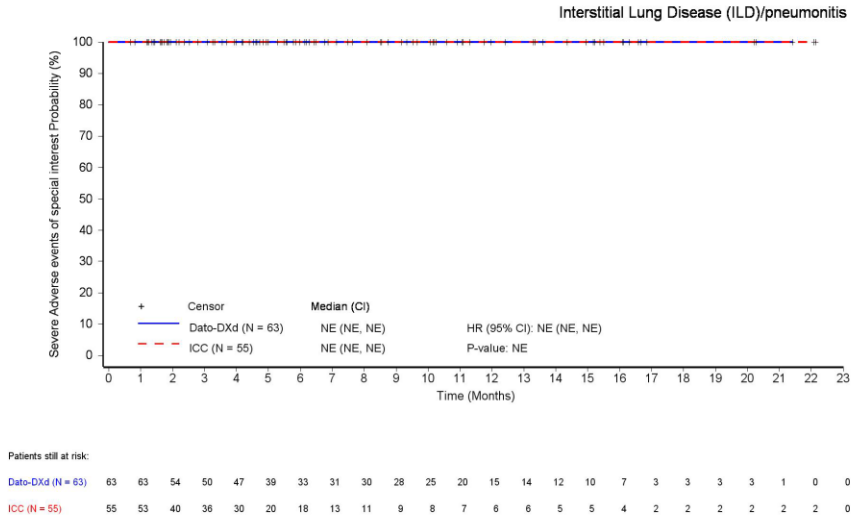
Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

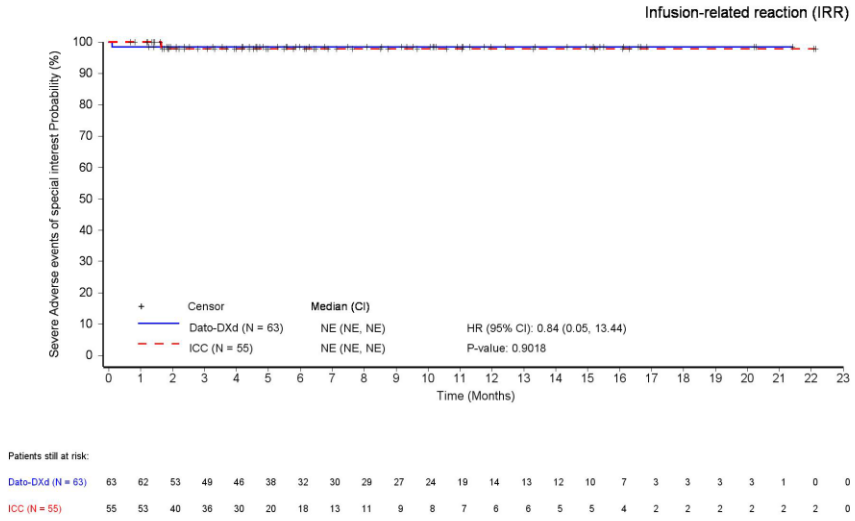
Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

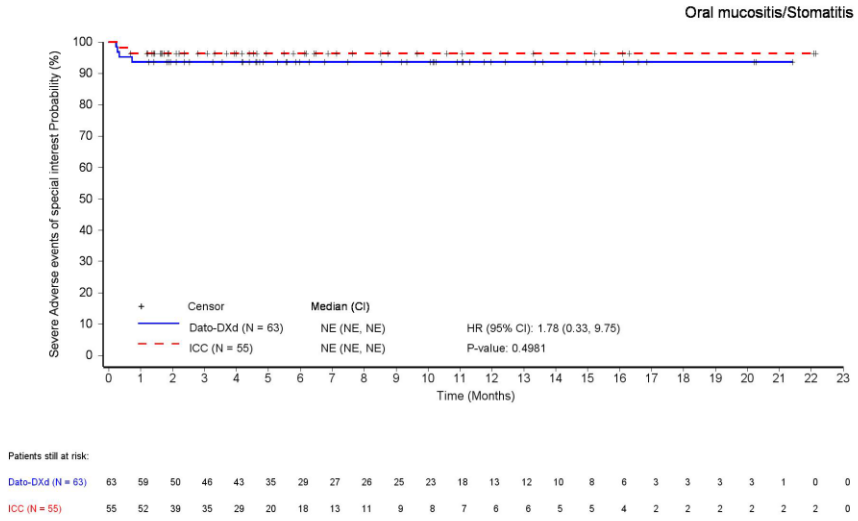
Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

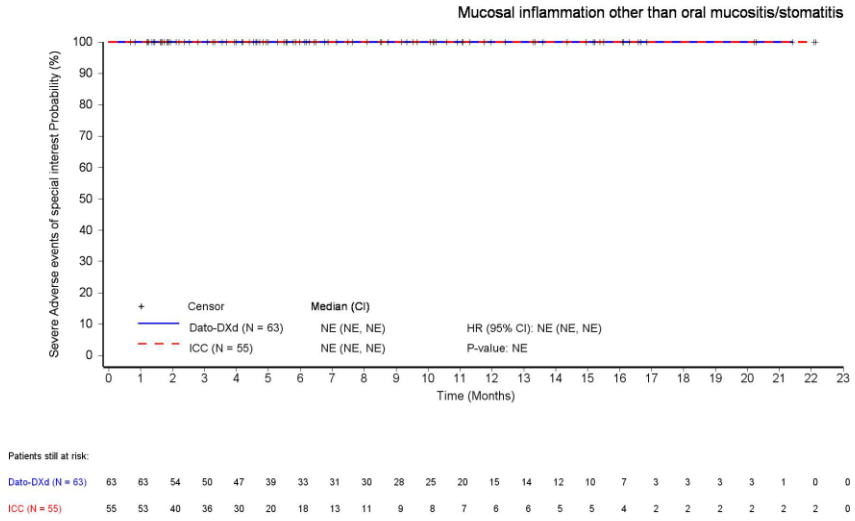
Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

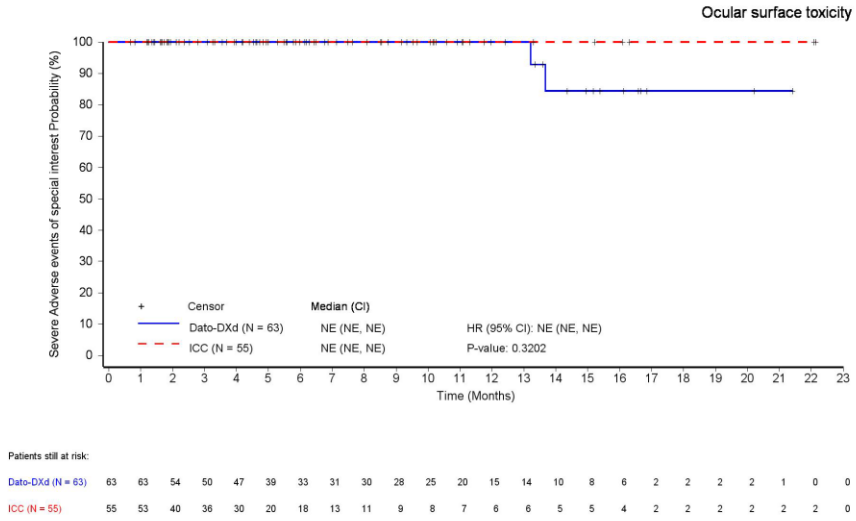
Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

Figure 4.54.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from stratified Cox proportional hazards model, stratified by the randomization stratification factors and two-sided p-value is from a stratified log-rank test using the same randomization stratification factors. ICC: Investigator's Choice of Chemotherapy.
NE: not estimable, CI: confidence interval.

Data source: ADAM.ADTTEAE
Run date: 21FEB2025 - 11:32; Program name: F_2_3_1.sas; Output name: DE.F_AESISEV_mSASA.rtf

Schwere UESI (CTCAE-Grad ≥3) – Prüfung der Kriterien der Anhebungsregel

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	2 (3.6)	
Number of subjects censored, n (%)	59 (93.7)	53 (96.4)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.78
85% Confidence Interval			(0.51, 6.21)
Stratified log-rank p-value [c]			0.4981

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Table 4.54.6 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	2 (3.2)	0	
Number of subjects censored, n (%)	61 (96.8)	55 (100)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			NE
85% Confidence Interval			(NE, NE)
Stratified log-rank p-value [c]			0.3202

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_6.sas; Output name: DE.T_AESISEV_INC_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9991
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	2 (0.8)	263 (99.2)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.1667	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9991
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	2 (0.8)	263 (99.2)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.1783	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Infusion-related reaction (IRR)

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9206
mSASA	63	1 (1.6)	62 (98.4)	NE (NE, NE)	55	1 (1.8)	54 (98.2)	NE (NE, NE)	0.82 (0.05, 13.10)	0.8870	
non-mSASA	265	1 (0.4)	264 (99.6)	NE (NE, NE)	265	1 (0.4)	264 (99.6)	NE (NE, NE)	0.65 (0.04, 10.40)	0.7572	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Oral mucositis/Stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4464
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	2 (3.6)	53 (96.4)	NE (NE, NE)	1.77 (0.32, 9.67)	0.5035	
non-mSASA	265	22 (8.3)	243 (91.7)	NE (NE, NE)	265	6 (2.3)	259 (97.7)	NE (NE, NE)	3.36 (1.36, 8.30)	0.0053	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											NE
mSASA	63	0	63 (100)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	NE	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Table 4.54.4 Severe Adverse events of special interest (NCI CTCAE grade ≥ 3) - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA
Ocular surface toxicity

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											>0.9999
mSASA	63	2 (3.2)	61 (96.8)	NE (NE, NE)	55	0	55 (100)	NE (NE, NE)	NE (NE, NE)	0.3474	
non-mSASA	265	5 (1.9)	260 (98.1)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.0687	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADTTEAE
Run date: 28FEB2025 - 7:31; Program name: t_4_52_4.sas; Output name: DE.T_AESISEV_SUB_mSASA_Add.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Adjudicated Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Interstitial Lung Disease (ILD)/pneumonitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	1 (3.0)	32 (97.0)	-	28	1 (3.6)	27 (96.4)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	1 (1.9)	51 (98.1)	-	45	1 (2.2)	44 (97.8)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	1 (3.3)	29 (96.7)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	1 (1.9)	51 (98.1)	-	41	1 (2.4)	40 (97.6)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Non-Asian	32	1 (3.1)	31 (96.9)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	1 (3.2)	30 (96.8)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	1 (20.0)	4 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
No	57	1 (1.8)	56 (98.2)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	1 (1.6)	61 (98.4)	-	54	1 (1.9)	53 (98.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	1 (3.2)	30 (96.8)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	1 (2.9)	34 (97.1)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	1 (4.5)	21 (95.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	1 (2.0)	48 (98.0)	-	42	1 (2.4)	41 (97.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	1 (3.4)	28 (96.6)	-	27	1 (3.7)	26 (96.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Infusion-related reaction (IRR)

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	1 (1.7)	58 (98.3)	-	55	1 (1.8)	54 (98.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	3 (9.1)	30 (90.9)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	-	27	2 (7.4)	25 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	4 (7.7)	48 (92.3)	-	45	1 (2.2)	44 (97.8)	-	-	-	
No	11	0	11 (100)	-	10	1 (10.0)	9 (90.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	2 (10.5)	17 (89.5)	-	13	2 (15.4)	11 (84.6)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	1 (3.1)	31 (96.9)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	2 (3.8)	50 (96.2)	-	41	1 (2.4)	40 (97.6)	-	-	-	
≥65 years	11	2 (18.2)	9 (81.8)	-	14	1 (7.1)	13 (92.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	1 (4.8)	20 (95.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Non-Asian	32	3 (9.4)	29 (90.6)	-	26	1 (3.8)	25 (96.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	2 (6.5)	29 (93.5)	-	41	2 (4.9)	39 (95.1)	-	-	-	
Vinorelbine	11	2 (18.2)	9 (81.8)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
No	57	4 (7.0)	53 (93.0)	-	49	1 (2.0)	48 (98.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	4 (6.5)	58 (93.5)	-	54	2 (3.7)	52 (96.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	3 (9.7)	28 (90.3)	-	24	1 (4.2)	23 (95.8)	-	-	-	
Asian	21	1 (4.8)	20 (95.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	2 (5.7)	33 (94.3)	-	33	0	33 (100)	-	-	-	
≥1	28	2 (7.1)	26 (92.9)	-	22	2 (9.1)	20 (90.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	3 (6.1)	46 (93.9)	-	42	1 (2.4)	41 (97.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	1 (4.5)	21 (95.5)	-	19	1 (5.3)	18 (94.7)	-	-	-	
>12 months	29	3 (10.3)	26 (89.7)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Oral mucositis/Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	4 (6.8)	55 (93.2)	-	55	2 (3.6)	53 (96.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	0	41 (100)	-	-	-	
≥65 years	11	0	11 (100)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	0	57 (100)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	0	33 (100)	-	-	-	
≥1	28	0	28 (100)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	0	49 (100)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	0	29 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Mucosal inflammation other than oral mucositis/stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	2 (6.1)	31 (93.9)	-	28	0	28 (100)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	2 (3.8)	50 (96.2)	-	45	0	45 (100)	-	-	-	
No	11	0	11 (100)	-	10	0	10 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	1 (5.3)	18 (94.7)	-	13	0	13 (100)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	1 (3.1)	31 (96.9)	-	30	0	30 (100)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	1 (1.9)	51 (98.1)	-	41	0	41 (100)	-	-	-	
≥65 years	11	1 (9.1)	10 (90.9)	-	14	0	14 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	1 (3.1)	31 (96.9)	-	26	0	26 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
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[c] Two-sided p-value from unstratified log-rank test.
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Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	1 (4.8)	20 (95.2)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	0	41 (100)	-	-	-	
Vinorelbine	11	1 (9.1)	10 (90.9)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	0	6 (100)	-	-	-	
No	57	2 (3.5)	55 (96.5)	-	49	0	49 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	2 (3.2)	60 (96.8)	-	54	0	54 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	1 (3.2)	30 (96.8)	-	24	0	24 (100)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black/African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	1 (2.9)	34 (97.1)	-	33	0	33 (100)	-	-	-	
≥1	28	1 (3.6)	27 (96.4)	-	22	0	22 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	0	6 (100)	-	-	-	
≥6 months	49	2 (4.1)	47 (95.9)	-	42	0	42 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	0	19 (100)	-	-	-	
>12 months	29	2 (6.9)	27 (93.1)	-	27	0	27 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

Table 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Ocular surface toxicity

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	2 (3.4)	57 (96.6)	-	55	0	55 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: t_2_11_2.sas; Output name: DE.T_AESISEV_SUB_mSASA_FA.rtf

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Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Figure 4.54.2 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADTTEAE
Run date: 06MAY2025 - 10:53; Program name: f_2_11_2.sas; Output name: DE.F_AESISEV_SUB_mSASA_FA.rtf

Unerwünschte Ereignisse nach SOC und PT

Jegliche UE nach SOC und PT

Jegliche UE nach SOC und PT – Hauptanalyse

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	47 (74.6)	32 (58.2)	
Number of subjects censored, n (%)	16 (25.4)	23 (41.8)	
Median time to first event (months) [a]	0.3	3.0	
95% Confidence Interval	(0.1 , 1.2)	(0.8 , 4.3)	
Cox proportional hazards model [b]			
Hazard Ratio			1.69
95% Confidence Interval			(1.07, 2.66)
Stratified log-rank p-value [c]			0.0246

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	32 (50.8)	11 (20.0)	
Number of subjects censored, n (%)	31 (49.2)	44 (80.0)	
Median time to first event (months) [a]	4.9	NE	
95% Confidence Interval	(0.8 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.82
95% Confidence Interval			(1.41, 5.64)
Stratified log-rank p-value [c]			0.0021

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	30 (47.6)	9 (16.4)	
Number of subjects censored, n (%)	33 (52.4)	46 (83.6)	
Median time to first event (months) [a]	4.5	NE	
95% Confidence Interval	(2.1 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			3.50
95% Confidence Interval			(1.66, 7.39)
Stratified log-rank p-value [c]			0.0005

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	25 (39.7)	10 (18.2)	
Number of subjects censored, n (%)	38 (60.3)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(3.7 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.25
95% Confidence Interval			(1.08, 4.70)
Stratified log-rank p-value [c]			0.0268

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Vomiting

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	14 (22.2)	5 (9.1)	
Number of subjects censored, n (%)	49 (77.8)	50 (90.9)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.53
95% Confidence Interval			(0.91, 7.03)
Stratified log-rank p-value [c]			0.0649

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Diarrhoea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	5 (7.9)	8 (14.5)	
Number of subjects censored, n (%)	58 (92.1)	47 (85.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(15.5 , NE)	(11.8 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.50
95% Confidence Interval			(0.16, 1.55)
Stratified log-rank p-value [c]			0.2231

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Abdominal pain

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	6 (10.9)	
Number of subjects censored, n (%)	59 (93.7)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.48
95% Confidence Interval			(0.13, 1.69)
Stratified log-rank p-value [c]			0.2406

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	38 (60.3)	26 (47.3)	
Number of subjects censored, n (%)	25 (39.7)	29 (52.7)	
Median time to first event (months) [a]	3.4	6.2	
95% Confidence Interval	(1.4 , 6.5)	(1.3 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.13
95% Confidence Interval			(0.68, 1.87)
Stratified log-rank p-value [c]			0.6359

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Fatigue

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	16 (25.4)	11 (20.0)	
Number of subjects censored, n (%)	47 (74.6)	44 (80.0)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(12.0 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.94
95% Confidence Interval			(0.43, 2.07)
Stratified log-rank p-value [c]			0.8787

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Asthenia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	11 (17.5)	10 (18.2)	
Number of subjects censored, n (%)	52 (82.5)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.99
95% Confidence Interval			(0.42, 2.32)
Stratified log-rank p-value [c]			0.9677

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Pyrexia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	7 (11.1)	6 (10.9)	
Number of subjects censored, n (%)	56 (88.9)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.91
95% Confidence Interval			(0.30, 2.70)
Stratified log-rank p-value [c]			0.8599

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	38 (60.3)	23 (41.8)	
Number of subjects censored, n (%)	25 (39.7)	32 (58.2)	
Median time to first event (months) [a]	4.2	5.1	
95% Confidence Interval	(3.2 , 6.3)	(4.5 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.17
95% Confidence Interval			(0.69, 1.99)
Stratified log-rank p-value [c]			0.5512

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations, PT: COVID-19

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	15 (23.8)	8 (14.5)	
Number of subjects censored, n (%)	48 (76.2)	47 (85.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(12.2 , NE)	(5.6 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.10
95% Confidence Interval			(0.45, 2.65)
Stratified log-rank p-value [c]			0.8367

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations, PT: Upper respiratory tract infection

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	3 (4.8)	6 (10.9)	
Number of subjects censored, n (%)	60 (95.2)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.34
95% Confidence Interval			(0.08, 1.35)
Stratified log-rank p-value [c]			0.1065

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	36 (57.1)	24 (43.6)	
Number of subjects censored, n (%)	27 (42.9)	31 (56.4)	
Median time to first event (months) [a]	4.2	4.1	
95% Confidence Interval	(0.8 , 13.4)	(1.4 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.30
95% Confidence Interval			(0.77, 2.20)
Stratified log-rank p-value [c]			0.3443

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	27 (42.9)	17 (30.9)	
Number of subjects censored, n (%)	36 (57.1)	38 (69.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(2.1 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.34
95% Confidence Interval			(0.73, 2.45)
Stratified log-rank p-value [c]			0.3649

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders, PT: Palmar-plantar erythrodysaesthesia syndrome

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	2 (3.2)	6 (10.9)	
Number of subjects censored, n (%)	61 (96.8)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.28
95% Confidence Interval			(0.06, 1.38)
Stratified log-rank p-value [c]			0.0946

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	36 (57.1)	10 (18.2)	
Number of subjects censored, n (%)	27 (42.9)	45 (81.8)	
Median time to first event (months) [a]	4.2	NE	
95% Confidence Interval	(2.8 , 9.4)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.87
95% Confidence Interval			(1.42, 5.82)
Stratified log-rank p-value [c]			0.0022

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	20 (31.7)	4 (7.3)	
Number of subjects censored, n (%)	43 (68.3)	51 (92.7)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(8.0 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			3.46
95% Confidence Interval			(1.17, 10.24)
Stratified log-rank p-value [c]			0.0164

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Punctate keratitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	9 (14.3)	3 (5.5)	
Number of subjects censored, n (%)	54 (85.7)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(14.2 , NE)	(9.5 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.66
95% Confidence Interval			(0.44, 6.20)
Stratified log-rank p-value [c]			0.4481

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Blepharitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	9 (14.3)	2 (3.6)	
Number of subjects censored, n (%)	54 (85.7)	53 (96.4)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(11.4 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.37
95% Confidence Interval			(0.50, 11.15)
Stratified log-rank p-value [c]			0.2618

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	26 (41.3)	25 (45.5)	
Number of subjects censored, n (%)	37 (58.7)	30 (54.5)	
Median time to first event (months) [a]	13.1	4.8	
95% Confidence Interval	(4.9 , NE)	(2.6 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.59
95% Confidence Interval			(0.34, 1.05)
Stratified log-rank p-value [c]			0.0692

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Aspartate aminotransferase increased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	13 (20.6)	12 (21.8)	
Number of subjects censored, n (%)	50 (79.4)	43 (78.2)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(13.1 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.69
95% Confidence Interval			(0.31, 1.54)
Stratified log-rank p-value [c]			0.3583

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Alanine aminotransferase increased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	9 (14.3)	10 (18.2)	
Number of subjects censored, n (%)	54 (85.7)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.67
95% Confidence Interval			(0.27, 1.66)
Stratified log-rank p-value [c]			0.3866

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Weight decreased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	7 (11.1)	5 (9.1)	
Number of subjects censored, n (%)	56 (88.9)	50 (90.9)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.70
95% Confidence Interval			(0.20, 2.44)
Stratified log-rank p-value [c]			0.5860

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	11 (20.0)	
Number of subjects censored, n (%)	59 (93.7)	44 (80.0)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(7.4 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.23
95% Confidence Interval			(0.07, 0.72)
Stratified log-rank p-value [c]			0.0065

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Respiratory, thoracic and mediastinal disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	21 (33.3)	10 (18.2)	
Number of subjects censored, n (%)	42 (66.7)	45 (81.8)	
Median time to first event (months) [a]	12.0	NE	
95% Confidence Interval	(7.3 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.66
95% Confidence Interval			(0.78, 3.53)
Stratified log-rank p-value [c]			0.1860

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	8 (12.7)	4 (7.3)	
Number of subjects censored, n (%)	55 (87.3)	51 (92.7)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.58
95% Confidence Interval			(0.48, 5.26)
Stratified log-rank p-value [c]			0.4504

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	15 (23.8)	24 (43.6)	
Number of subjects censored, n (%)	48 (76.2)	31 (56.4)	
Median time to first event (months) [a]	17.4	6.6	
95% Confidence Interval	(17.4 , NE)	(2.0 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.41
95% Confidence Interval			(0.22, 0.80)
Stratified log-rank p-value [c]			0.0065

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Anaemia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	12 (19.0)	14 (25.5)	
Number of subjects censored, n (%)	51 (81.0)	41 (74.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(17.4 , NE)	(6.6 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.63
95% Confidence Interval			(0.29, 1.37)
Stratified log-rank p-value [c]			0.2344

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	16 (29.1)	
Number of subjects censored, n (%)	59 (93.7)	39 (70.9)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.16
95% Confidence Interval			(0.05, 0.49)
Stratified log-rank p-value [c]			0.0003

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	15 (23.8)	21 (38.2)	
Number of subjects censored, n (%)	48 (76.2)	34 (61.8)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(12.4 , NE)	(3.0 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.40
95% Confidence Interval			(0.20, 0.80)
Stratified log-rank p-value [c]			0.0078

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	6 (9.5)	13 (23.6)	
Number of subjects censored, n (%)	57 (90.5)	42 (76.4)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.27
95% Confidence Interval			(0.10, 0.77)
Stratified log-rank p-value [c]			0.0088

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Musculoskeletal and connective tissue disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	14 (22.2)	16 (29.1)	
Number of subjects censored, n (%)	49 (77.8)	39 (70.9)	
Median time to first event (months) [a]	NE	10.1	
95% Confidence Interval	(NE, NE)	(5.5 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.56
95% Confidence Interval			(0.27, 1.16)
Stratified log-rank p-value [c]			0.1125

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	6 (10.9)	
Number of subjects censored, n (%)	59 (93.7)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.46
95% Confidence Interval			(0.13, 1.66)
Stratified log-rank p-value [c]			0.2230

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	11 (17.5)	17 (30.9)	
Number of subjects censored, n (%)	52 (82.5)	38 (69.1)	
Median time to first event (months) [a]	NE	12.1	
95% Confidence Interval	(NE, NE)	(12.1 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.47
95% Confidence Interval			(0.22, 1.01)
Stratified log-rank p-value [c]			0.0479

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders, PT: Headache

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	7 (12.7)	
Number of subjects censored, n (%)	59 (93.7)	48 (87.3)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.33
95% Confidence Interval			(0.09, 1.17)
Stratified log-rank p-value [c]			0.0728

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Injury, poisoning and procedural complications

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	7 (11.1)	3 (5.5)	
Number of subjects censored, n (%)	56 (88.9)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(15.5 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.72
95% Confidence Interval			(0.44, 6.77)
Stratified log-rank p-value [c]			0.4294

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Vascular disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	6 (9.5)	6 (10.9)	
Number of subjects censored, n (%)	57 (90.5)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(12.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.64
95% Confidence Interval			(0.20, 2.04)
Stratified log-rank p-value [c]			0.4512

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

Table 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

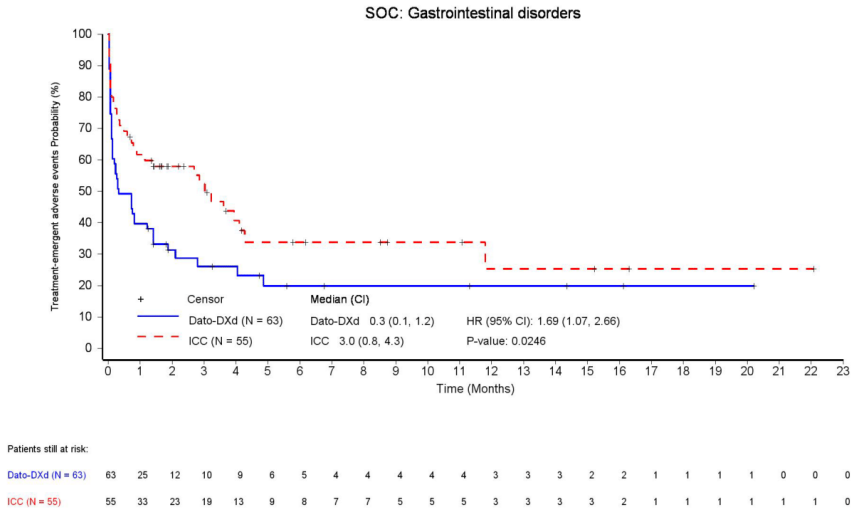
SOC: Hepatobiliary disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	1 (1.6)	6 (10.9)	
Number of subjects censored, n (%)	62 (98.4)	49 (89.1)	
Median time to first event (months) [a]	NE	17.2	
95% Confidence Interval	(NE, NE)	(17.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.16
95% Confidence Interval			(0.02, 1.40)
Stratified log-rank p-value [c]			0.0594

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:04; Program name: t_4_67_1.sas; Output name: DE.T_TEAESOCPT2_mSASA_FA.rtf

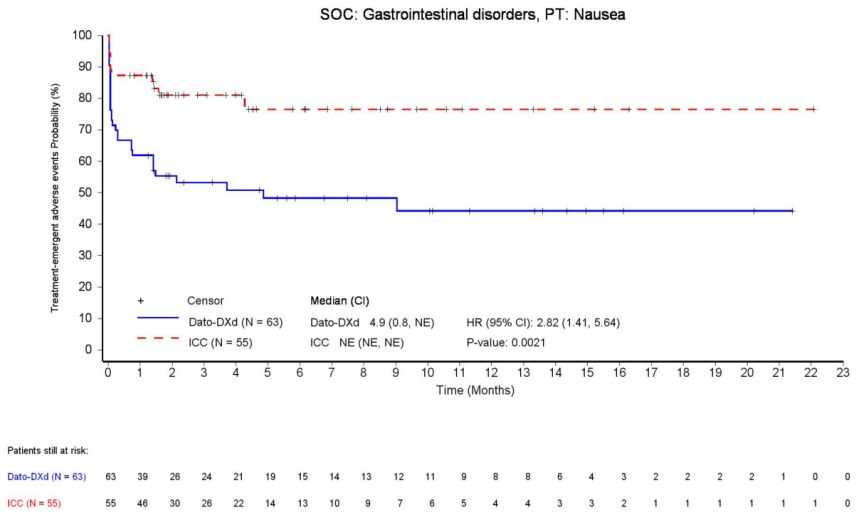
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

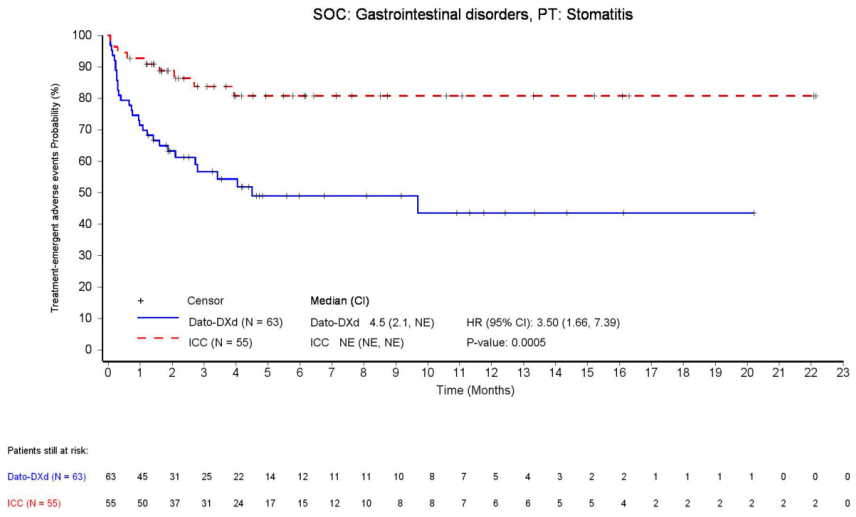
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



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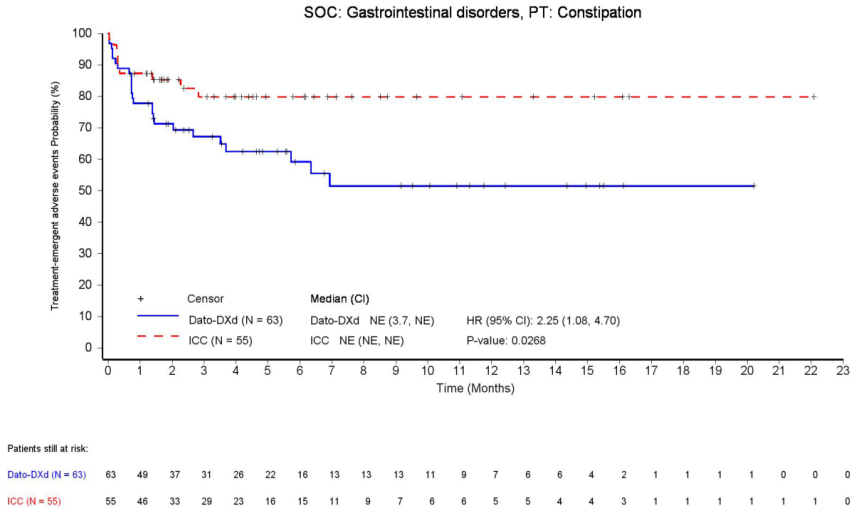
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

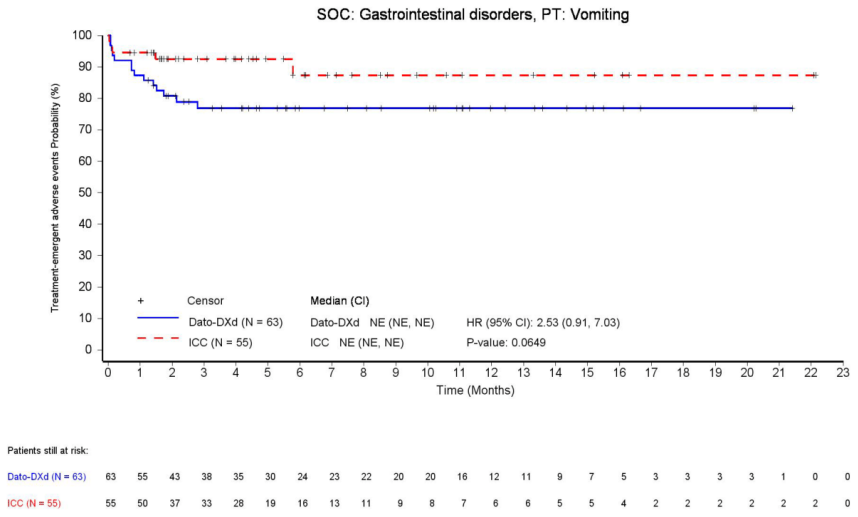
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

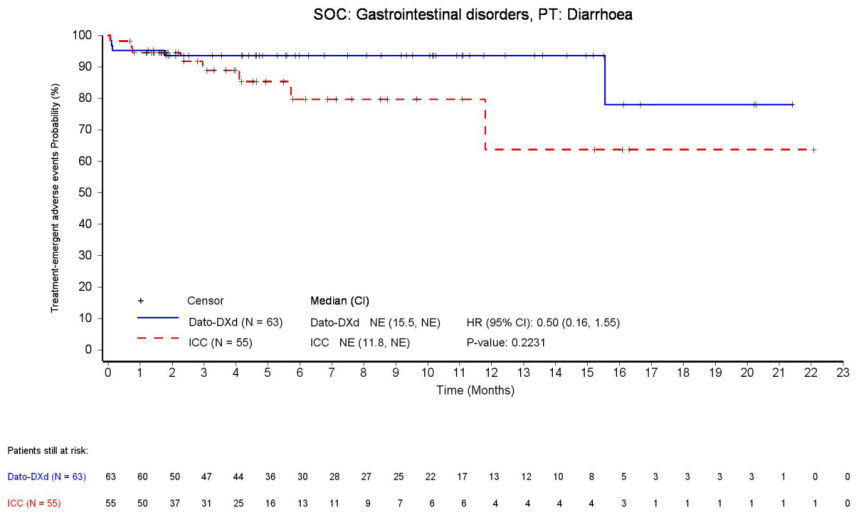
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

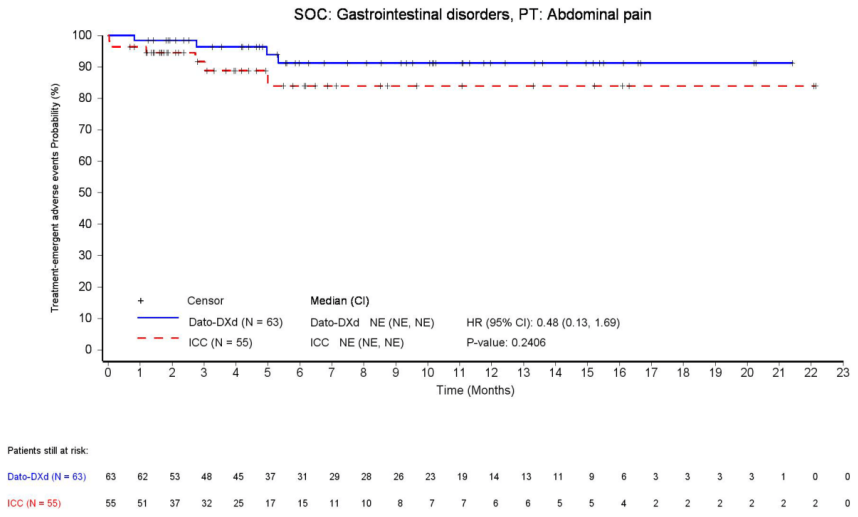
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

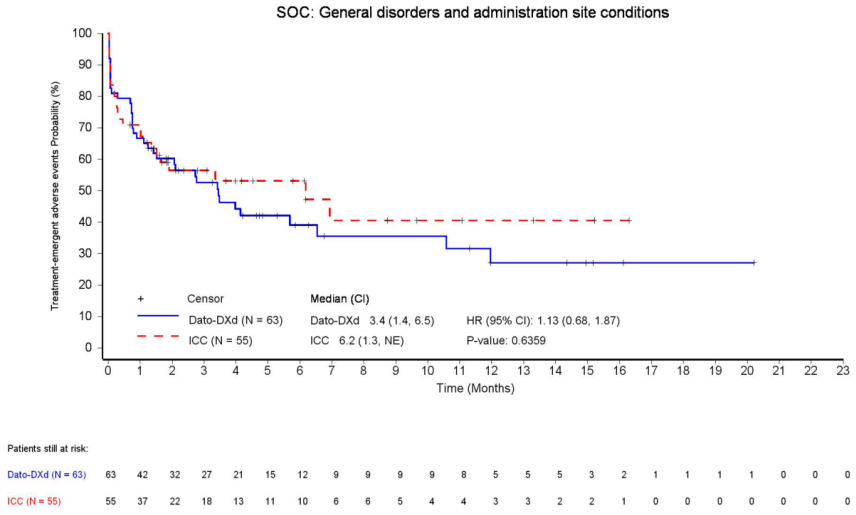
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



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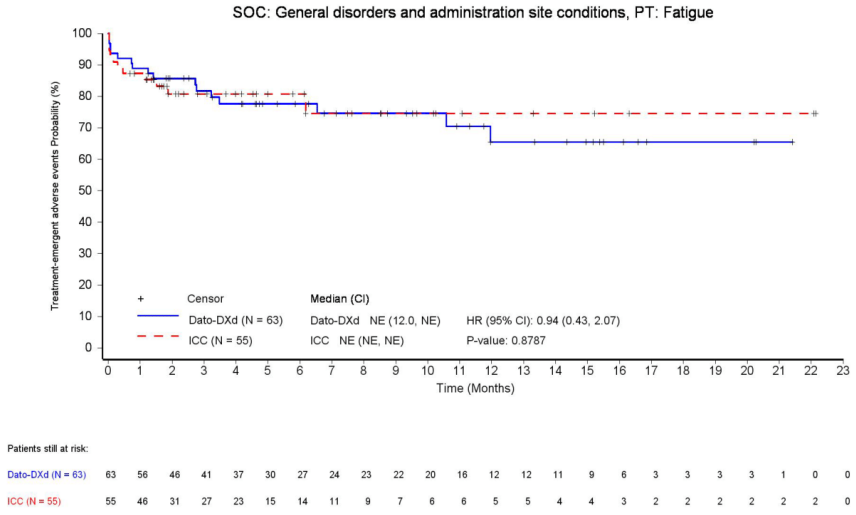

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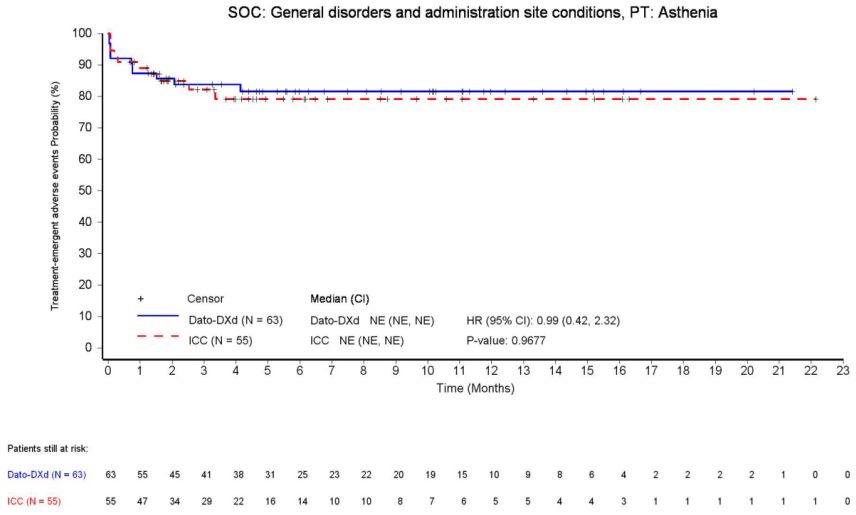

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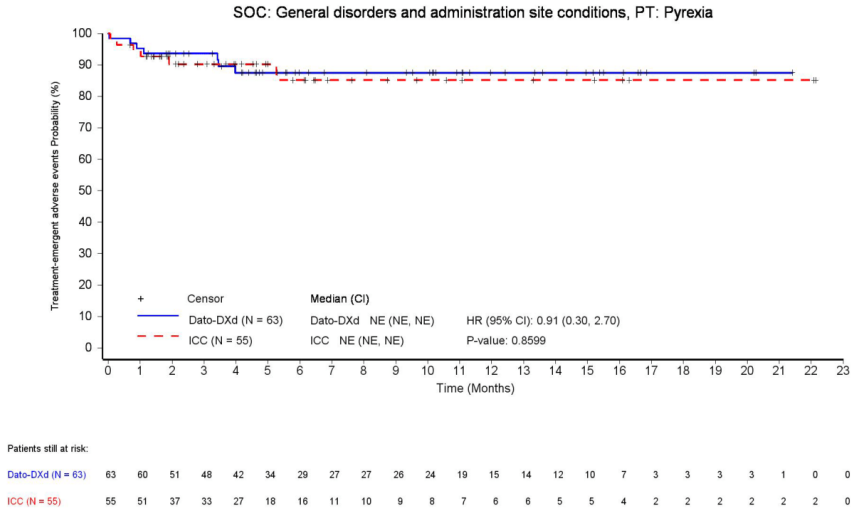

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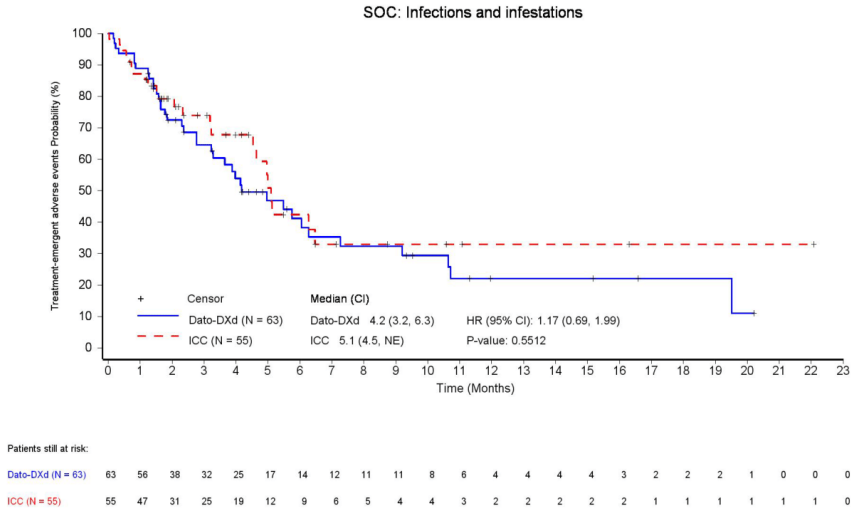

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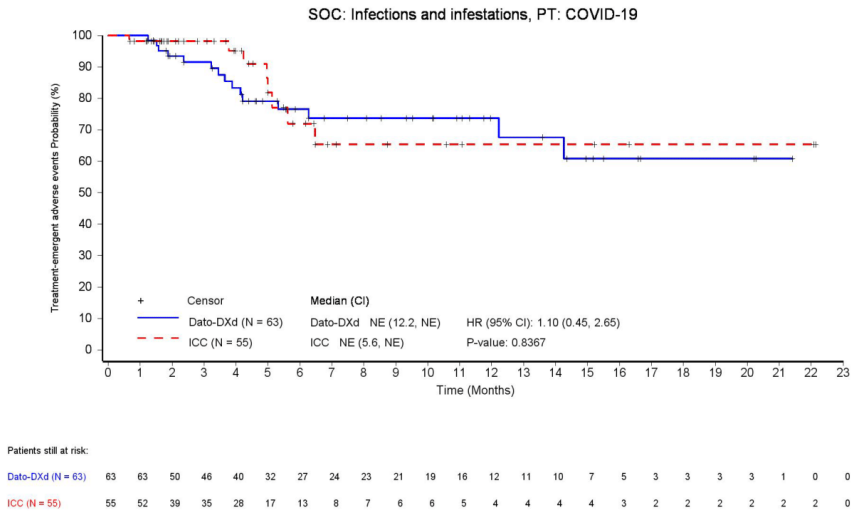

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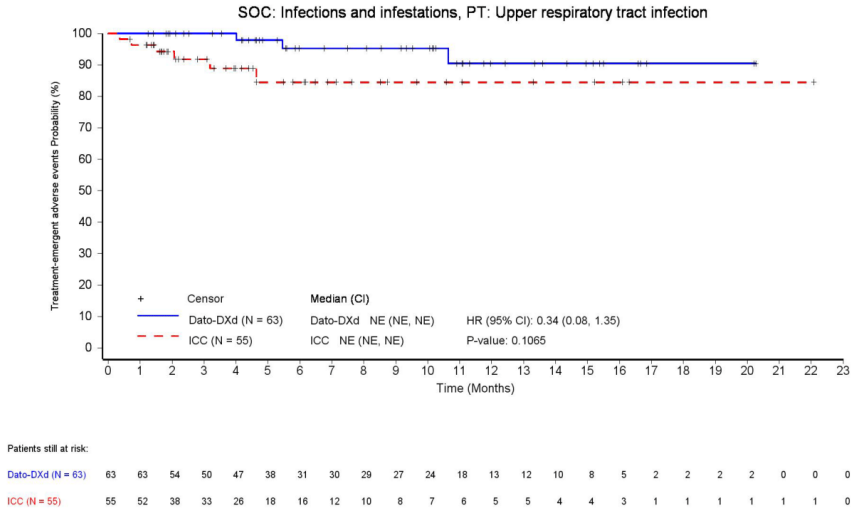

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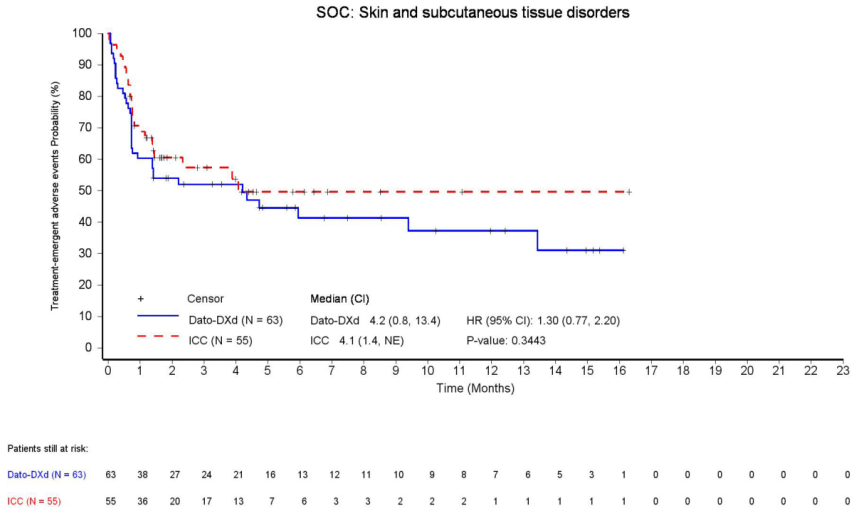

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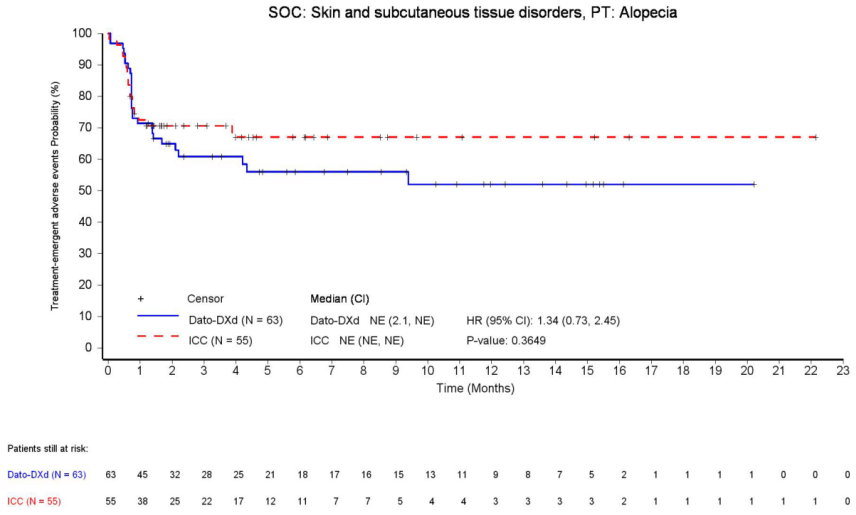

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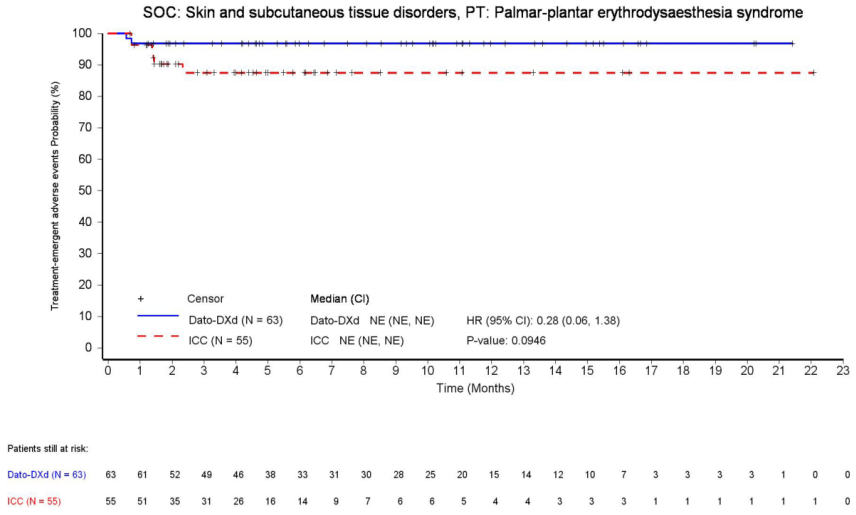

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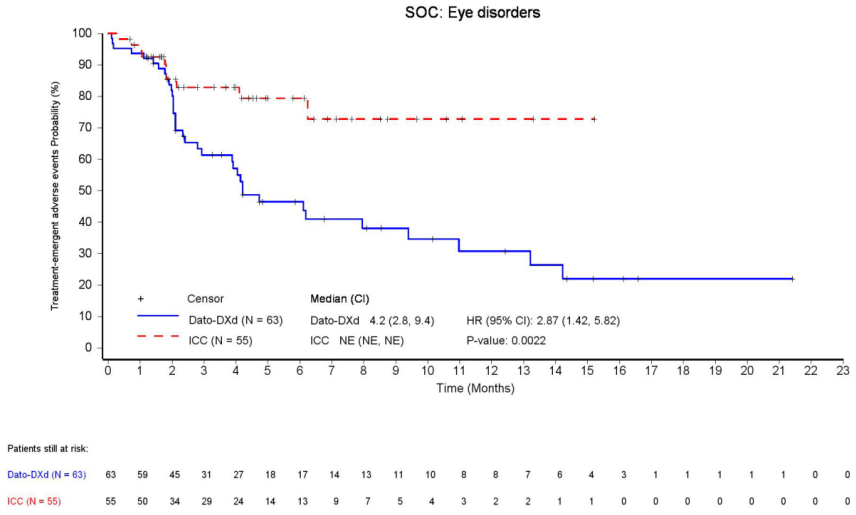

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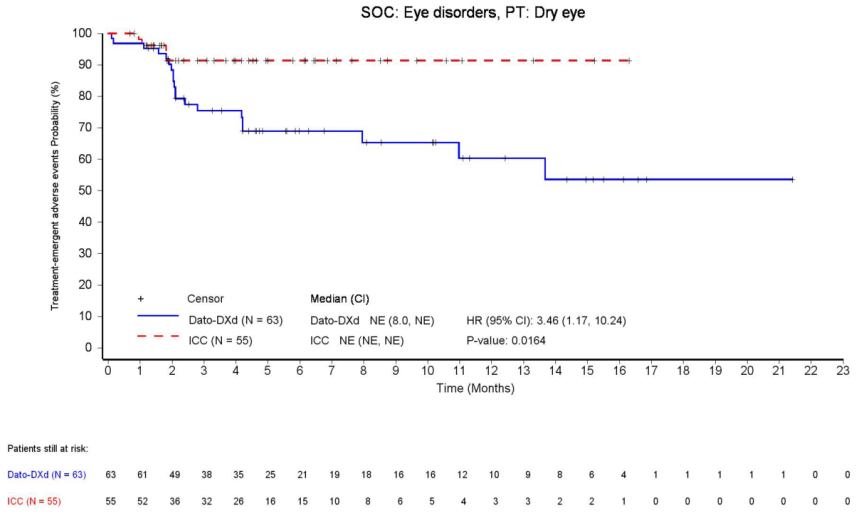

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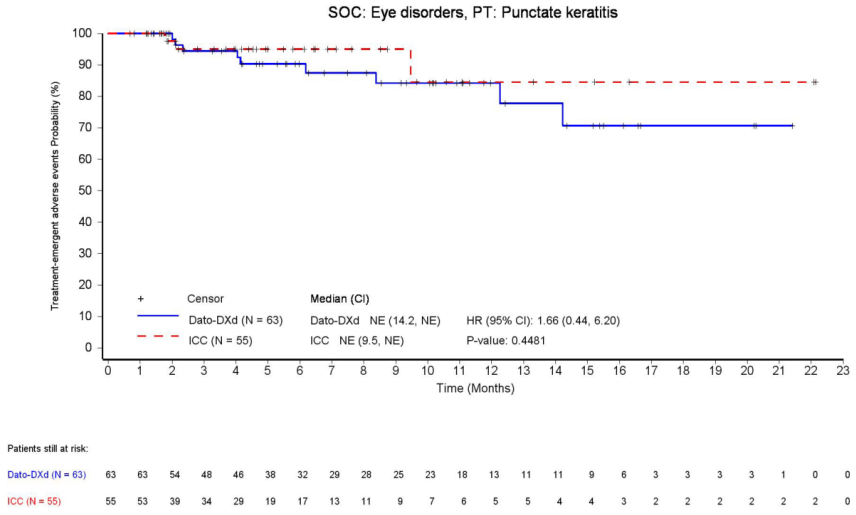

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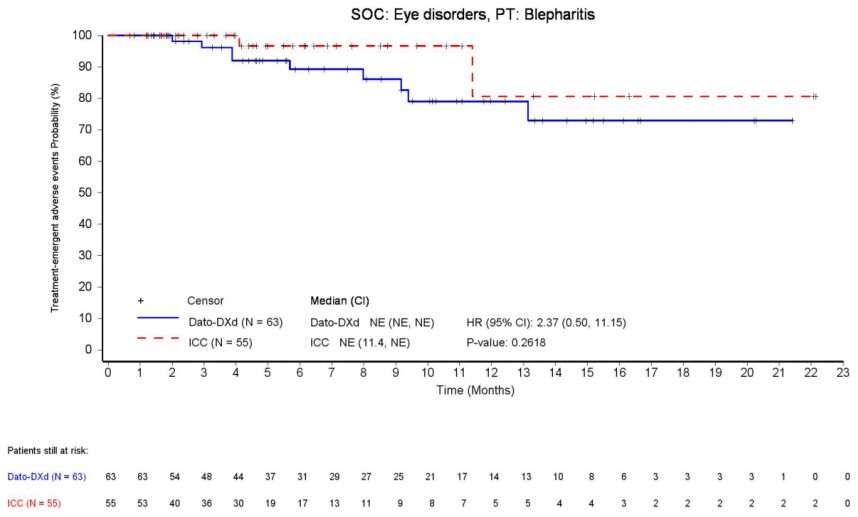

Patients still at risk:

Dato-DXd (N = 63)	63	63	54	48	44	37	31	29	27	25	21	17	14	13	10	8	6	3	3	3	3	1	0	0
ICC (N = 55)	55	53	40	36	30	19	17	13	11	9	8	7	5	5	4	4	3	2	2	2	2	2	2	0

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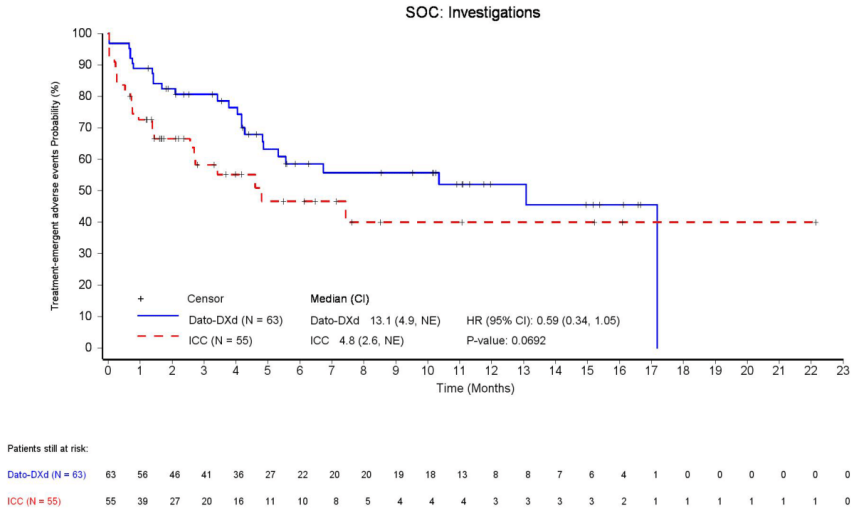

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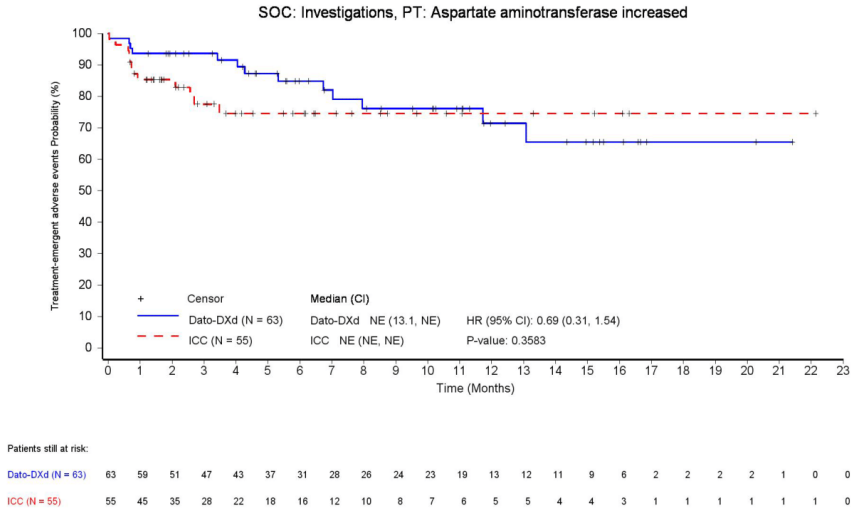

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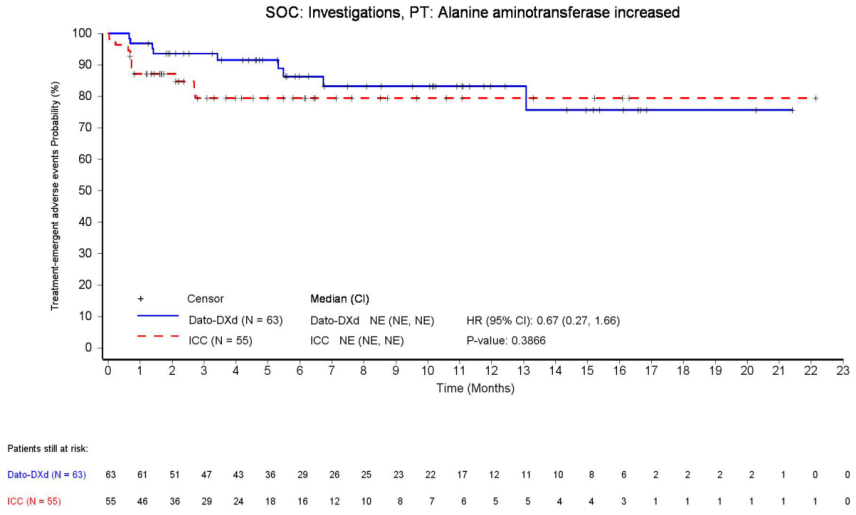

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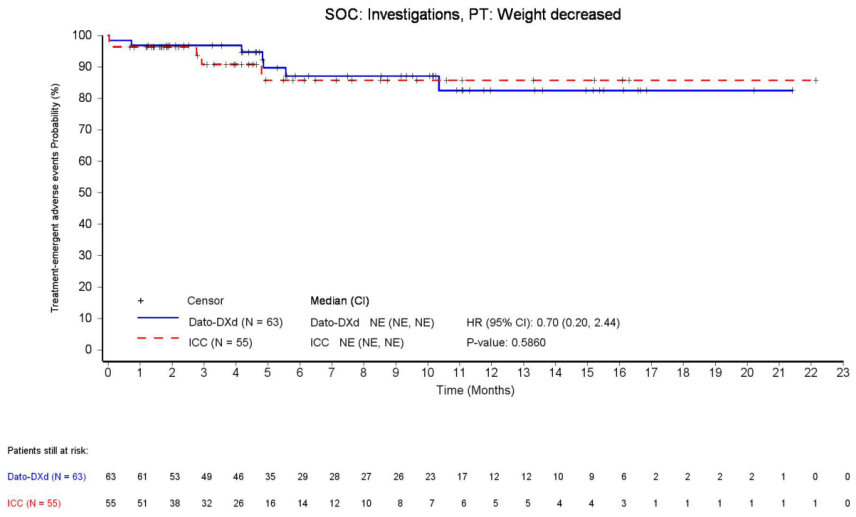

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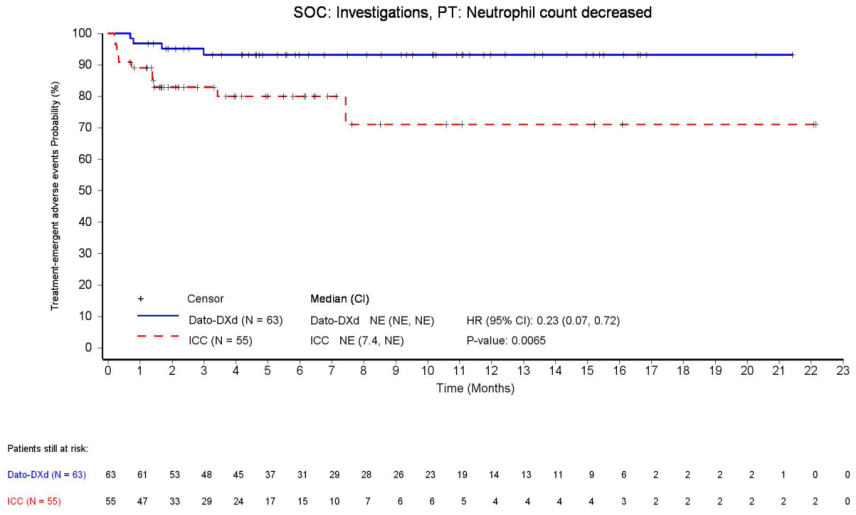

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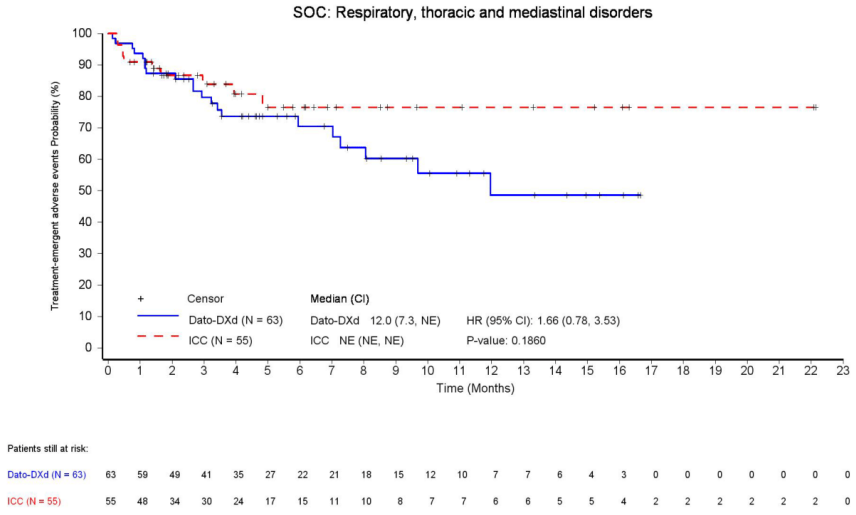

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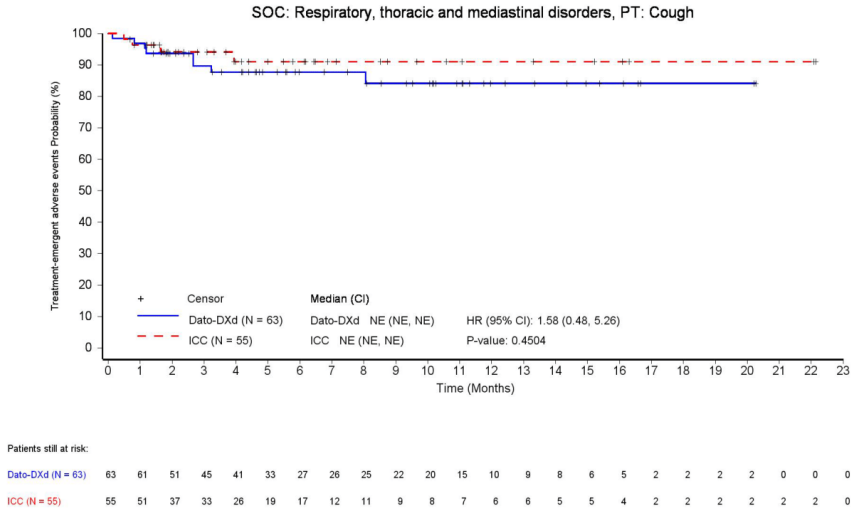

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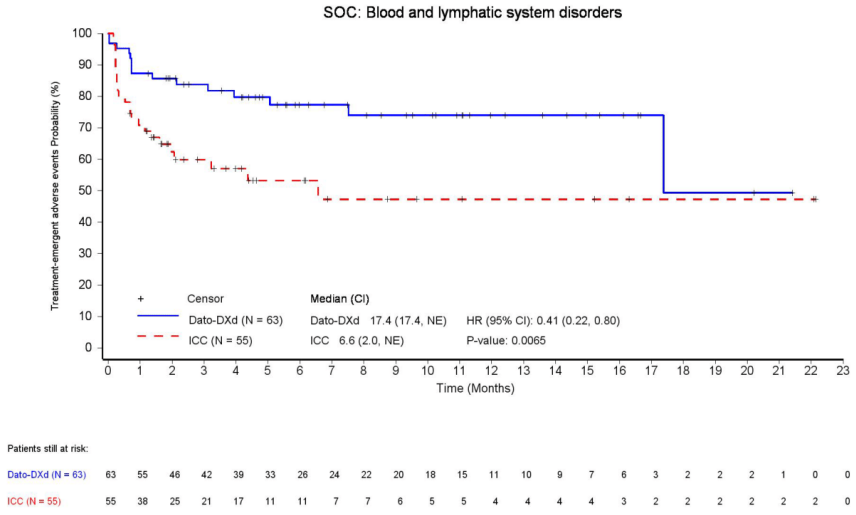

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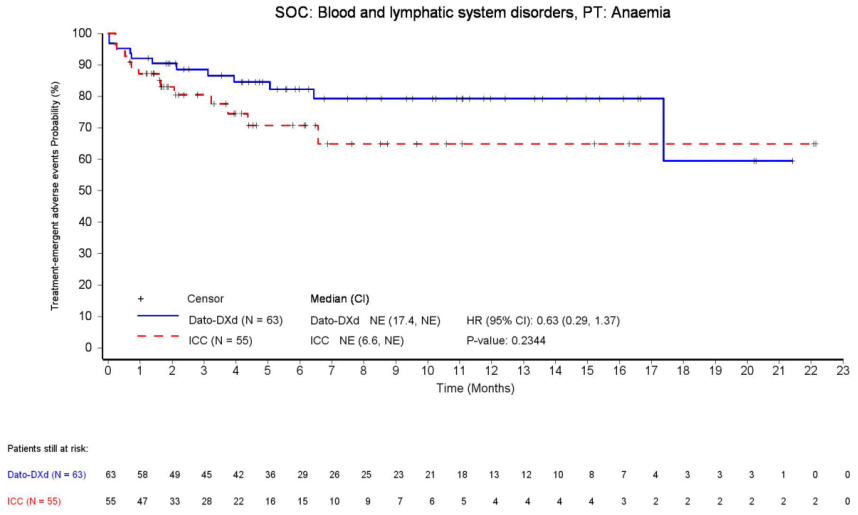

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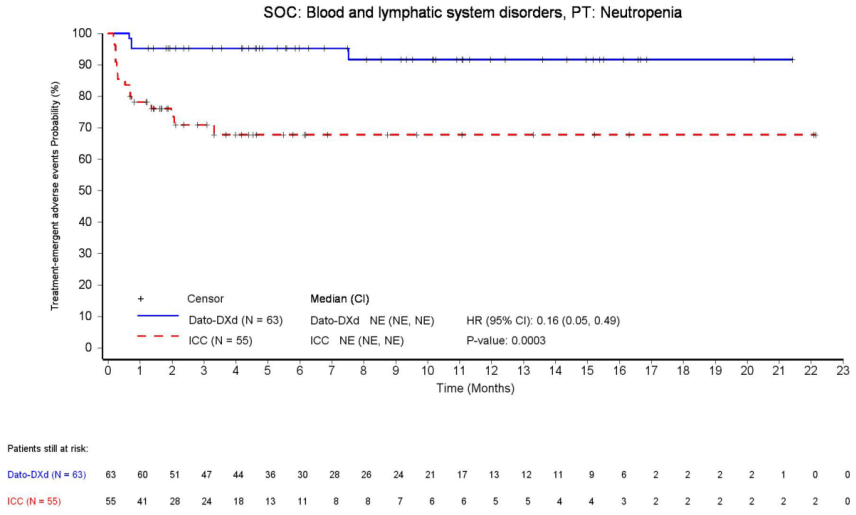

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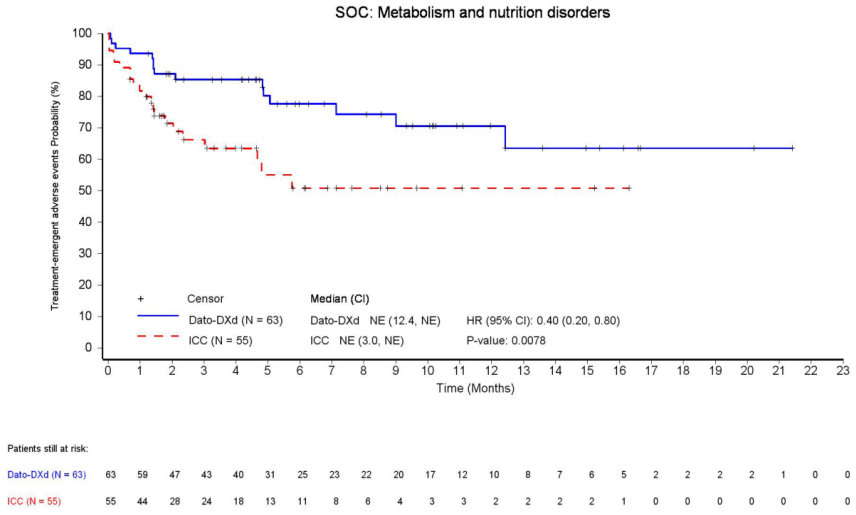

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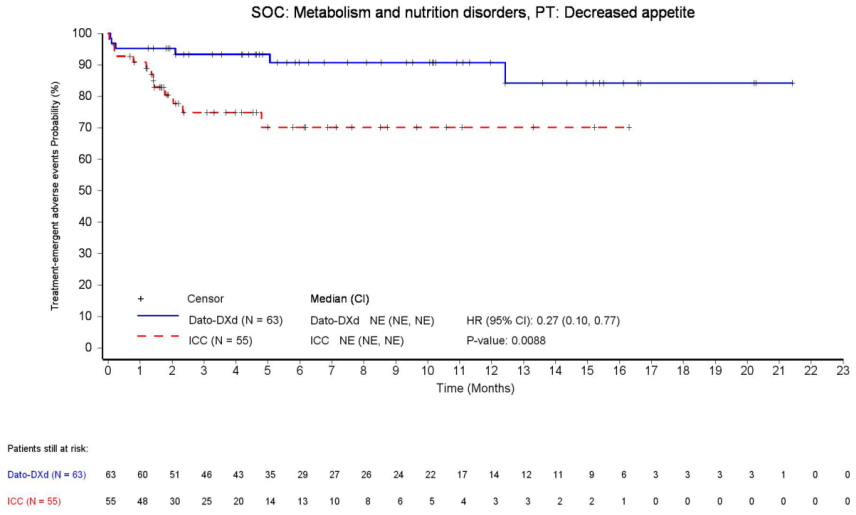
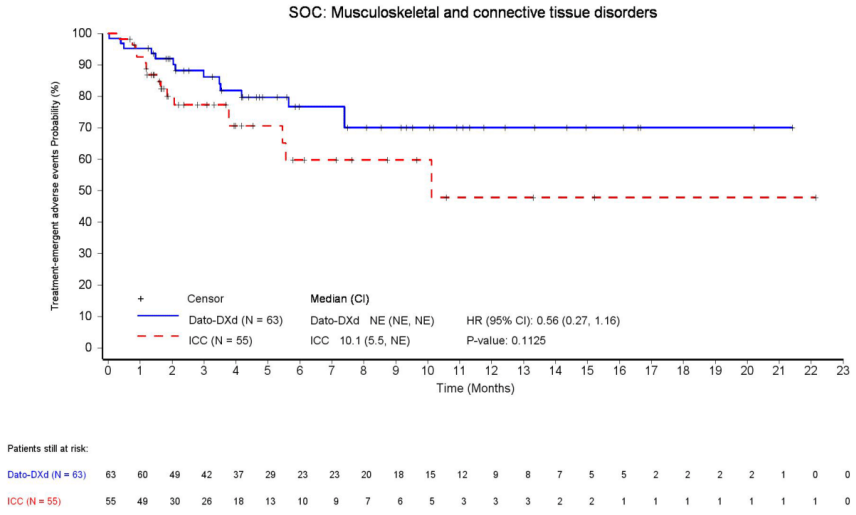


Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

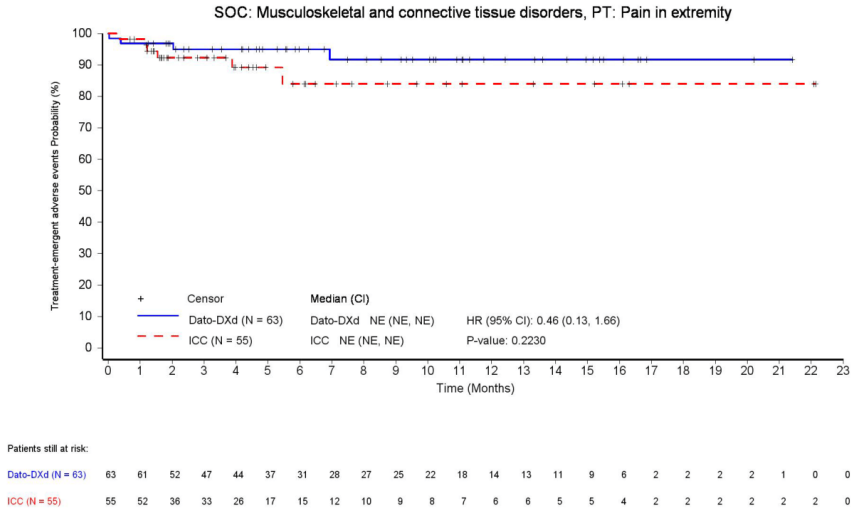
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

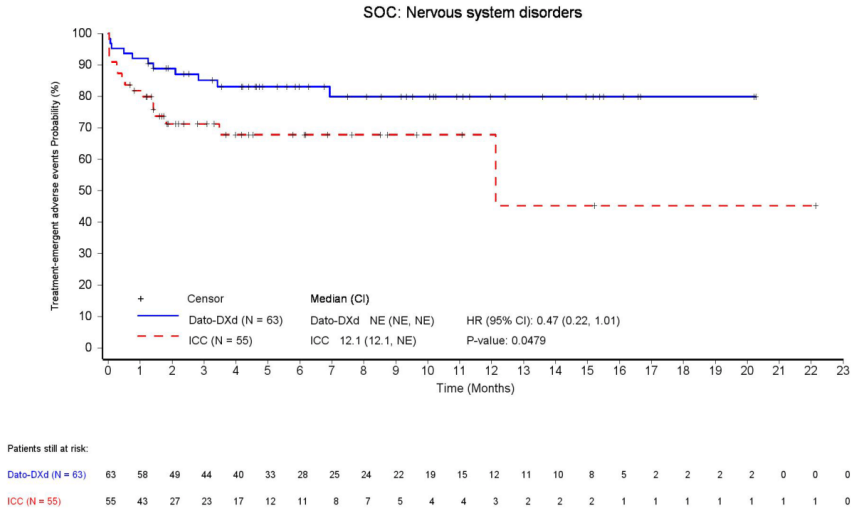
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



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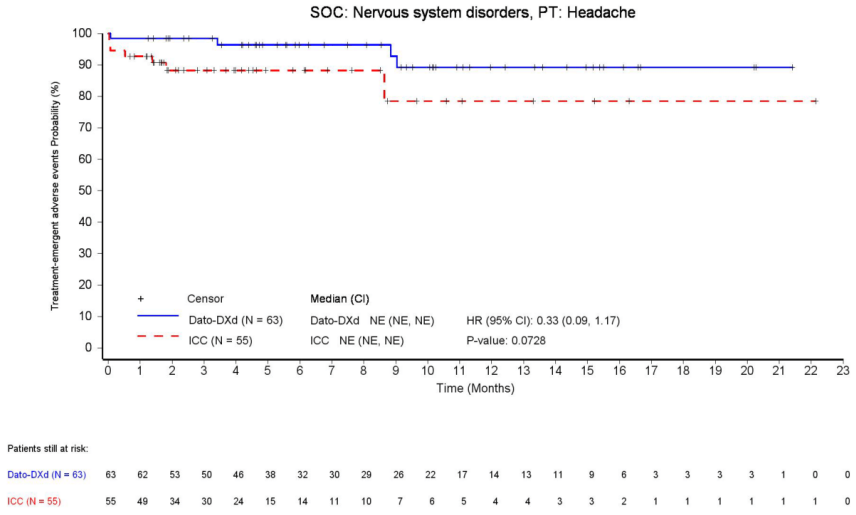
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

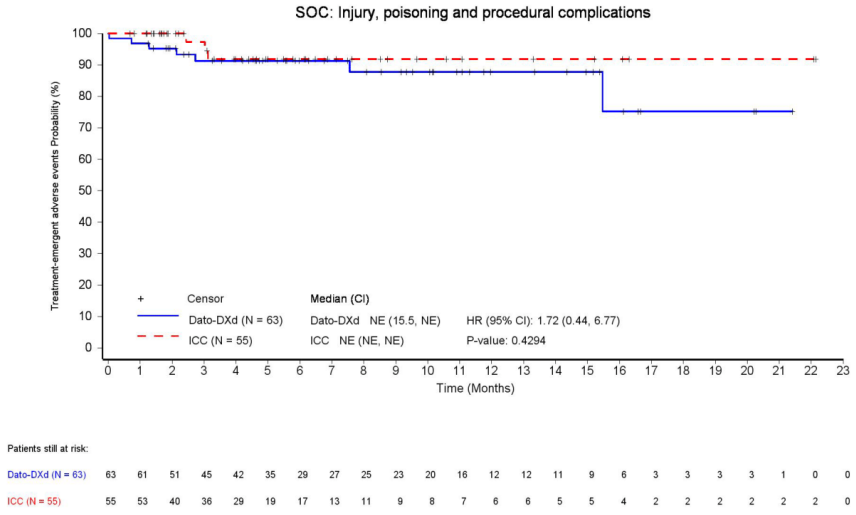
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

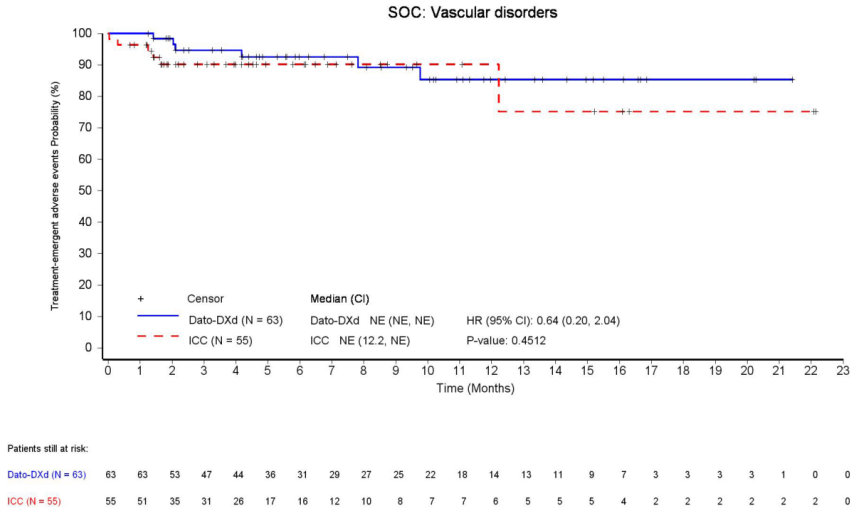
Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



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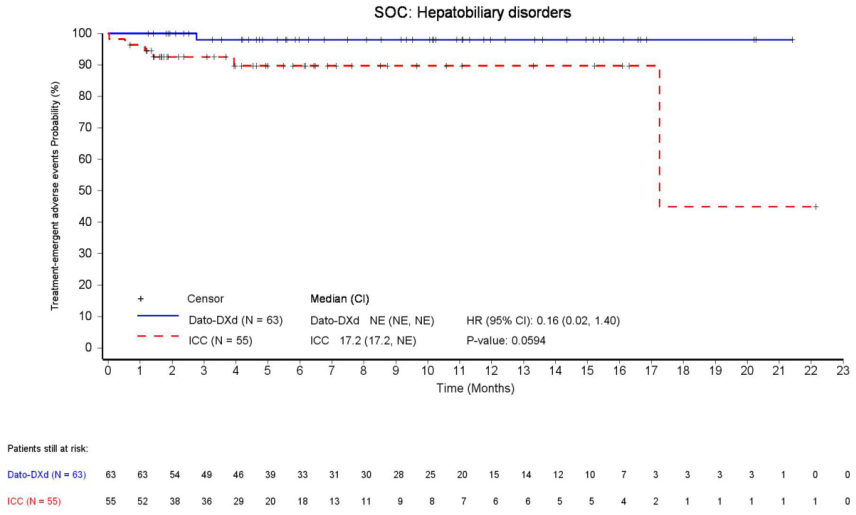
Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Figure 4.55.3 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:09; Program name: f_4_67_1.sas; Output name: DE.F_TEAESOCPT2_mSASA_FA.rtf

Jegliche UE nach SOC und PT – Prüfung der Kriterien der Anhebungsregel

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Vomiting

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	14 (22.2)	5 (9.1)	
Number of subjects censored, n (%)	49 (77.8)	50 (90.9)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.53
85% Confidence Interval			(1.20, 5.36)
Stratified log-rank p-value [c]			0.0649

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Diarrhoea

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	5 (7.9)	8 (14.5)	
Number of subjects censored, n (%)	58 (92.1)	47 (85.5)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(15.5 , NE)	(11.8 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.50
85% Confidence Interval			(0.22, 1.15)
Stratified log-rank p-value [c]			0.2231

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Abdominal pain

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Fatigue

Stopped at step 3

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Asthenia

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Pyrexia

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	38 (60.3)	23 (41.8)	
Number of subjects censored, n (%)	25 (39.7)	32 (58.2)	
Median time to first event (months) [a]	4.2	5.1	
85% Confidence Interval	(3.6 , 6.0)	(4.6 , 6.5)	
Cox proportional hazards model [b]			
Hazard Ratio			1.17
85% Confidence Interval			(0.80, 1.73)
Stratified log-rank p-value [c]			0.5512

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations, PT: COVID-19

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations, PT: Upper respiratory tract infection

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	36 (57.1)	24 (43.6)	
Number of subjects censored, n (%)	27 (42.9)	31 (56.4)	
Median time to first event (months) [a]	4.2	4.1	
85% Confidence Interval	(1.4 , 9.4)	(2.3 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.30
85% Confidence Interval			(0.89, 1.91)
Stratified log-rank p-value [c]			0.3443

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	27 (42.9)	17 (30.9)	
Number of subjects censored, n (%)	36 (57.1)	38 (69.1)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(4.2 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.34
85% Confidence Interval			(0.85, 2.09)
Stratified log-rank p-value [c]			0.3649

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Skin and subcutaneous tissue disorders, PT: Palmar-plantar erythrodysaesthesia syndrome

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	2 (3.2)	6 (10.9)	
Number of subjects censored, n (%)	61 (96.8)	49 (89.1)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.28
85% Confidence Interval			(0.09, 0.90)
Stratified log-rank p-value [c]			0.0946

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Punctate keratitis

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Blepharitis

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	9 (14.3)	2 (3.6)	
Number of subjects censored, n (%)	54 (85.7)	53 (96.4)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(11.4 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			2.37
85% Confidence Interval			(0.76, 7.39)
Stratified log-rank p-value [c]			0.2618

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	26 (41.3)	25 (45.5)	
Number of subjects censored, n (%)	37 (58.7)	30 (54.5)	
Median time to first event (months) [a]	13.1	4.8	
85% Confidence Interval	(5.6 , NE)	(2.7 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.59
85% Confidence Interval			(0.39, 0.90)
Stratified log-rank p-value [c]			0.0692

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Aspartate aminotransferase increased

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Alanine aminotransferase increased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	9 (14.3)	10 (18.2)	
Number of subjects censored, n (%)	54 (85.7)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.67
85% Confidence Interval			(0.35, 1.31)
Stratified log-rank p-value [c]			0.3866

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Weight decreased

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Respiratory, thoracic and mediastinal disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	21 (33.3)	10 (18.2)	
Number of subjects censored, n (%)	42 (66.7)	45 (81.8)	
Median time to first event (months) [a]	12.0	NE	
85% Confidence Interval	(8.0 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.66
85% Confidence Interval			(0.95, 2.89)
Stratified log-rank p-value [c]			0.1860

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Anaemia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	12 (19.0)	14 (25.5)	
Number of subjects censored, n (%)	51 (81.0)	41 (74.5)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(17.4 , NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.63
85% Confidence Interval			(0.36, 1.11)
Stratified log-rank p-value [c]			0.2344

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Musculoskeletal and connective tissue disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	14 (22.2)	16 (29.1)	
Number of subjects censored, n (%)	49 (77.8)	39 (70.9)	
Median time to first event (months) [a]	NE	10.1	
85% Confidence Interval	(NE, NE)	(5.6 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.56
85% Confidence Interval			(0.33, 0.95)
Stratified log-rank p-value [c]			0.1125

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders, PT: Headache

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Injury, poisoning and procedural complications

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Vascular disorders

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Hepatobiliary disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	1 (1.6)	6 (10.9)	
Number of subjects censored, n (%)	62 (98.4)	49 (89.1)	
Median time to first event (months) [a]	NE	17.2	
85% Confidence Interval	(NE, NE)	(17.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.16
85% Confidence Interval			(0.03, 0.79)
Stratified log-rank p-value [c]			0.0594

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_73_1.sas; Output name: DE.T_TEAESOCPTINC2_mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4919
mSASA	63	47 (74.6)	16 (25.4)	0.3 (0.1 , 1.2)	55	32 (58.2)	23 (41.8)	3.0 (0.8 , 4.3)	1.69 (1.07, 2.65)	0.0228	
non-mSASA	265	236 (89.1)	29 (10.9)	0.2 (0.1 , 0.3)	265	168 (63.4)	97 (36.6)	1.3 (0.8 , 1.7)	2.03 (1.66, 2.48)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6825
mSASA	63	32 (50.8)	31 (49.2)	4.9 (0.8 , NE)	55	11 (20.0)	44 (80.0)	NE (NE, NE)	2.88 (1.45, 5.72)	0.0015	
non-mSASA	265	159 (60.0)	106 (40.0)	1.4 (0.7 , 2.8)	265	77 (29.1)	188 (70.9)	NE (NE, NE)	2.56 (1.95, 3.37)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.5073
mSASA	63	30 (47.6)	33 (52.4)	4.5 (2.1 , NE)	55	9 (16.4)	46 (83.6)	NE (NE, NE)	3.44 (1.63, 7.26)	0.0005	
non-mSASA	265	149 (56.2)	116 (43.8)	3.5 (2.8 , 5.7)	265	39 (14.7)	226 (85.3)	NE (NE, NE)	4.60 (3.23, 6.55)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7651
mSASA	63	25 (39.7)	38 (60.3)	NE (3.7 , NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	2.24 (1.08, 4.67)	0.0262	
non-mSASA	265	96 (36.2)	169 (63.8)	20.4 (12.8 , NE)	265	48 (18.1)	217 (81.9)	NE (NE, NE)	1.97 (1.39, 2.78)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Vomiting

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6352
mSASA	63	14 (22.2)	49 (77.8)	NE (NE, NE)	55	5 (9.1)	50 (90.9)	NE (NE, NE)	2.43 (0.87, 6.75)	0.0787	
non-mSASA	265	68 (25.7)	197 (74.3)	NE (NE, NE)	265	36 (13.6)	229 (86.4)	NE (NE, NE)	1.81 (1.21, 2.72)	0.0036	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Diarrhoea

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.8678
mSASA	63	5 (7.9)	58 (92.1)	NE (15.5 , NE)	55	8 (14.5)	47 (85.5)	NE (11.8 , NE)	0.42 (0.14, 1.31)	0.1255	
non-mSASA	265	36 (13.6)	229 (86.4)	NE (NE, NE)	265	57 (21.5)	208 (78.5)	NE (NE, NE)	0.48 (0.31, 0.73)	0.0005	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders, PT: Abdominal pain

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6224
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (NE, NE)	0.44 (0.12, 1.58)	0.1968	
non-mSASA	265	20 (7.5)	245 (92.5)	NE (NE, NE)	265	24 (9.1)	241 (90.9)	NE (NE, NE)	0.64 (0.35, 1.17)	0.1473	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6907
mSASA	63	38 (60.3)	25 (39.7)	3.4 (1.4 , 6.5)	55	26 (47.3)	29 (52.7)	6.2 (1.3 , NE)	1.16 (0.71, 1.92)	0.5486	
non-mSASA	265	150 (56.6)	115 (43.4)	4.1 (1.9 , 6.9)	265	137 (51.7)	128 (48.3)	4.8 (2.7 , 6.7)	1.06 (0.84, 1.34)	0.6299	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions, PT: Fatigue

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4065
mSASA	63	16 (25.4)	47 (74.6)	NE (12.0 , NE)	55	11 (20.0)	44 (80.0)	NE (NE, NE)	1.05 (0.48, 2.28)	0.8981	
non-mSASA	265	81 (30.6)	184 (69.4)	NE (NE, NE)	265	50 (18.9)	215 (81.1)	NE (NE, NE)	1.58 (1.11, 2.26)	0.0101	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions, PT: Asthenia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.8655
mSASA	63	11 (17.5)	52 (82.5)	NE (NE, NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	0.92 (0.39, 2.16)	0.8388	
non-mSASA	265	45 (17.0)	220 (83.0)	NE (NE, NE)	265	50 (18.9)	215 (81.1)	NE (22.1 , NE)	0.81 (0.54, 1.21)	0.2913	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions, PT: Pyrexia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4577
mSASA	63	7 (11.1)	56 (88.9)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (NE, NE)	0.90 (0.30, 2.69)	0.8549	
non-mSASA	265	21 (7.9)	244 (92.1)	NE (NE, NE)	265	33 (12.5)	232 (87.5)	NE (NE, NE)	0.52 (0.30, 0.90)	0.0170	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Infections and infestations

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7409
mSASA	63	38 (60.3)	25 (39.7)	4.2 (3.2 , 6.3)	55	23 (41.8)	32 (58.2)	5.1 (4.5 , NE)	1.22 (0.73, 2.06)	0.4433	
non-mSASA	265	149 (56.2)	116 (43.8)	4.9 (4.3 , 5.8)	265	99 (37.4)	166 (62.6)	8.1 (6.8 , 16.9)	1.36 (1.06, 1.76)	0.0166	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Infections and infestations, PT: COVID-19

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6810
mSASA	63	15 (23.8)	48 (76.2)	NE (12.2 , NE)	55	8 (14.5)	47 (85.5)	NE (5.6 , NE)	1.19 (0.50, 2.83)	0.6908	
non-mSASA	265	51 (19.2)	214 (80.8)	NE (23.9 , NE)	265	38 (14.3)	227 (85.7)	NE (16.9 , NE)	1.04 (0.68, 1.59)	0.8553	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Infections and infestations, PT: Upper respiratory tract infection

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.1603
mSASA	63	3 (4.8)	60 (95.2)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (NE, NE)	0.29 (0.07, 1.20)	0.0705	
non-mSASA	265	15 (5.7)	250 (94.3)	NE (NE, NE)	265	12 (4.5)	253 (95.5)	NE (NE, NE)	0.88 (0.41, 1.90)	0.7451	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Skin and subcutaneous tissue disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7408
mSASA	63	36 (57.1)	27 (42.9)	4.2 (0.8 , 13.4)	55	24 (43.6)	31 (56.4)	4.1 (1.4 , NE)	1.27 (0.75, 2.13)	0.3862	
non-mSASA	265	155 (58.5)	110 (41.5)	2.7 (1.4 , 4.3)	265	118 (44.5)	147 (55.5)	5.3 (3.4 , NE)	1.40 (1.10, 1.78)	0.0063	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4650
mSASA	63	27 (42.9)	36 (57.1)	NE (2.1 , NE)	55	17 (30.9)	38 (69.1)	NE (NE, NE)	1.29 (0.70, 2.38)	0.4173	
non-mSASA	265	103 (38.9)	162 (61.1)	NE (NE, NE)	265	62 (23.4)	203 (76.6)	NE (NE, NE)	1.67 (1.22, 2.29)	0.0013	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Skin and subcutaneous tissue disorders, PT: Palmar-plantar erythrodysaesthesia syndrome

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6010
mSASA	63	2 (3.2)	61 (96.8)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (NE, NE)	0.27 (0.05, 1.33)	0.0828	
non-mSASA	265	7 (2.6)	258 (97.4)	NE (NE, NE)	265	39 (14.7)	226 (85.3)	NE (NE, NE)	0.14 (0.06, 0.31)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Eye disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.3100
mSASA	63	36 (57.1)	27 (42.9)	4.2 (2.8 , 9.4)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	2.75 (1.36, 5.57)	0.0033	
non-mSASA	265	149 (56.2)	116 (43.8)	4.2 (4.0 , 6.5)	265	81 (30.6)	184 (69.4)	8.5 (6.6 , NE)	1.87 (1.43, 2.45)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.1829
mSASA	63	20 (31.7)	43 (68.3)	NE (8.0 , NE)	55	4 (7.3)	51 (92.7)	NE (NE, NE)	3.52 (1.20, 10.34)	0.0147	
non-mSASA	265	71 (26.8)	194 (73.2)	NE (14.6 , NE)	265	38 (14.3)	227 (85.7)	NE (NE, NE)	1.63 (1.10, 2.42)	0.0148	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Eye disorders, PT: Punctate keratitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6067
mSASA	63	9 (14.3)	54 (85.7)	NE (14.2 , NE)	55	3 (5.5)	52 (94.5)	NE (9.5 , NE)	1.70 (0.46, 6.34)	0.4237	
non-mSASA	265	32 (12.1)	233 (87.9)	NE (NE, NE)	265	19 (7.2)	246 (92.8)	NE (NE, NE)	1.20 (0.68, 2.12)	0.5382	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Eye disorders, PT: Blepharitis

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.8311
mSASA	63	9 (14.3)	54 (85.7)	NE (NE, NE)	55	2 (3.6)	53 (96.4)	NE (11.4 , NE)	2.43 (0.52, 11.37)	0.2448	
non-mSASA	265	17 (6.4)	248 (93.6)	NE (NE, NE)	265	4 (1.5)	261 (98.5)	NE (NE, NE)	3.38 (1.13, 10.06)	0.0202	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4762
mSASA	63	26 (41.3)	37 (58.7)	13.1 (4.9 , NE)	55	25 (45.5)	30 (54.5)	4.8 (2.6 , NE)	0.62 (0.36, 1.09)	0.0932	
non-mSASA	265	97 (36.6)	168 (63.4)	16.4 (11.6 , NE)	265	128 (48.3)	137 (51.7)	4.6 (2.5 , 11.1)	0.51 (0.39, 0.67)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations, PT: Aspartate aminotransferase increased

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9761
mSASA	63	13 (20.6)	50 (79.4)	NE (13.1 , NE)	55	12 (21.8)	43 (78.2)	NE (NE, NE)	0.69 (0.31, 1.52)	0.3539	
non-mSASA	265	40 (15.1)	225 (84.9)	NE (24.0 , NE)	265	45 (17.0)	220 (83.0)	NE (NE, NE)	0.68 (0.44, 1.05)	0.0798	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations, PT: Alanine aminotransferase increased

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.8676
mSASA	63	9 (14.3)	54 (85.7)	NE (NE, NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	0.63 (0.25, 1.55)	0.3061	
non-mSASA	265	24 (9.1)	241 (90.9)	NE (NE, NE)	265	35 (13.2)	230 (86.8)	NE (NE, NE)	0.56 (0.33, 0.94)	0.0275	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations, PT: Weight decreased

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.2770
mSASA	63	7 (11.1)	56 (88.9)	NE (NE, NE)	55	5 (9.1)	50 (90.9)	NE (NE, NE)	0.85 (0.27, 2.71)	0.7862	
non-mSASA	265	24 (9.1)	241 (90.9)	NE (NE, NE)	265	10 (3.8)	255 (96.2)	NE (NE, NE)	1.88 (0.89, 3.95)	0.0918	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9528
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	11 (20.0)	44 (80.0)	NE (7.4 , NE)	0.25 (0.08, 0.80)	0.0119	
non-mSASA	265	20 (7.5)	245 (92.5)	NE (NE, NE)	265	61 (23.0)	204 (77.0)	NE (NE, NE)	0.26 (0.16, 0.43)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Respiratory, thoracic and mediastinal disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7999
mSASA	63	21 (33.3)	42 (66.7)	12.0 (7.3 , NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	1.58 (0.74, 3.35)	0.2339	
non-mSASA	265	95 (35.8)	170 (64.2)	23.7 (12.2 , NE)	265	59 (22.3)	206 (77.7)	NE (NE, NE)	1.47 (1.06, 2.04)	0.0203	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7307
mSASA	63	8 (12.7)	55 (87.3)	NE (NE, NE)	55	4 (7.3)	51 (92.7)	NE (NE, NE)	1.53 (0.46, 5.09)	0.4886	
non-mSASA	265	38 (14.3)	227 (85.7)	NE (NE, NE)	265	28 (10.6)	237 (89.4)	NE (NE, NE)	1.21 (0.74, 1.97)	0.4534	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6388
mSASA	63	15 (23.8)	48 (76.2)	17.4 (17.4 , NE)	55	24 (43.6)	31 (56.4)	6.6 (2.0 , NE)	0.41 (0.21, 0.78)	0.0051	
non-mSASA	265	60 (22.6)	205 (77.4)	NE (18.6 , NE)	265	123 (46.4)	142 (53.6)	5.5 (2.2 , NE)	0.33 (0.24, 0.45)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders, PT: Anaemia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7111
mSASA	63	12 (19.0)	51 (81.0)	NE (17.4 , NE)	55	14 (25.5)	41 (74.5)	NE (6.6 , NE)	0.60 (0.27, 1.30)	0.1880	
non-mSASA	265	43 (16.2)	222 (83.8)	NE (NE, NE)	265	66 (24.9)	199 (75.1)	NE (17.1 , NE)	0.51 (0.34, 0.75)	0.0005	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9800
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	16 (29.1)	39 (70.9)	NE (NE, NE)	0.17 (0.06, 0.51)	0.0004	
non-mSASA	265	15 (5.7)	250 (94.3)	NE (NE, NE)	265	68 (25.7)	197 (74.3)	NE (NE, NE)	0.16 (0.09, 0.28)	<0.0001	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.0723
mSASA	63	15 (23.8)	48 (76.2)	NE (12.4 , NE)	55	21 (38.2)	34 (61.8)	NE (3.0 , NE)	0.43 (0.22, 0.85)	0.0120	
non-mSASA	265	92 (34.7)	173 (65.3)	NE (13.6 , NE)	265	86 (32.5)	179 (67.5)	NE (15.1 , NE)	0.91 (0.68, 1.23)	0.5460	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.0201
mSASA	63	6 (9.5)	57 (90.5)	NE (NE, NE)	55	13 (23.6)	42 (76.4)	NE (NE, NE)	0.30 (0.11, 0.80)	0.0108	
non-mSASA	265	50 (18.9)	215 (81.1)	NE (NE, NE)	265	41 (15.5)	224 (84.5)	NE (NE, NE)	1.10 (0.73, 1.67)	0.6437	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Musculoskeletal and connective tissue disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7811
mSASA	63	14 (22.2)	49 (77.8)	NE (NE, NE)	55	16 (29.1)	39 (70.9)	10.1 (5.5 , NE)	0.55 (0.27, 1.14)	0.1023	
non-mSASA	265	69 (26.0)	196 (74.0)	20.8 (19.5 , NE)	265	80 (30.2)	185 (69.8)	NE (9.8 , NE)	0.63 (0.45, 0.87)	0.0049	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.2622
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (NE, NE)	0.47 (0.13, 1.69)	0.2379	
non-mSASA	265	16 (6.0)	249 (94.0)	NE (NE, NE)	265	13 (4.9)	252 (95.1)	NE (NE, NE)	0.98 (0.47, 2.04)	0.9575	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Nervous system disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.3349
mSASA	63	11 (17.5)	52 (82.5)	NE (NE, NE)	55	17 (30.9)	38 (69.1)	12.1 (12.1 , NE)	0.43 (0.20, 0.93)	0.0286	
non-mSASA	265	76 (28.7)	189 (71.3)	NE (24.5 , NE)	265	104 (39.2)	161 (60.8)	10.5 (4.8 , NE)	0.60 (0.45, 0.81)	0.0008	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Nervous system disorders, PT: Headache

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.2405
mSASA	63	4 (6.3)	59 (93.7)	NE (NE, NE)	55	7 (12.7)	48 (87.3)	NE (NE, NE)	0.33 (0.09, 1.15)	0.0695	
non-mSASA	265	25 (9.4)	240 (90.6)	NE (NE, NE)	265	25 (9.4)	240 (90.6)	NE (NE, NE)	0.83 (0.48, 1.45)	0.5177	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Injury, poisoning and procedural complications

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.6358
mSASA	63	7 (11.1)	56 (88.9)	NE (15.5 , NE)	55	3 (5.5)	52 (94.5)	NE (NE, NE)	1.74 (0.45, 6.76)	0.4173	
non-mSASA	265	24 (9.1)	241 (90.9)	NE (NE, NE)	265	16 (6.0)	249 (94.0)	NE (NE, NE)	1.09 (0.57, 2.07)	0.7940	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Vascular disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4963
mSASA	63	6 (9.5)	57 (90.5)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	NE (12.2 , NE)	0.62 (0.20, 1.94)	0.4025	
non-mSASA	265	28 (10.6)	237 (89.4)	NE (NE, NE)	265	22 (8.3)	243 (91.7)	NE (NE, NE)	1.08 (0.62, 1.90)	0.7837	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.73.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Hepatobiliary disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.2996
mSASA	63	1 (1.6)	62 (98.4)	NE (NE, NE)	55	6 (10.9)	49 (89.1)	17.2 (17.2 , NE)	0.13 (0.02, 1.07)	0.0245	
non-mSASA	265	6 (2.3)	259 (97.7)	NE (NE, NE)	265	12 (4.5)	253 (95.5)	NE (NE, NE)	0.33 (0.12, 0.90)	0.0233	

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:03; Program name: t_4_72_2.sas; Output name: DE.T_TEAESOCPT2_mSASA_vs_non-mSASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9152
Region 1 [US, Canada, Europe]	33	26 (78.8)	7 (21.2)	0.3 (0.1, 0.8)	28	18 (64.3)	10 (35.7)	2.7 (0.5, 4.3)	1.80 (0.98, 3.31)	0.0617	
Region 2 [Rest of World]	30	21 (70.0)	9 (30.0)	0.7 (0.1, 4.0)	27	14 (51.9)	13 (48.1)	3.9 (0.4, NE)	1.61 (0.82, 3.17)	0.1605	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.6552
Yes	52	38 (73.1)	14 (26.9)	0.7 (0.1, 1.4)	45	27 (60.0)	18 (40.0)	3.0 (0.8, 4.3)	1.63 (0.99, 2.68)	0.0559	
No	11	9 (81.8)	2 (18.2)	0.2 (0.0, 4.9)	10	5 (50.0)	5 (50.0)	3.2 (0.1, NE)	2.03 (0.67, 6.13)	0.1959	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	17 (89.5)	2 (10.5)	-	13	9 (69.2)	4 (30.8)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	21 (65.6)	11 (34.4)	-	30	19 (63.3)	11 (36.7)	-	-	-	
Neither taxanes nor anthracyclines	11	8 (72.7)	3 (27.3)	-	9	4 (44.4)	5 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.6207
<65 years	52	37 (71.2)	15 (28.8)	0.7 (0.1, 1.4)	41	23 (56.1)	18 (43.9)	3.0 (0.8, 4.3)	1.62 (0.96, 2.73)	0.0720	
≥65 years	11	10 (90.9)	1 (9.1)	0.3 (0.0, 2.1)	14	9 (64.3)	5 (35.7)	3.0 (0.1, NE)	2.02 (0.81, 5.05)	0.1166	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.3660
Asian	21	14 (66.7)	7 (33.3)	1.9 (0.1, 4.9)	21	8 (38.1)	13 (61.9)	11.8 (3.6, NE)	2.17 (0.91, 5.19)	0.0756	
Non-Asian	32	25 (78.1)	7 (21.9)	0.3 (0.1, 1.2)	26	18 (69.2)	8 (30.8)	0.9 (0.2, 4.1)	1.40 (0.76, 2.59)	0.2751	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.2558
Capecitabine	21	16 (76.2)	5 (23.8)	0.3 (0.1, 2.1)	9	3 (33.3)	6 (66.7)	NE (0.7, NE)	4.12 (1.18, 14.34)	0.0168	
Eribulin mesylate	31	22 (71.0)	9 (29.0)	0.3 (0.1, 1.2)	41	26 (63.4)	15 (36.6)	2.9 (0.3, 4.3)	1.43 (0.80, 2.55)	0.2169	
Vinorelbine	11	9 (81.8)	2 (18.2)	1.4 (0.1, 4.9)	5	3 (60.0)	2 (40.0)	1.4 (0.2, NE)	0.95 (0.23, 3.86)	0.9244	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.0443
Yes	6	2 (33.3)	4 (66.7)	NE (0.1, NE)	6	4 (66.7)	2 (33.3)	2.5 (0.0, NE)	0.38 (0.07, 2.16)	0.2209	
No	57	45 (78.9)	12 (21.1)	0.3 (0.1, 0.8)	49	28 (57.1)	21 (42.9)	3.2 (0.8, 11.8)	2.03 (1.26, 3.28)	0.0032	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	1 (100)	0	-	-	-	
Female	62	46 (74.2)	16 (25.8)	-	54	31 (57.4)	23 (42.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	25 (80.6)	6 (19.4)	-	24	16 (66.7)	8 (33.3)	-	-	-	
Asian	21	14 (66.7)	7 (33.3)	-	21	8 (38.1)	13 (61.9)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.8849
0	35	26 (74.3)	9 (25.7)	0.7 (0.1, 1.9)	33	20 (60.6)	13 (39.4)	3.0 (0.8, 4.3)	1.67 (0.93, 3.01)	0.0861	
≥1	28	21 (75.0)	7 (25.0)	0.3 (0.1, 1.4)	22	12 (54.5)	10 (45.5)	2.5 (0.1, NE)	1.66 (0.81, 3.39)	0.1539	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	4 (66.7)	2 (33.3)	-	-	-	
≥6 months	49	35 (71.4)	14 (28.6)	-	42	25 (59.5)	17 (40.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.9718
≤12 months	22	16 (72.7)	6 (27.3)	0.5 (0.1, 1.9)	19	13 (68.4)	6 (31.6)	3.0 (0.1, NE)	1.63 (0.76, 3.53)	0.2076	
>12 months	29	21 (72.4)	8 (27.6)	0.7 (0.1, 2.1)	27	15 (55.6)	12 (44.4)	2.9 (0.5, NE)	1.59 (0.82, 3.09)	0.1721	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	3 (75.0)	1 (25.0)	-	0	0	0	-	-	-	
No	59	44 (74.6)	15 (25.4)	-	55	32 (58.2)	23 (41.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.6803
Region 1 [US, Canada, Europe]	33	19 (57.6)	14 (42.4)	2.1 (0.1, NE)	28	6 (21.4)	22 (78.6)	NE (4.3, NE)	3.33 (1.32, 8.37)	0.0071	
Region 2 [Rest of World]	30	13 (43.3)	17 (56.7)	NE (0.7, NE)	27	5 (18.5)	22 (81.5)	NE (NE, NE)	2.42 (0.86, 6.80)	0.0766	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9237
Yes	52	26 (50.0)	26 (50.0)	3.7 (0.7, NE)	45	9 (20.0)	36 (80.0)	NE (NE, NE)	2.88 (1.35, 6.14)	0.0044	
No	11	6 (54.5)	5 (45.5)	4.9 (0.0, NE)	10	2 (20.0)	8 (80.0)	NE (0.1, NE)	2.88 (0.57, 14.61)	0.1670	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	9 (47.4)	10 (52.6)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	16 (50.0)	16 (50.0)	-	30	7 (23.3)	23 (76.7)	-	-	-	
Neither taxanes nor anthracyclines	11	6 (54.5)	5 (45.5)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.3455
<65 years	52	27 (51.9)	25 (48.1)	3.7 (0.7, NE)	41	10 (24.4)	31 (75.6)	NE (4.3, NE)	2.40 (1.16, 4.97)	0.0145	
≥65 years	11	5 (45.5)	6 (54.5)	NE (0.1, NE)	14	1 (7.1)	13 (92.9)	NE (NE, NE)	6.66 (0.77, 57.27)	0.0451	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.2174
Asian	21	8 (38.1)	13 (61.9)	NE (0.7, NE)	21	1 (4.8)	20 (95.2)	NE (NE, NE)	8.50 (1.06, 68.21)	0.0155	
Non-Asian	32	18 (56.3)	14 (43.8)	2.1 (0.3, NE)	26	7 (26.9)	19 (73.1)	NE (1.6, NE)	2.26 (0.94, 5.42)	0.0581	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.5417
Capecitabine	21	10 (47.6)	11 (52.4)	9.0 (0.1, NE)	9	1 (11.1)	8 (88.9)	NE (1.4, NE)	5.46 (0.70, 42.71)	0.0700	
Eribulin mesylate	31	16 (51.6)	15 (48.4)	2.1 (0.7, NE)	41	8 (19.5)	33 (80.5)	NE (NE, NE)	2.97 (1.27, 6.95)	0.0078	
Vinorelbine	11	6 (54.5)	5 (45.5)	4.9 (0.1, NE)	5	2 (40.0)	3 (60.0)	NE (1.4, NE)	1.29 (0.25, 6.68)	0.7704	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.1967
Yes	6	2 (33.3)	4 (66.7)	NE (0.1, NE)	6	2 (33.3)	4 (66.7)	NE (0.0, NE)	0.91 (0.13, 6.45)	0.8821	
No	57	30 (52.6)	27 (47.4)	3.7 (0.7, NE)	49	9 (18.4)	40 (81.6)	NE (NE, NE)	3.38 (1.60, 7.12)	0.0007	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	31 (50.0)	31 (50.0)	-	54	11 (20.4)	43 (79.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	18 (58.1)	13 (41.9)	-	24	5 (20.8)	19 (79.2)	-	-	-	
Asian	21	8 (38.1)	13 (61.9)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9443
0	35	16 (45.7)	19 (54.3)	9.0 (0.7, NE)	33	6 (18.2)	27 (81.8)	NE (NE, NE)	2.83 (1.11, 7.24)	0.0235	
≥1	28	16 (57.1)	12 (42.9)	1.4 (0.2, NE)	22	5 (22.7)	17 (77.3)	NE (NE, NE)	2.87 (1.05, 7.84)	0.0300	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	22 (44.9)	27 (55.1)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7508
≤12 months	22	13 (59.1)	9 (40.9)	2.1 (0.1, NE)	19	4 (21.1)	15 (78.9)	NE (NE, NE)	3.34 (1.08, 10.32)	0.0268	
>12 months	29	13 (44.8)	16 (55.2)	NE (0.7, NE)	27	5 (18.5)	22 (81.5)	NE (4.3, NE)	2.78 (0.99, 7.80)	0.0435	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Nausea

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	30 (50.8)	29 (49.2)	-	55	11 (20.0)	44 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.4759
Region 1 [US, Canada, Europe]	33	14 (42.4)	19 (57.6)	9.7 (2.8, NE)	28	5 (17.9)	23 (82.1)	NE (NE, NE)	2.63 (0.95, 7.30)	0.0541	
Region 2 [Rest of World]	30	16 (53.3)	14 (46.7)	2.7 (1.0, NE)	27	4 (14.8)	23 (85.2)	NE (NE, NE)	4.51 (1.50, 13.52)	0.0032	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.6655
Yes	52	25 (48.1)	27 (51.9)	4.5 (1.9, NE)	45	8 (17.8)	37 (82.2)	NE (NE, NE)	3.22 (1.45, 7.15)	0.0024	
No	11	5 (45.5)	6 (54.5)	4.0 (0.2, NE)	10	1 (10.0)	9 (90.0)	NE (0.3, NE)	5.12 (0.60, 43.82)	0.0969	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	14 (73.7)	5 (26.3)	-	13	5 (38.5)	8 (61.5)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	12 (37.5)	20 (62.5)	-	30	4 (13.3)	26 (86.7)	-	-	-	
Neither taxanes nor anthracyclines	11	4 (36.4)	7 (63.6)	-	9	0	9 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.5844
<65 years	52	23 (44.2)	29 (55.8)	9.7 (2.7, NE)	41	7 (17.1)	34 (82.9)	NE (NE, NE)	3.09 (1.32, 7.21)	0.0059	
≥65 years	11	7 (63.6)	4 (36.4)	2.1 (0.3, NE)	14	2 (14.3)	12 (85.7)	NE (NE, NE)	4.84 (1.00, 23.32)	0.0299	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9329
Asian	21	10 (47.6)	11 (52.4)	4.0 (1.0, NE)	21	3 (14.3)	18 (85.7)	NE (3.9, NE)	3.59 (0.99, 13.06)	0.0377	
Non-Asian	32	14 (43.8)	18 (56.3)	9.7 (1.1, NE)	26	4 (15.4)	22 (84.6)	NE (NE, NE)	3.37 (1.11, 10.26)	0.0226	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8959
Capecitabine	21	10 (47.6)	11 (52.4)	9.7 (1.4, NE)	9	1 (11.1)	8 (88.9)	NE (3.9, NE)	5.32 (0.68, 41.62)	0.0749	
Eribulin mesylate	31	14 (45.2)	17 (54.8)	NE (1.0, NE)	41	8 (19.5)	33 (80.5)	NE (NE, NE)	2.88 (1.20, 6.88)	0.0127	
Vinorelbine	11	6 (54.5)	5 (45.5)	4.0 (0.2, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.0856	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9892
Yes	6	0	6 (100)	NE (NE, NE)	6	3 (50.0)	3 (50.0)	3.9 (0.3, NE)	0.00 (0.00, NE)	0.0436	
No	57	30 (52.6)	27 (47.4)	3.4 (1.4, NE)	49	6 (12.2)	43 (87.8)	NE (NE, NE)	5.44 (2.26, 13.08)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	29 (46.8)	33 (53.2)	-	54	9 (16.7)	45 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	14 (45.2)	17 (54.8)	-	24	4 (16.7)	20 (83.3)	-	-	-	
Asian	21	10 (47.6)	11 (52.4)	-	21	3 (14.3)	18 (85.7)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9174
0	35	15 (42.9)	20 (57.1)	9.7 (2.1, NE)	33	5 (15.2)	28 (84.8)	NE (NE, NE)	3.33 (1.21, 9.17)	0.0136	
≥1	28	15 (53.6)	13 (46.4)	4.0 (1.0, NE)	22	4 (18.2)	18 (81.8)	NE (NE, NE)	3.65 (1.21, 11.01)	0.0137	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	22 (44.9)	27 (55.1)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.4233
≤12 months	22	11 (50.0)	11 (50.0)	4.5 (0.8, NE)	19	5 (26.3)	14 (73.7)	NE (2.7, NE)	2.27 (0.79, 6.58)	0.1195	
>12 months	29	13 (44.8)	16 (55.2)	9.7 (2.1, NE)	27	3 (11.1)	24 (88.9)	NE (NE, NE)	4.73 (1.34, 16.61)	0.0076	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Stomatitis

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	2 (50.0)	2 (50.0)	-	0	0	0	-	-	-	
No	59	28 (47.5)	31 (52.5)	-	55	9 (16.4)	46 (83.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.7089
Region 1 [US, Canada, Europe]	33	16 (48.5)	17 (51.5)	6.9 (1.4, NE)	28	7 (25.0)	21 (75.0)	NE (2.8, NE)	2.03 (0.83, 4.95)	0.1122	
Region 2 [Rest of World]	30	9 (30.0)	21 (70.0)	NE (5.7, NE)	27	3 (11.1)	24 (88.9)	NE (NE, NE)	2.73 (0.74, 10.11)	0.1153	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.1159
Yes	52	22 (42.3)	30 (57.7)	NE (2.0, NE)	45	7 (15.6)	38 (84.4)	NE (NE, NE)	3.00 (1.28, 7.03)	0.0078	
No	11	3 (27.3)	8 (72.7)	NE (5.7, NE)	10	3 (30.0)	7 (70.0)	NE (0.3, NE)	0.69 (0.14, 3.55)	0.6595	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	8 (42.1)	11 (57.9)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	12 (37.5)	20 (62.5)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	5 (45.5)	6 (54.5)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7740
<65 years	52	19 (36.5)	33 (63.5)	NE (5.7, NE)	41	6 (14.6)	35 (85.4)	NE (NE, NE)	2.52 (1.01, 6.32)	0.0408	
≥65 years	11	6 (54.5)	5 (45.5)	2.7 (0.1, NE)	14	4 (28.6)	10 (71.4)	NE (0.3, NE)	1.93 (0.54, 6.83)	0.2922	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.3583
Asian	21	5 (23.8)	16 (76.2)	NE (6.3, NE)	21	1 (4.8)	20 (95.2)	NE (NE, NE)	5.03 (0.59, 43.07)	0.1013	
Non-Asian	32	14 (43.8)	18 (56.3)	6.9 (2.0, NE)	26	7 (26.9)	19 (73.1)	NE (2.8, NE)	1.66 (0.67, 4.11)	0.2713	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.0588
Capecitabine	21	10 (47.6)	11 (52.4)	5.7 (2.7, NE)	9	1 (11.1)	8 (88.9)	NE (2.8, NE)	5.45 (0.69, 42.88)	0.0707	
Eribulin mesylate	31	13 (41.9)	18 (58.1)	NE (0.8, NE)	41	7 (17.1)	34 (82.9)	NE (NE, NE)	2.71 (1.08, 6.80)	0.0261	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (6.3, NE)	5	2 (40.0)	3 (60.0)	2.3 (0.2, NE)	0.14 (0.01, 1.62)	0.0706	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.4503
Yes	6	1 (16.7)	5 (83.3)	NE (1.4, NE)	6	1 (16.7)	5 (83.3)	NE (0.3, NE)	0.91 (0.06, 14.63)	0.9486	
No	57	24 (42.1)	33 (57.9)	6.9 (3.5, NE)	49	9 (18.4)	40 (81.6)	NE (NE, NE)	2.43 (1.13, 5.23)	0.0191	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	24 (38.7)	38 (61.3)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	14 (45.2)	17 (54.8)	-	24	7 (29.2)	17 (70.8)	-	-	-	
Asian	21	5 (23.8)	16 (76.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.7890
0	35	10 (28.6)	25 (71.4)	NE (6.9, NE)	33	5 (15.2)	28 (84.8)	NE (NE, NE)	1.94 (0.66, 5.66)	0.2205	
≥1	28	15 (53.6)	13 (46.4)	3.5 (1.4, NE)	22	5 (22.7)	17 (77.3)	NE (NE, NE)	2.34 (0.85, 6.46)	0.0854	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	0	6 (100)	-	-	-	
≥6 months	49	21 (42.9)	28 (57.1)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.7056
≤12 months	22	9 (40.9)	13 (59.1)	NE (0.8, NE)	19	3 (15.8)	16 (84.2)	NE (NE, NE)	2.98 (0.81, 11.07)	0.0861	
>12 months	29	12 (41.4)	17 (58.6)	6.9 (2.0, NE)	27	5 (18.5)	22 (81.5)	NE (NE, NE)	2.24 (0.79, 6.36)	0.1208	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders, PT: Constipation

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	24 (40.7)	35 (59.3)	-	55	10 (18.2)	45 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.1610
Region 1 [US, Canada, Europe]	33	22 (66.7)	11 (33.3)	3.9 (2.1, 8.0)	28	4 (14.3)	24 (85.7)	NE (NE, NE)	4.35 (1.49, 12.70)	0.0032	
Region 2 [Rest of World]	30	14 (46.7)	16 (53.3)	9.4 (2.4, NE)	27	6 (22.2)	21 (77.8)	NE (6.2, NE)	1.72 (0.65, 4.51)	0.2679	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.3471
Yes	52	31 (59.6)	21 (40.4)	4.2 (2.8, 8.0)	45	8 (17.8)	37 (82.2)	NE (6.2, NE)	3.20 (1.47, 6.96)	0.0020	
No	11	5 (45.5)	6 (54.5)	14.2 (2.0, NE)	10	2 (20.0)	8 (80.0)	NE (0.3, NE)	1.52 (0.28, 8.31)	0.6415	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	11 (57.9)	8 (42.1)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	15 (46.9)	17 (53.1)	-	30	4 (13.3)	26 (86.7)	-	-	-	
Neither taxanes nor anthracyclines	11	9 (81.8)	2 (18.2)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9396
<65 years	52	30 (57.7)	22 (42.3)	4.0 (2.1, 9.4)	41	8 (19.5)	33 (80.5)	NE (NE, NE)	2.66 (1.21, 5.83)	0.0113	
≥65 years	11	6 (54.5)	5 (45.5)	13.2 (2.3, NE)	14	2 (14.3)	12 (85.7)	NE (6.2, NE)	2.42 (0.48, 12.13)	0.2660	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.7101
Asian	21	10 (47.6)	11 (52.4)	4.7 (2.0, NE)	21	3 (14.3)	18 (85.7)	NE (6.2, NE)	3.30 (0.90, 12.06)	0.0563	
Non-Asian	32	17 (53.1)	15 (46.9)	9.4 (2.1, 14.2)	26	5 (19.2)	21 (80.8)	NE (NE, NE)	2.20 (0.80, 6.08)	0.1205	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8032
Capecitabine	21	10 (47.6)	11 (52.4)	6.2 (2.0, NE)	9	1 (11.1)	8 (88.9)	NE (1.0, NE)	4.63 (0.59, 36.45)	0.1098	
Eribulin mesylate	31	17 (54.8)	14 (45.2)	4.0 (2.1, 14.2)	41	8 (19.5)	33 (80.5)	NE (6.2, NE)	2.81 (1.20, 6.58)	0.0136	
Vinorelbine	11	9 (81.8)	2 (18.2)	4.2 (1.9, NE)	5	1 (20.0)	4 (80.0)	NE (1.8, NE)	1.00 (0.11, 8.83)	0.9998	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9885
Yes	6	1 (16.7)	5 (83.3)	NE (4.1, NE)	6	0	6 (100)	NE (NE, NE)	NE (NE, NE)	0.3865	
No	57	35 (61.4)	22 (38.6)	4.2 (2.3, 8.0)	49	10 (20.4)	39 (79.6)	NE (6.2, NE)	2.74 (1.35, 5.55)	0.0035	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	35 (56.5)	27 (43.5)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	17 (54.8)	14 (45.2)	-	24	5 (20.8)	19 (79.2)	-	-	-	
Asian	21	10 (47.6)	11 (52.4)	-	21	3 (14.3)	18 (85.7)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.3453
0	35	17 (48.6)	18 (51.4)	6.2 (3.9, 14.2)	33	7 (21.2)	26 (78.8)	NE (6.2, NE)	2.00 (0.83, 4.83)	0.1162	
≥1	28	19 (67.9)	9 (32.1)	4.0 (2.0, 8.0)	22	3 (13.6)	19 (86.4)	NE (4.1, NE)	4.42 (1.29, 15.13)	0.0097	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	0	6 (100)	-	-	-	
≥6 months	49	27 (55.1)	22 (44.9)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.2179
≤12 months	22	16 (72.7)	6 (27.3)	2.1 (2.0, 4.2)	19	4 (21.1)	15 (78.9)	NE (4.1, NE)	5.08 (1.69, 15.29)	0.0014	
>12 months	29	15 (51.7)	14 (48.3)	8.0 (3.9, 13.2)	27	5 (18.5)	22 (81.5)	NE (6.2, NE)	2.17 (0.78, 6.00)	0.1276	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	35 (59.3)	24 (40.7)	-	55	10 (18.2)	45 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.3813
Region 1 [US, Canada, Europe]	33	11 (33.3)	22 (66.7)	13.7 (8.0, NE)	28	3 (10.7)	25 (89.3)	NE (NE, NE)	2.03 (0.55, 7.47)	0.2720	
Region 2 [Rest of World]	30	9 (30.0)	21 (70.0)	NE (4.2, NE)	27	1 (3.7)	26 (96.3)	NE (NE, NE)	7.68 (0.97, 60.66)	0.0224	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.5619
Yes	52	17 (32.7)	35 (67.3)	13.7 (8.0, NE)	45	3 (6.7)	42 (93.3)	NE (NE, NE)	3.99 (1.16, 13.64)	0.0170	
No	11	3 (27.3)	8 (72.7)	NE (2.0, NE)	10	1 (10.0)	9 (90.0)	NE (1.1, NE)	2.43 (0.25, 23.38)	0.4281	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	6 (31.6)	13 (68.4)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	10 (31.3)	22 (68.8)	-	30	2 (6.7)	28 (93.3)	-	-	-	
Neither taxanes nor anthracyclines	11	3 (27.3)	8 (72.7)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9901
<65 years	52	18 (34.6)	34 (65.4)	13.7 (4.2, NE)	41	4 (9.8)	37 (90.2)	NE (NE, NE)	2.71 (0.91, 8.09)	0.0629	
≥65 years	11	2 (18.2)	9 (81.8)	NE (8.0, NE)	14	0	14 (100)	NE (NE, NE)	NE (NE, NE)	0.2132	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9928
Asian	21	7 (33.3)	14 (66.7)	NE (2.4, NE)	21	0	21 (100)	NE (NE, NE)	NE (NE, NE)	0.0124	
Non-Asian	32	9 (28.1)	23 (71.9)	NE (4.2, NE)	26	3 (11.5)	23 (88.5)	NE (NE, NE)	2.15 (0.58, 7.96)	0.2398	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3731
Capecitabine	21	7 (33.3)	14 (66.7)	13.7 (2.8, NE)	9	1 (11.1)	8 (88.9)	NE (1.0, NE)	2.64 (0.32, 21.54)	0.3476	
Eribulin mesylate	31	9 (29.0)	22 (71.0)	NE (4.2, NE)	41	2 (4.9)	39 (95.1)	NE (NE, NE)	5.73 (1.24, 26.54)	0.0116	
Vinorelbine	11	4 (36.4)	7 (63.6)	11.0 (2.4, NE)	5	1 (20.0)	4 (80.0)	NE (1.8, NE)	0.35 (0.03, 4.04)	0.3809	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9996
Yes	6	0	6 (100)	NE (NE, NE)	6	0	6 (100)	NE (NE, NE)	NE (NE, NE)	NE	
No	57	20 (35.1)	37 (64.9)	13.7 (8.0, NE)	49	4 (8.2)	45 (91.8)	NE (NE, NE)	3.57 (1.22, 10.50)	0.0132	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	19 (30.6)	43 (69.4)	-	54	4 (7.4)	50 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	9 (29.0)	22 (71.0)	-	24	3 (12.5)	21 (87.5)	-	-	-	
Asian	21	7 (33.3)	14 (66.7)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9885
0	35	10 (28.6)	25 (71.4)	13.7 (11.0, NE)	33	4 (12.1)	29 (87.9)	NE (NE, NE)	1.94 (0.61, 6.19)	0.2528	
≥1	28	10 (35.7)	18 (64.3)	NE (2.4, NE)	22	0	22 (100)	NE (NE, NE)	NE (NE, NE)	0.0100	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	3 (100)	0	-	6	0	6 (100)	-	-	-	
≥6 months	49	13 (26.5)	36 (73.5)	-	42	4 (9.5)	38 (90.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3373
≤12 months	22	9 (40.9)	13 (59.1)	NE (2.0, NE)	19	1 (5.3)	18 (94.7)	NE (NE, NE)	9.42 (1.19, 74.50)	0.0094	
>12 months	29	8 (27.6)	21 (72.4)	13.7 (8.0, NE)	27	2 (7.4)	25 (92.6)	NE (NE, NE)	2.58 (0.54, 12.26)	0.2184	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Eye disorders, PT: Dry eye

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	1 (25.0)	3 (75.0)	-	0	0	0	-	-	-	
No	59	19 (32.2)	40 (67.8)	-	55	4 (7.3)	51 (92.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9920
Region 1 [US, Canada, Europe]	33	0	33 (100)	NE (NE, NE)	28	2 (7.1)	26 (92.9)	NE (NE, NE)	0.00 (0.00, NE)	0.0989	
Region 2 [Rest of World]	30	4 (13.3)	26 (86.7)	NE (NE, NE)	27	9 (33.3)	18 (66.7)	7.4 (1.4, NE)	0.29 (0.09, 0.96)	0.0316	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9927
Yes	52	4 (7.7)	48 (92.3)	NE (NE, NE)	45	9 (20.0)	36 (80.0)	NE (7.4, NE)	0.30 (0.09, 0.99)	0.0369	
No	11	0	11 (100)	NE (NE, NE)	10	2 (20.0)	8 (80.0)	NE (0.2, NE)	0.00 (0.00, NE)	0.1277	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	1 (5.3)	18 (94.7)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	3 (9.4)	29 (90.6)	-	30	6 (20.0)	24 (80.0)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9925
<65 years	52	4 (7.7)	48 (92.3)	NE (NE, NE)	41	7 (17.1)	34 (82.9)	NE (7.4, NE)	0.37 (0.11, 1.26)	0.0970	
≥65 years	11	0	11 (100)	NE (NE, NE)	14	4 (28.6)	10 (71.4)	NE (1.4, NE)	0.00 (0.00, NE)	0.0540	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9944
Asian	21	4 (19.0)	17 (81.0)	NE (NE, NE)	21	9 (42.9)	12 (57.1)	7.4 (1.4, NE)	0.28 (0.08, 0.94)	0.0293	
Non-Asian	32	0	32 (100)	NE (NE, NE)	26	2 (7.7)	24 (92.3)	NE (NE, NE)	0.00 (0.00, NE)	0.1106	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.9902
Capecitabine	21	1 (4.8)	20 (95.2)	NE (NE, NE)	9	2 (22.2)	7 (77.8)	NE (1.4, NE)	0.19 (0.02, 2.13)	0.1336	
Eribulin mesylate	31	2 (6.5)	29 (93.5)	NE (NE, NE)	41	9 (22.0)	32 (78.0)	NE (NE, NE)	0.25 (0.05, 1.18)	0.0585	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (3.0, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	0.6547	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9921
Yes	6	0	6 (100)	NE (NE, NE)	6	1 (16.7)	5 (83.3)	7.4 (NE, NE)	0.00 (0.00, NE)	0.1573	
No	57	4 (7.0)	53 (93.0)	NE (NE, NE)	49	10 (20.4)	39 (79.6)	NE (NE, NE)	0.29 (0.09, 0.93)	0.0274	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	1 (100)	0	-	-	-	
Female	62	4 (6.5)	58 (93.5)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	2 (8.3)	22 (91.7)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	9 (42.9)	12 (57.1)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.5402
0	35	3 (8.6)	32 (91.4)	NE (NE, NE)	33	7 (21.2)	26 (78.8)	NE (7.4, NE)	0.33 (0.08, 1.27)	0.0883	
≥1	28	1 (3.6)	27 (96.4)	NE (NE, NE)	22	4 (18.2)	18 (81.8)	NE (NE, NE)	0.18 (0.02, 1.62)	0.0849	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	3 (6.1)	46 (93.9)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	2 (9.1)	20 (90.9)	-	19	6 (31.6)	13 (68.4)	-	-	-	
>12 months	29	2 (6.9)	27 (93.1)	-	27	3 (11.1)	24 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	4 (6.8)	55 (93.2)	-	55	11 (20.0)	44 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.7914
Region 1 [US, Canada, Europe]	33	10 (30.3)	23 (69.7)	17.4 (7.5, NE)	28	14 (50.0)	14 (50.0)	4.4 (0.7, NE)	0.43 (0.19, 0.99)	0.0417	
Region 2 [Rest of World]	30	5 (16.7)	25 (83.3)	NE (NE, NE)	27	10 (37.0)	17 (63.0)	NE (1.6, NE)	0.35 (0.12, 1.04)	0.0476	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.8606
Yes	52	13 (25.0)	39 (75.0)	17.4 (17.4, NE)	45	20 (44.4)	25 (55.6)	6.6 (1.6, NE)	0.41 (0.20, 0.83)	0.0100	
No	11	2 (18.2)	9 (81.8)	NE (1.4, NE)	10	4 (40.0)	6 (60.0)	NE (0.2, NE)	0.37 (0.07, 2.03)	0.2303	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	5 (26.3)	14 (73.7)	-	13	4 (30.8)	9 (69.2)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	8 (25.0)	24 (75.0)	-	30	17 (56.7)	13 (43.3)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.7288
<65 years	52	12 (23.1)	40 (76.9)	NE (NE, NE)	41	19 (46.3)	22 (53.7)	4.4 (1.0, NE)	0.38 (0.19, 0.80)	0.0074	
≥65 years	11	3 (27.3)	8 (72.7)	17.4 (7.5, NE)	14	5 (35.7)	9 (64.3)	NE (2.0, NE)	0.27 (0.05, 1.44)	0.1028	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.4621
Asian	21	4 (19.0)	17 (81.0)	NE (NE, NE)	21	5 (23.8)	16 (76.2)	NE (6.6, NE)	0.70 (0.19, 2.61)	0.5894	
Non-Asian	32	7 (21.9)	25 (78.1)	17.4 (NE, NE)	26	12 (46.2)	14 (53.8)	4.4 (0.7, NE)	0.37 (0.14, 0.94)	0.0296	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8325
Capecitabine	21	9 (42.9)	12 (57.1)	NE (2.1, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	0.0370	
Eribulin mesylate	31	4 (12.9)	27 (87.1)	17.4 (NE, NE)	41	22 (53.7)	19 (46.3)	2.0 (0.7, NE)	0.17 (0.06, 0.50)	0.0003	
Vinorelbine	11	2 (18.2)	9 (81.8)	NE (5.1, NE)	5	2 (40.0)	3 (60.0)	4.4 (2.1, NE)	0.11 (0.01, 1.32)	0.0393	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9905
Yes	6	0	6 (100)	NE (NE, NE)	6	3 (50.0)	3 (50.0)	NE (0.2, NE)	0.00 (0.00, NE)	0.0549	
No	57	15 (26.3)	42 (73.7)	17.4 (17.4, NE)	49	21 (42.9)	28 (57.1)	6.6 (2.0, NE)	0.47 (0.24, 0.91)	0.0216	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	15 (24.2)	47 (75.8)	-	54	24 (44.4)	30 (55.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	7 (22.6)	24 (77.4)	-	24	10 (41.7)	14 (58.3)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	5 (23.8)	16 (76.2)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.1686
0	35	7 (20.0)	28 (80.0)	NE (NE, NE)	33	11 (33.3)	22 (66.7)	NE (4.4, NE)	0.56 (0.22, 1.45)	0.2203	
≥1	28	8 (28.6)	20 (71.4)	17.4 (7.5, NE)	22	13 (59.1)	9 (40.9)	1.4 (0.3, NE)	0.19 (0.07, 0.51)	0.0003	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	3 (50.0)	3 (50.0)	-	-	-	
≥6 months	49	11 (22.4)	38 (77.6)	-	42	18 (42.9)	24 (57.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.3799
≤12 months	22	5 (22.7)	17 (77.3)	17.4 (NE, NE)	19	10 (52.6)	9 (47.4)	6.6 (0.3, NE)	0.26 (0.08, 0.82)	0.0131	
>12 months	29	8 (27.6)	21 (72.4)	NE (5.1, NE)	27	10 (37.0)	17 (63.0)	NE (1.3, NE)	0.54 (0.21, 1.39)	0.1957	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	15 (25.4)	44 (74.6)	-	55	24 (43.6)	31 (56.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9829
Region 1 [US, Canada, Europe]	33	3 (9.1)	30 (90.9)	NE (NE, NE)	28	11 (39.3)	17 (60.7)	NE (0.7, NE)	0.15 (0.04, 0.57)	0.0015	
Region 2 [Rest of World]	30	1 (3.3)	29 (96.7)	NE (NE, NE)	27	5 (18.5)	22 (81.5)	NE (NE, NE)	0.16 (0.02, 1.35)	0.0530	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9925
Yes	52	4 (7.7)	48 (92.3)	NE (NE, NE)	45	14 (31.1)	31 (68.9)	NE (3.3, NE)	0.19 (0.06, 0.58)	0.0012	
No	11	0	11 (100)	NE (NE, NE)	10	2 (20.0)	8 (80.0)	NE (0.2, NE)	0.00 (0.00, NE)	0.1277	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	2 (15.4)	11 (84.6)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	4 (12.5)	28 (87.5)	-	30	11 (36.7)	19 (63.3)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.5352
<65 years	52	3 (5.8)	49 (94.2)	NE (NE, NE)	41	13 (31.7)	28 (68.3)	NE (3.3, NE)	0.15 (0.04, 0.52)	0.0005	
≥65 years	11	1 (9.1)	10 (90.9)	NE (7.5, NE)	14	3 (21.4)	11 (78.6)	NE (2.0, NE)	0.28 (0.03, 2.83)	0.2569	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.1197
Asian	21	1 (4.8)	20 (95.2)	NE (NE, NE)	21	1 (4.8)	20 (95.2)	NE (3.3, NE)	0.80 (0.05, 13.04)	0.8764	
Non-Asian	32	1 (3.1)	31 (96.9)	NE (NE, NE)	26	10 (38.5)	16 (61.5)	NE (0.7, NE)	0.06 (0.01, 0.50)	0.0004	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.6201
Capecitabine	21	2 (9.5)	19 (90.5)	NE (NE, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	0.3474	
Eribulin mesylate	31	1 (3.2)	30 (96.8)	NE (NE, NE)	41	15 (36.6)	26 (63.4)	NE (2.0, NE)	0.07 (0.01, 0.53)	0.0007	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (NE, NE)	5	1 (20.0)	4 (80.0)	NE (2.1, NE)	0.33 (0.02, 5.30)	0.4106	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9911
Yes	6	0	6 (100)	NE (NE, NE)	6	2 (33.3)	4 (66.7)	3.3 (0.2, NE)	0.00 (0.00, NE)	0.0715	
No	57	4 (7.0)	53 (93.0)	NE (NE, NE)	49	14 (28.6)	35 (71.4)	NE (NE, NE)	0.19 (0.06, 0.59)	0.0014	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	4 (6.5)	58 (93.5)	-	54	16 (29.6)	38 (70.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	1 (3.2)	30 (96.8)	-	24	8 (33.3)	16 (66.7)	-	-	-	
Asian	21	1 (4.8)	20 (95.2)	-	21	1 (4.8)	20 (95.2)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.5017
0	35	2 (5.7)	33 (94.3)	NE (NE, NE)	33	7 (21.2)	26 (78.8)	NE (NE, NE)	0.24 (0.05, 1.16)	0.0540	
≥1	28	2 (7.1)	26 (92.9)	NE (NE, NE)	22	9 (40.9)	13 (59.1)	3.3 (0.3, NE)	0.09 (0.02, 0.46)	0.0005	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	3 (6.1)	46 (93.9)	-	42	12 (28.6)	30 (71.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.8222
≤12 months	22	2 (9.1)	20 (90.9)	NE (NE, NE)	19	6 (31.6)	13 (68.4)	NE (0.5, NE)	0.25 (0.05, 1.22)	0.0614	
>12 months	29	2 (6.9)	27 (93.1)	NE (NE, NE)	27	8 (29.6)	19 (70.4)	NE (2.0, NE)	0.16 (0.03, 0.79)	0.0107	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	4 (6.8)	55 (93.2)	-	55	16 (29.1)	39 (70.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9849
Region 1 [US, Canada, Europe]	33	9 (27.3)	24 (72.7)	12.4 (5.1, NE)	28	12 (42.9)	16 (57.1)	5.7 (1.4, NE)	0.38 (0.15, 0.94)	0.0302	
Region 2 [Rest of World]	30	6 (20.0)	24 (80.0)	NE (NE, NE)	27	9 (33.3)	18 (66.7)	NE (2.0, NE)	0.48 (0.17, 1.38)	0.1634	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9660
Yes	52	12 (23.1)	40 (76.9)	NE (12.4, NE)	45	17 (37.8)	28 (62.2)	NE (3.0, NE)	0.45 (0.21, 0.95)	0.0315	
No	11	3 (27.3)	8 (72.7)	NE (1.4, NE)	10	4 (40.0)	6 (60.0)	4.7 (1.2, NE)	0.31 (0.05, 1.84)	0.1778	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	3 (15.8)	16 (84.2)	-	13	6 (46.2)	7 (53.8)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	2 (66.7)	1 (33.3)	-	-	-	
Both taxanes and anthracyclines	32	7 (21.9)	25 (78.1)	-	30	10 (33.3)	20 (66.7)	-	-	-	
Neither taxanes nor anthracyclines	11	4 (36.4)	7 (63.6)	-	9	3 (33.3)	6 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.2223
<65 years	52	10 (19.2)	42 (80.8)	NE (NE, NE)	41	16 (39.0)	25 (61.0)	5.7 (2.3, NE)	0.37 (0.17, 0.82)	0.0107	
≥65 years	11	5 (45.5)	6 (54.5)	12.4 (5.1, NE)	14	5 (35.7)	9 (64.3)	NE (1.8, NE)	0.75 (0.21, 2.68)	0.6629	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.9717
Asian	21	4 (19.0)	17 (81.0)	NE (NE, NE)	21	7 (33.3)	14 (66.7)	NE (1.8, NE)	0.52 (0.15, 1.78)	0.2872	
Non-Asian	32	8 (25.0)	24 (75.0)	NE (7.1, NE)	26	11 (42.3)	15 (57.7)	5.7 (2.3, NE)	0.40 (0.16, 1.01)	0.0439	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.1078
Capecitabine	21	6 (28.6)	15 (71.4)	NE (4.8, NE)	9	1 (11.1)	8 (88.9)	NE (1.4, NE)	2.21 (0.26, 18.38)	0.4458	
Eribulin mesylate	31	5 (16.1)	26 (83.9)	NE (9.0, NE)	41	16 (39.0)	25 (61.0)	5.7 (2.3, NE)	0.26 (0.09, 0.73)	0.0063	
Vinorelbine	11	4 (36.4)	7 (63.6)	NE (0.7, NE)	5	4 (80.0)	1 (20.0)	1.4 (0.0, NE)	0.21 (0.05, 0.98)	0.0308	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.4750
Yes	6	1 (16.7)	5 (83.3)	NE (9.0, NE)	6	3 (50.0)	3 (50.0)	4.7 (0.0, NE)	0.24 (0.02, 2.32)	0.1805	
No	57	14 (24.6)	43 (75.4)	NE (12.4, NE)	49	18 (36.7)	31 (63.3)	NE (3.0, NE)	0.49 (0.24, 0.99)	0.0423	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	1 (100)	0	-	-	-	
Female	62	14 (22.6)	48 (77.4)	-	54	20 (37.0)	34 (63.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	8 (25.8)	23 (74.2)	-	24	10 (41.7)	14 (58.3)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	7 (33.3)	14 (66.7)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.9686
0	35	6 (17.1)	29 (82.9)	NE (9.0, NE)	33	11 (33.3)	22 (66.7)	NE (3.0, NE)	0.37 (0.14, 1.01)	0.0430	
≥1	28	9 (32.1)	19 (67.9)	NE (5.1, NE)	22	10 (45.5)	12 (54.5)	4.7 (0.4, NE)	0.43 (0.17, 1.12)	0.0753	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	3 (50.0)	3 (50.0)	-	-	-	
≥6 months	49	12 (24.5)	37 (75.5)	-	42	17 (40.5)	25 (59.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.5103
≤12 months	22	4 (18.2)	18 (81.8)	NE (5.1, NE)	19	8 (42.1)	11 (57.9)	NE (0.7, NE)	0.36 (0.11, 1.21)	0.0867	
>12 months	29	8 (27.6)	21 (72.4)	NE (7.1, NE)	27	9 (33.3)	18 (66.7)	NE (1.4, NE)	0.58 (0.22, 1.50)	0.2516	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	15 (25.4)	44 (74.6)	-	55	21 (38.2)	34 (61.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.6985
Region 1 [US, Canada, Europe]	33	4 (12.1)	29 (87.9)	NE (12.4, NE)	28	7 (25.0)	21 (75.0)	NE (4.8, NE)	0.27 (0.07, 1.07)	0.0471	
Region 2 [Rest of World]	30	2 (6.7)	28 (93.3)	NE (NE, NE)	27	6 (22.2)	21 (77.8)	NE (2.3, NE)	0.27 (0.05, 1.33)	0.0845	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9911
Yes	52	6 (11.5)	46 (88.5)	NE (NE, NE)	45	10 (22.2)	35 (77.8)	NE (NE, NE)	0.40 (0.15, 1.12)	0.0729	
No	11	0	11 (100)	NE (NE, NE)	10	3 (30.0)	7 (70.0)	NE (1.2, NE)	0.00 (0.00, NE)	0.0415	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	4 (30.8)	9 (69.2)	-	-	-	
Anthracyclines alone	1	1 (100)	0	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	4 (12.5)	28 (87.5)	-	30	6 (20.0)	24 (80.0)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.0955
<65 years	52	3 (5.8)	49 (94.2)	NE (NE, NE)	41	10 (24.4)	31 (75.6)	NE (4.8, NE)	0.19 (0.05, 0.69)	0.0049	
≥65 years	11	3 (27.3)	8 (72.7)	NE (5.1, NE)	14	3 (21.4)	11 (78.6)	NE (2.0, NE)	0.92 (0.18, 4.64)	0.9180	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5404
Asian	21	2 (9.5)	19 (90.5)	NE (NE, NE)	21	3 (14.3)	18 (85.7)	NE (2.0, NE)	0.58 (0.10, 3.51)	0.5518	
Non-Asian	32	3 (9.4)	29 (90.6)	NE (NE, NE)	26	7 (26.9)	19 (73.1)	NE (4.8, NE)	0.27 (0.07, 1.04)	0.0407	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.3747
Capecitabine	21	3 (14.3)	18 (85.7)	NE (12.4, NE)	9	1 (11.1)	8 (88.9)	NE (1.4, NE)	0.95 (0.10, 9.33)	0.9643	
Eribulin mesylate	31	2 (6.5)	29 (93.5)	NE (NE, NE)	41	10 (24.4)	31 (75.6)	NE (NE, NE)	0.21 (0.05, 0.97)	0.0277	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (NE, NE)	5	2 (40.0)	3 (60.0)	4.8 (1.4, NE)	0.14 (0.01, 1.70)	0.0790	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9906
Yes	6	0	6 (100)	NE (NE, NE)	6	1 (16.7)	5 (83.3)	NE (0.0, NE)	0.00 (0.00, NE)	0.3173	
No	57	6 (10.5)	51 (89.5)	NE (NE, NE)	49	12 (24.5)	37 (75.5)	NE (4.8, NE)	0.32 (0.12, 0.87)	0.0191	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	5 (8.1)	57 (91.9)	-	54	13 (24.1)	41 (75.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	3 (9.7)	28 (90.3)	-	24	6 (25.0)	18 (75.0)	-	-	-	
Asian	21	2 (9.5)	19 (90.5)	-	21	3 (14.3)	18 (85.7)	-	-	-	
Other*	1	0	1 (100)	-	2	1 (50.0)	1 (50.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.7426
0	35	2 (5.7)	33 (94.3)	NE (NE, NE)	33	7 (21.2)	26 (78.8)	NE (4.8, NE)	0.22 (0.04, 1.04)	0.0358	
≥1	28	4 (14.3)	24 (85.7)	NE (12.4, NE)	22	6 (27.3)	16 (72.7)	NE (1.4, NE)	0.30 (0.07, 1.25)	0.0815	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	2 (66.7)	1 (33.3)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	4 (8.2)	45 (91.8)	-	42	11 (26.2)	31 (73.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	4 (18.2)	18 (81.8)	-	19	5 (26.3)	14 (73.7)	-	-	-	
>12 months	29	2 (6.9)	27 (93.1)	-	27	5 (18.5)	22 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Metabolism and nutrition disorders, PT: Decreased appetite

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	6 (10.2)	53 (89.8)	-	55	13 (23.6)	42 (76.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.2420
Region 1 [US, Canada, Europe]	33	7 (21.2)	26 (78.8)	NE (6.9, NE)	28	7 (25.0)	21 (75.0)	NE (3.5, NE)	0.65 (0.23, 1.86)	0.4216	
Region 2 [Rest of World]	30	4 (13.3)	26 (86.7)	NE (NE, NE)	27	10 (37.0)	17 (63.0)	12.1 (1.4, NE)	0.29 (0.09, 0.96)	0.0306	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9886
Yes	52	11 (21.2)	41 (78.8)	NE (NE, NE)	45	13 (28.9)	32 (71.1)	12.1 (12.1, NE)	0.59 (0.26, 1.32)	0.1968	
No	11	0	11 (100)	NE (NE, NE)	10	4 (40.0)	6 (60.0)	NE (0.0, NE)	0.00 (0.00, NE)	0.0221	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	3 (15.8)	16 (84.2)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	7 (21.9)	25 (78.1)	-	30	9 (30.0)	21 (70.0)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	5 (55.6)	4 (44.4)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.1182
<65 years	52	7 (13.5)	45 (86.5)	NE (NE, NE)	41	13 (31.7)	28 (68.3)	NE (3.5, NE)	0.31 (0.12, 0.80)	0.0103	
≥65 years	11	4 (36.4)	7 (63.6)	NE (1.2, NE)	14	4 (28.6)	10 (71.4)	12.1 (1.4, NE)	1.13 (0.28, 4.56)	0.8644	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian											0.5136
Asian	21	4 (19.0)	17 (81.0)	NE (NE, NE)	21	5 (23.8)	16 (76.2)	12.1 (12.1, NE)	0.76 (0.20, 2.87)	0.6887	
Non-Asian	32	6 (18.8)	26 (81.3)	NE (NE, NE)	26	9 (34.6)	17 (65.4)	NE (1.8, NE)	0.40 (0.14, 1.13)	0.0743	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.8010
Capecitabine	21	5 (23.8)	16 (76.2)	NE (6.9, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	0.1343	
Eribulin mesylate	31	5 (16.1)	26 (83.9)	NE (NE, NE)	41	15 (36.6)	26 (63.4)	12.1 (3.5, NE)	0.33 (0.12, 0.92)	0.0266	
Vinorelbine	11	1 (9.1)	10 (90.9)	NE (NE, NE)	5	2 (40.0)	3 (60.0)	NE (0.4, NE)	0.17 (0.01, 1.85)	0.0971	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.4733
Yes	6	1 (16.7)	5 (83.3)	NE (0.5, NE)	6	3 (50.0)	3 (50.0)	NE (0.3, NE)	0.27 (0.03, 2.61)	0.2262	
No	57	10 (17.5)	47 (82.5)	NE (NE, NE)	49	14 (28.6)	35 (71.4)	12.1 (12.1, NE)	0.48 (0.21, 1.08)	0.0705	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	1 (100)	0	-	1	0	1 (100)	-	-	-	
Female	62	10 (16.1)	52 (83.9)	-	54	17 (31.5)	37 (68.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	5 (16.1)	26 (83.9)	-	24	7 (29.2)	17 (70.8)	-	-	-	
Asian	21	4 (19.0)	17 (81.0)	-	21	5 (23.8)	16 (76.2)	-	-	-	
Other*	1	1 (100)	0	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline											0.7822
0	35	5 (14.3)	30 (85.7)	NE (NE, NE)	33	10 (30.3)	23 (69.7)	12.1 (3.5, NE)	0.36 (0.12, 1.07)	0.0546	
≥1	28	6 (21.4)	22 (78.6)	NE (NE, NE)	22	7 (31.8)	15 (68.2)	NE (0.7, NE)	0.55 (0.18, 1.63)	0.2765	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	1 (33.3)	2 (66.7)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	10 (20.4)	39 (79.6)	-	42	16 (38.1)	26 (61.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor											0.8575
≤12 months	22	3 (13.6)	19 (86.4)	NE (NE, NE)	19	5 (26.3)	14 (73.7)	12.1 (NE, NE)	0.57 (0.13, 2.53)	0.4546	
>12 months	29	7 (24.1)	22 (75.9)	NE (6.9, NE)	27	9 (33.3)	18 (66.7)	NE (1.5, NE)	0.57 (0.21, 1.55)	0.2640	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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SOC: Nervous system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	11 (18.6)	48 (81.4)	-	55	17 (30.9)	38 (69.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:05; Program name: t_4_67_2.sas; Output name: DE.T_TEAESOCPT2_SUB_mSASA_FA.rtf

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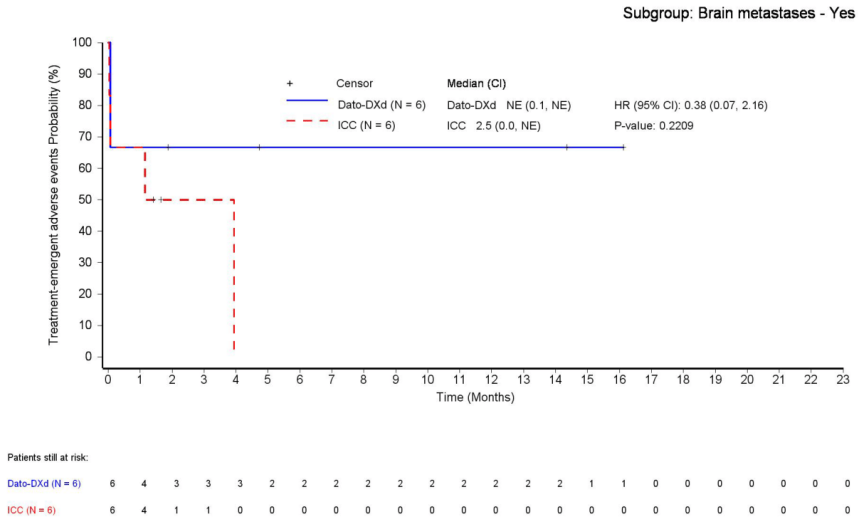
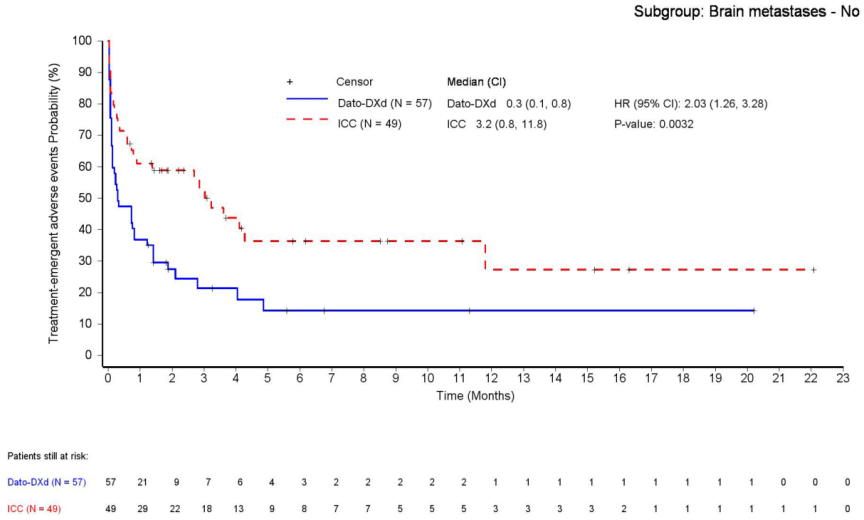
Figure 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Subgroup: SOC: Gastrointestinal disorders



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: f_4_67_2.sas; Output name: DE.F_TEAESOCPT3_SUB_mSASA_FA.rtf

Figure 4.55.4 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 10% in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A
Subgroup: SOC: Gastrointestinal disorders



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: f_4_67_2.sas; Output name: DE.F_TEAESOCPT3_SUB_mSASA_FA.rtf

Schwerwiegende UE nach SOC und PT

Schwerwiegende UE nach SOC und PT – Hauptanalyse

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Table 4.56.3 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0 (0.0)	3 (5.5)	
Number of subjects censored, n (%)	63 (100.0)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
95% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0596

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESERSOCPT2_mSASA_FA.rtf

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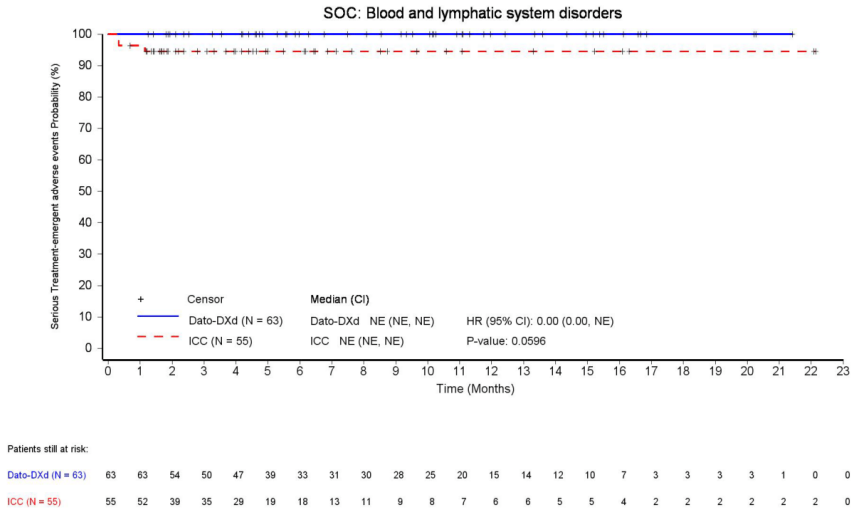
Figure 4.56.3 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Patients still at risk:

Dato-DXd (N = 63)	63	63	54	50	47	39	33	31	30	28	25	20	15	14	12	10	7	3	3	3	3	1	0	0
ICC (N = 55)	55	52	39	35	29	19	18	13	11	9	8	7	6	6	5	5	4	2	2	2	2	2	2	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: f_4_67_1.sas; Output name: DE.F_TEAESERSOCPT2_mSASA_FA.rtf

Schwerwiegende UE nach SOC und PT – Prüfung der Kriterien der Anhebungsregel

Daiichi Sankyo
Data Intelligence – Evidence Generation
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Statistical analyses for AMNOG (HTA Germany)

Table 4.75.5 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0	3 (5.5)	
Number of subjects censored, n (%)	63 (100)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
85% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0596

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:36; Program name: t_4_73_1.sas; Output name: DE.T_TEAESERSOCPTINC2_mSASA_FA.rtf

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Data Intelligence – Evidence Generation
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Statistical analyses for AMNOG (HTA Germany)

Table 4.75.6 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9922
mSASA	63	0	63 (100)	NE (NE, NE)	55	3 (5.5)	52 (94.5)	NE (NE, NE)	0.00 (0.00, NE)	0.0605	
non-mSASA	265	2 (0.8)	263 (99.2)	NE (NE, NE)	265	6 (2.3)	259 (97.7)	NE (NE, NE)	0.28 (0.06, 1.41)	0.1007	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:04; Program name: t_4_74_6.sas; Output name: DE.T_TEAESERSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Schwerwiegende UE nach SOC und PT – Subgruppenanalysen

Daiichi Sankyo
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D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Table 4.56.4 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESERSOCPT2_SUB_mSASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 4.56.4 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: f_4_67_2.sas; Output name: DE.F_TEAESERSOCPT2_SUB_mSASA_FA.rtf

Schwere UE (CTCAE-Grad ≥3) nach SOC und PT

Schwere UE (CTCAE-Grad ≥3) nach SOC und PT – Hauptanalyse

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	7 (11.1)	4 (7.3)	
Number of subjects censored, n (%)	56 (88.9)	51 (92.7)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(12.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			1.46
95% Confidence Interval			(0.42, 5.02)
Stratified log-rank p-value [c]			0.5479

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	4 (6.3)	11 (20.0)	
Number of subjects censored, n (%)	59 (93.7)	44 (80.0)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(17.2 , NE)	(8.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.23
95% Confidence Interval			(0.07, 0.74)
Stratified log-rank p-value [c]			0.0074

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0 (0.0)	7 (12.7)	
Number of subjects censored, n (%)	63 (100.0)	48 (87.3)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(8.2 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
95% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0018

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	3 (4.8)	4 (7.3)	
Number of subjects censored, n (%)	60 (95.2)	51 (92.7)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.57
95% Confidence Interval			(0.13, 2.55)
Stratified log-rank p-value [c]			0.4552

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	2 (3.2)	5 (9.1)	
Number of subjects censored, n (%)	61 (96.8)	50 (90.9)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.28
95% Confidence Interval			(0.05, 1.47)
Stratified log-rank p-value [c]			0.1101

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Fatigue

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	1 (1.6)	4 (7.3)	
Number of subjects censored, n (%)	62 (98.4)	51 (92.7)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.16
95% Confidence Interval			(0.02, 1.48)
Stratified log-rank p-value [c]			0.0670

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	1 (1.6)	14 (25.5)	
Number of subjects censored, n (%)	62 (98.4)	41 (74.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(17.4 , NE)	(11.7 , NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.05
95% Confidence Interval			(0.01, 0.38)
Stratified log-rank p-value [c]			<0.0001

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0 (0.0)	10 (18.2)	
Number of subjects censored, n (%)	63 (100.0)	45 (81.8)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
95% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0003

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Leukopenia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0 (0.0)	3 (5.5)	
Number of subjects censored, n (%)	63 (100.0)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
95% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0580

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Table 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Hepatobiliary disorders

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0 (0.0)	3 (5.5)	
Number of subjects censored, n (%)	63 (100.0)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
95% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
95% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0605

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_1.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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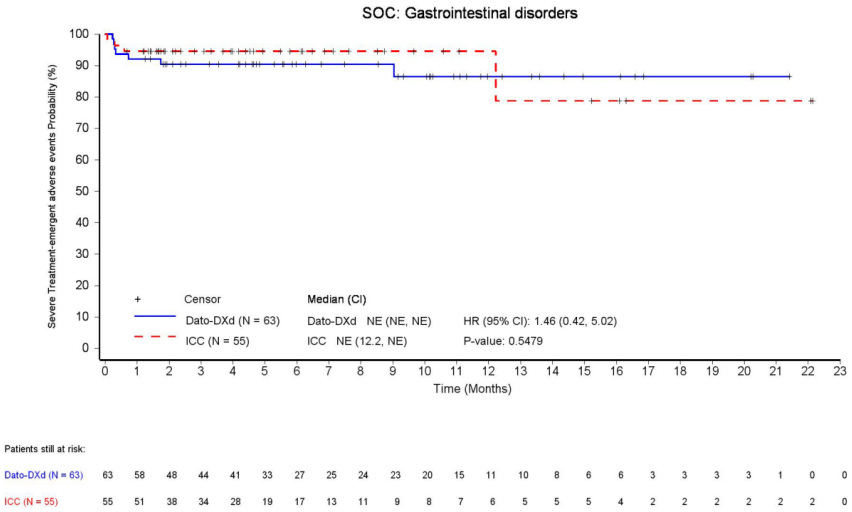
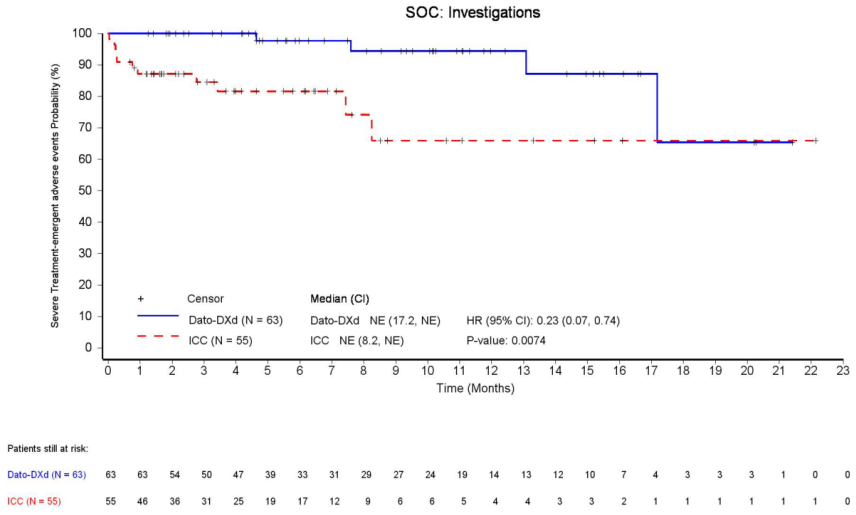
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



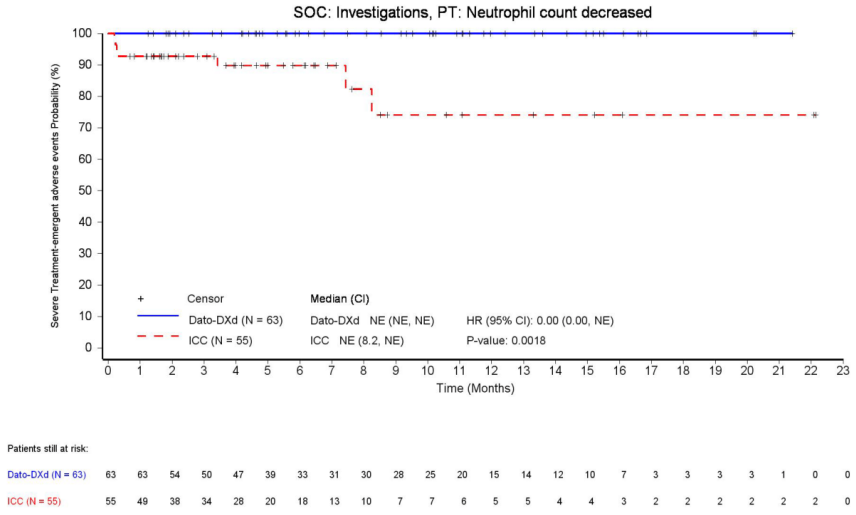
Patients still at risk:

Dato-DXd (N = 63)	63	63	54	50	47	39	33	31	29	27	24	19	14	13	12	10	7	4	3	3	3	1	0	0
ICC (N = 55)	55	46	36	31	25	19	17	12	9	6	6	5	4	4	3	3	2	1	1	1	1	1	1	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

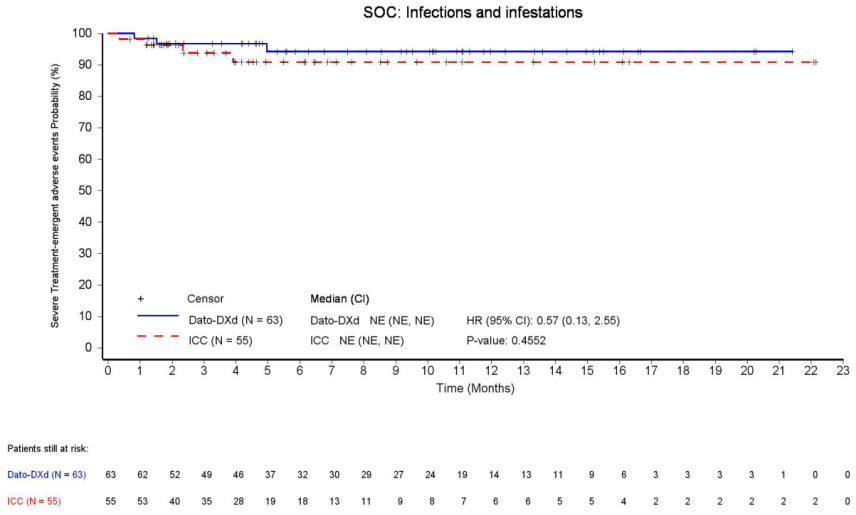
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

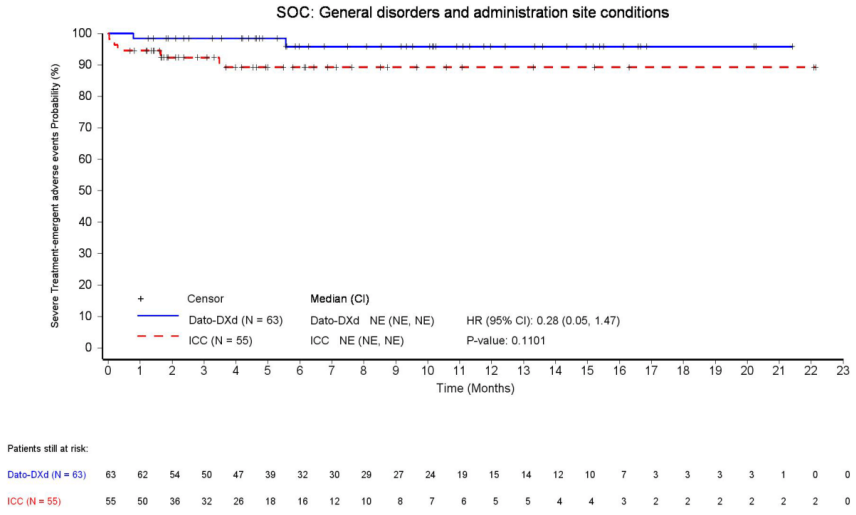
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

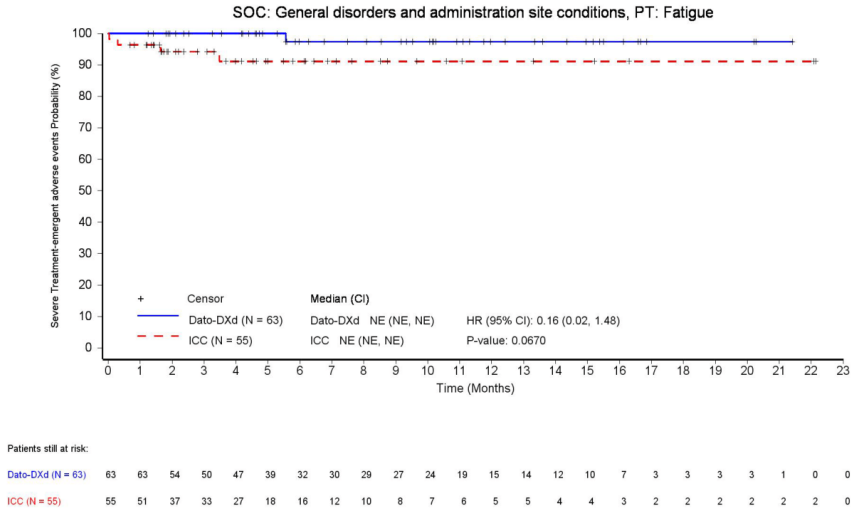
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

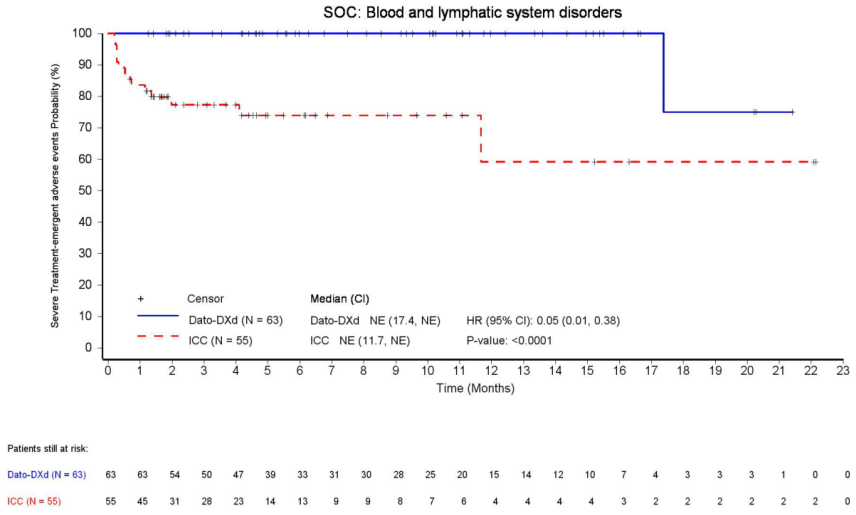
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

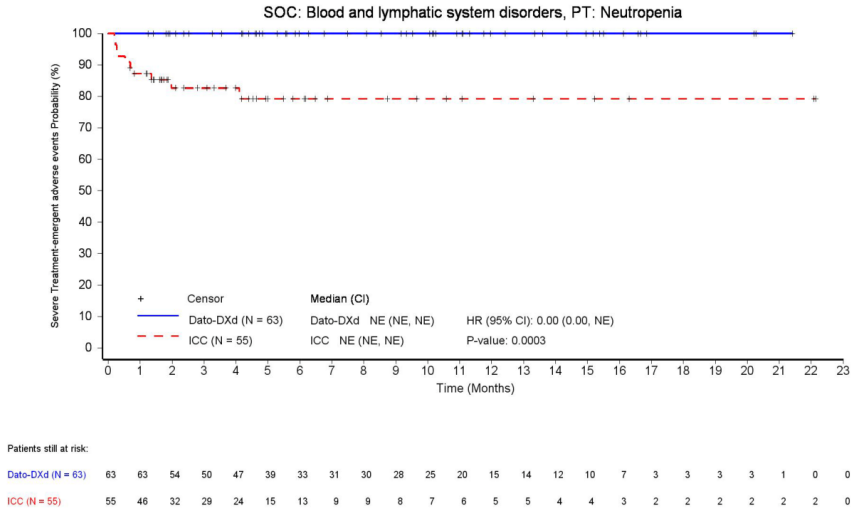
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

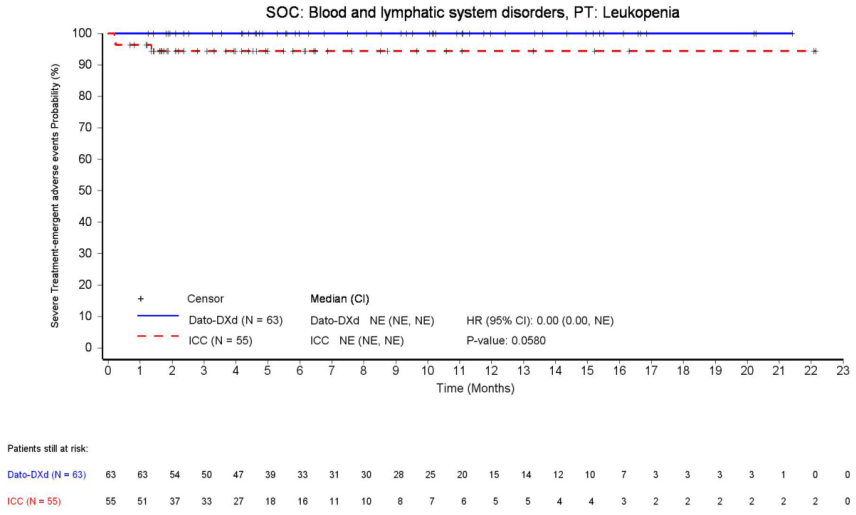
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

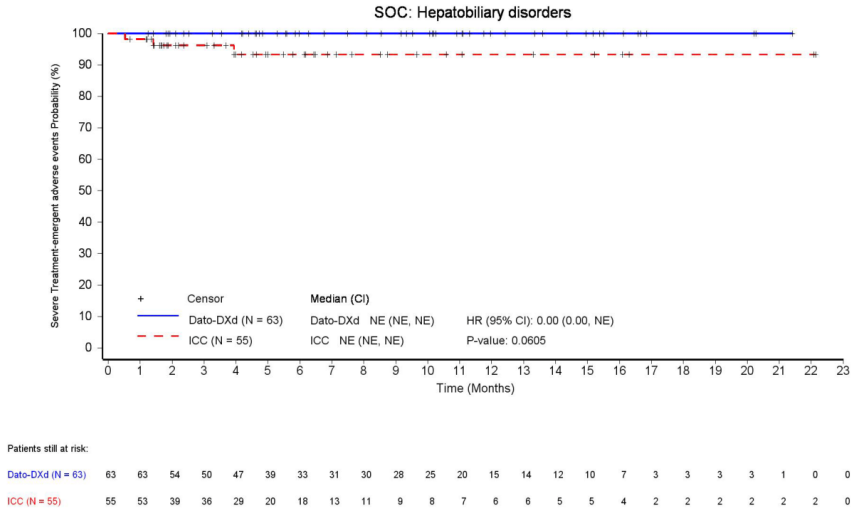
Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

Figure 4.57.3 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - DCO 24-Jul-2024 - Modified Safety Analysis Set A



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_1.sas; Output name: DE.F_TEAESEVSOCPT2_mSASA_FA.rtf

Daiichi Sankyo
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Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Gastrointestinal disorders

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Infections and infestations

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: General disorders and administration site conditions, PT: Fatigue

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

Stopped at step 1

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Leukopenia

	Dato-DXd (N=63)	ICC (N=55)	Dato-DXd vs ICC
Number of subjects with events, n (%)	0	3 (5.5)	
Number of subjects censored, n (%)	63 (100)	52 (94.5)	
Median time to first event (months) [a]	NE	NE	
85% Confidence Interval	(NE, NE)	(NE, NE)	
Cox proportional hazards model [b]			
Hazard Ratio			0.00
85% Confidence Interval			(0.00, NE)
Stratified log-rank p-value [c]			0.0580

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Table 4.74.5 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - Increased significance level - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Hepatobiliary disorders

Stopped at step 2

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 15MAY2025 - 11:34; Program name: t_4_73_1.sas; Output name: DE.T_TEAESEVSOCPTINC2_mSASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Gastrointestinal disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.7640
mSASA	63	7 (11.1)	56 (88.9)	NE (NE, NE)	55	4 (7.3)	51 (92.7)	NE (12.2 , NE)	1.36 (0.39, 4.68)	0.6260	
non-mSASA	265	37 (14.0)	228 (86.0)	NE (NE, NE)	265	19 (7.2)	246 (92.8)	NE (NE, NE)	1.68 (0.96, 2.94)	0.0637	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9444
mSASA	63	4 (6.3)	59 (93.7)	NE (17.2 , NE)	55	11 (20.0)	44 (80.0)	NE (8.2 , NE)	0.19 (0.06, 0.62)	0.0023	
non-mSASA	265	21 (7.9)	244 (92.1)	NE (NE, NE)	265	64 (24.2)	201 (75.8)	NE (NE, NE)	0.26 (0.16, 0.42)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9835
mSASA	63	0	63 (100)	NE (NE, NE)	55	7 (12.7)	48 (87.3)	NE (8.2 , NE)	0.00 (0.00, NE)	0.0009	
non-mSASA	265	3 (1.1)	262 (98.9)	NE (NE, NE)	265	45 (17.0)	220 (83.0)	NE (NE, NE)	0.06 (0.02, 0.18)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Infections and infestations

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.5597
mSASA	63	3 (4.8)	60 (95.2)	NE (NE, NE)	55	4 (7.3)	51 (92.7)	NE (NE, NE)	0.56 (0.12, 2.51)	0.4403	
non-mSASA	265	19 (7.2)	246 (92.8)	NE (NE, NE)	265	17 (6.4)	248 (93.6)	NE (20.8 , NE)	0.86 (0.44, 1.67)	0.6598	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.0577
mSASA	63	2 (3.2)	61 (96.8)	NE (NE, NE)	55	5 (9.1)	50 (90.9)	NE (NE, NE)	0.29 (0.05, 1.49)	0.1132	
non-mSASA	265	15 (5.7)	250 (94.3)	NE (NE, NE)	265	8 (3.0)	257 (97.0)	NE (NE, NE)	1.47 (0.62, 3.50)	0.3780	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: General disorders and administration site conditions, PT: Fatigue

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.0658
mSASA	63	1 (1.6)	62 (98.4)	NE (NE, NE)	55	4 (7.3)	51 (92.7)	NE (NE, NE)	0.17 (0.02, 1.53)	0.0739	
non-mSASA	265	7 (2.6)	258 (97.4)	NE (NE, NE)	265	3 (1.1)	262 (98.9)	NE (NE, NE)	1.91 (0.49, 7.50)	0.3434	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.4817
mSASA	63	1 (1.6)	62 (98.4)	NE (17.4 , NE)	55	14 (25.5)	41 (74.5)	NE (11.7 , NE)	0.05 (0.01, 0.36)	<0.0001	
non-mSASA	265	9 (3.4)	256 (96.6)	NE (NE, NE)	265	68 (25.7)	197 (74.3)	NE (NE, NE)	0.11 (0.05, 0.21)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9844
mSASA	63	0	63 (100)	NE (NE, NE)	55	10 (18.2)	45 (81.8)	NE (NE, NE)	0.00 (0.00, NE)	0.0003	
non-mSASA	265	1 (0.4)	264 (99.6)	NE (NE, NE)	265	50 (18.9)	215 (81.1)	NE (NE, NE)	0.02 (0.00, 0.12)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Blood and lymphatic system disorders, PT: Leukopenia

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											>0.9999
mSASA	63	0	63 (100)	NE (NE, NE)	55	3 (5.5)	52 (94.5)	NE (NE, NE)	0.00 (0.00, NE)	0.0586	
non-mSASA	265	0	265 (100)	NE (NE, NE)	265	8 (3.0)	257 (97.0)	NE (NE, NE)	0.00 (0.00, NE)	0.0023	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Table 4.74.6 Severe Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) with incidence ≥ 5% in at least one arm - Time-to-event analysis - DCO 24-Jul-2024 - mSASA vs non-mSASA

SOC: Hepatobiliary disorders

	Dato-DXd (N=328)				ICC (N=320)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
mSASA vs non-mSASA											0.9948
mSASA	63	0	63 (100)	NE (NE, NE)	55	3 (5.5)	52 (94.5)	NE (NE, NE)	0.00 (0.00, NE)	0.0513	
non-mSASA	265	2 (0.8)	263 (99.2)	NE (NE, NE)	265	0	265 (100)	NE (NE, NE)	NE (NE, NE)	0.2945	

N: number of subjects in analysis set; n: number of subjects in subgroup category %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable.PT: Preferred Term, SOC: System Organ Class.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.
The non-mSASA consists of all patients in mSAS not included into mSASA

Data source: ADAM.ADAE
Run date: 16MAY2025 - 15:03; Program name: t_4_74_6.sas; Output name: DE.T_TEAESEVSOCPT2_mSASA_vs_non-mSASA_FA.rtf

Schwere UE (CTCAE-Grad ≥3) nach SOC und PT – Subgruppenanalysen

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	4 (12.1)	29 (87.9)	-	28	2 (7.1)	26 (92.9)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	9 (33.3)	18 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9919
Yes	52	4 (7.7)	48 (92.3)	NE (17.2, NE)	45	7 (15.6)	38 (84.4)	NE (8.2, NE)	0.30 (0.09, 1.05)	0.0476	
No	11	0	11 (100)	NE (NE, NE)	10	4 (40.0)	6 (60.0)	NE (0.0, NE)	0.00 (0.00, NE)	0.0229	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	3 (9.4)	29 (90.6)	-	30	5 (16.7)	25 (83.3)	-	-	-	
Neither taxanes nor anthracyclines	11	1 (9.1)	10 (90.9)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.3322
<65 years	52	2 (3.8)	50 (96.2)	NE (13.1, NE)	41	8 (19.5)	33 (80.5)	NE (7.4, NE)	0.13 (0.03, 0.61)	0.0027	
≥65 years	11	2 (18.2)	9 (81.8)	17.2 (7.6, NE)	14	3 (21.4)	11 (78.6)	NE (8.2, NE)	0.27 (0.03, 2.65)	0.2284	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	8 (38.1)	13 (61.9)	-	-	-	
Non-Asian	32	3 (9.4)	29 (90.6)	-	26	3 (11.5)	23 (88.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											0.5396
Capecitabine	21	2 (9.5)	19 (90.5)	NE (NE, NE)	9	1 (11.1)	8 (88.9)	NE (7.4, NE)	0.72 (0.07, 7.96)	0.7874	
Eribulin mesylate	31	2 (6.5)	29 (93.5)	17.2 (13.1, NE)	41	10 (24.4)	31 (75.6)	NE (8.2, NE)	0.09 (0.01, 0.70)	0.0046	
Vinorelbine	11	0	11 (100)	NE (NE, NE)	5	0	5 (100)	NE (NE, NE)	NE (NE, NE)	NE	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9924
Yes	6	0	6 (100)	NE (NE, NE)	6	3 (50.0)	3 (50.0)	7.4 (0.0, NE)	0.00 (0.00, NE)	0.0436	
No	57	4 (7.0)	53 (93.0)	NE (17.2, NE)	49	8 (16.3)	41 (83.7)	NE (8.2, NE)	0.27 (0.08, 0.93)	0.0267	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	1 (100)	0	-	-	-	
Female	62	4 (6.5)	58 (93.5)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	3 (9.7)	28 (90.3)	-	24	3 (12.5)	21 (87.5)	-	-	-	
Asian	21	0	21 (100)	-	21	8 (38.1)	13 (61.9)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	2 (5.7)	33 (94.3)	-	33	7 (21.2)	26 (78.8)	-	-	-	
≥1	28	2 (7.1)	26 (92.9)	-	22	4 (18.2)	18 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	4 (8.2)	45 (91.8)	-	42	9 (21.4)	33 (78.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	1 (4.5)	21 (95.5)	-	19	4 (21.1)	15 (78.9)	-	-	-	
>12 months	29	3 (10.3)	26 (89.7)	-	27	3 (11.1)	24 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	4 (6.8)	55 (93.2)	-	55	11 (20.0)	44 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	1 (3.6)	27 (96.4)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	6 (22.2)	21 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	5 (11.1)	40 (88.9)	-	-	-	
No	11	0	11 (100)	-	10	2 (20.0)	8 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	2 (15.4)	11 (84.6)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	0	3 (100)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	4 (13.3)	26 (86.7)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	1 (11.1)	8 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	5 (12.2)	36 (87.8)	-	-	-	
≥65 years	11	0	11 (100)	-	14	2 (14.3)	12 (85.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	1 (3.8)	25 (96.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	1 (11.1)	8 (88.9)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	6 (14.6)	35 (85.4)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	0	5 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases*											-
Yes	6	0	6 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
No	57	0	57 (100)	-	49	6 (12.2)	43 (87.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	1 (100)	0	-	-	-	
Female	62	0	62 (100)	-	54	6 (11.1)	48 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	1 (4.2)	23 (95.8)	-	-	-	
Asian	21	0	21 (100)	-	21	6 (28.6)	15 (71.4)	-	-	-	
Other*	1	0	1 (100)	-	2	0	2 (100)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	5 (15.2)	28 (84.8)	-	-	-	
≥1	28	0	28 (100)	-	22	2 (9.1)	20 (90.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	0	49 (100)	-	42	5 (11.9)	37 (88.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	3 (15.8)	16 (84.2)	-	-	-	
>12 months	29	0	29 (100)	-	27	2 (7.4)	25 (92.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Investigations, PT: Neutrophil count decreased

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	7 (12.7)	48 (87.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region											0.9920
Region 1 [US, Canada, Europe]	33	1 (3.0)	32 (97.0)	NE (17.4, NE)	28	9 (32.1)	19 (67.9)	NE (2.0, NE)	0.07 (0.01, 0.57)	0.0012	
Region 2 [Rest of World]	30	0	30 (100)	NE (NE, NE)	27	5 (18.5)	22 (81.5)	NE (11.7, NE)	0.00 (0.00, NE)	0.0085	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor											0.9953
Yes	52	1 (1.9)	51 (98.1)	NE (17.4, NE)	45	13 (28.9)	32 (71.1)	NE (11.7, NE)	0.05 (0.01, 0.35)	<0.0001	
No	11	0	11 (100)	NE (NE, NE)	10	1 (10.0)	9 (90.0)	NE (0.3, NE)	0.00 (0.00, NE)	0.2943	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	3 (23.1)	10 (76.9)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	1 (3.1)	31 (96.9)	-	30	8 (26.7)	22 (73.3)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization											0.9920
<65 years	52	0	52 (100)	NE (NE, NE)	41	12 (29.3)	29 (70.7)	NE (4.1, NE)	0.00 (0.00, NE)	<0.0001	
≥65 years	11	1 (9.1)	10 (90.9)	NE (17.4, NE)	14	2 (14.3)	12 (85.7)	NE (11.7, NE)	0.00 (0.00, NE)	0.0955	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	2 (9.5)	19 (90.5)	-	-	-	
Non-Asian	32	1 (3.1)	31 (96.9)	-	26	7 (26.9)	19 (73.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy											>0.9999
Capecitabine	21	0	21 (100)	NE (NE, NE)	9	0	9 (100)	NE (NE, NE)	NE (NE, NE)	NE	
Eribulin mesylate	31	1 (3.2)	30 (96.8)	17.4 (NE, NE)	41	13 (31.7)	28 (68.3)	11.7 (11.7, NE)	0.08 (0.01, 0.60)	0.0017	
Vinorelbine	11	0	11 (100)	NE (NE, NE)	5	1 (20.0)	4 (80.0)	NE (4.1, NE)	0.00 (0.00, NE)	0.0253	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9942
Yes	6	0	6 (100)	NE (NE, NE)	6	1 (16.7)	5 (83.3)	NE (1.1, NE)	0.00 (0.00, NE)	0.3173	
No	57	1 (1.8)	56 (98.2)	NE (17.4, NE)	49	13 (26.5)	36 (73.5)	NE (11.7, NE)	0.05 (0.01, 0.38)	<0.0001	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	1 (1.6)	61 (98.4)	-	54	14 (25.9)	40 (74.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	1 (3.2)	30 (96.8)	-	24	5 (20.8)	19 (79.2)	-	-	-	
Asian	21	0	21 (100)	-	21	2 (9.5)	19 (90.5)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	6 (18.2)	27 (81.8)	-	-	-	
≥1	28	1 (3.6)	27 (96.4)	-	22	8 (36.4)	14 (63.6)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	2 (33.3)	4 (66.7)	-	-	-	
≥6 months	49	1 (2.0)	48 (98.0)	-	42	10 (23.8)	32 (76.2)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	1 (4.5)	21 (95.5)	-	19	4 (21.1)	15 (78.9)	-	-	-	
>12 months	29	0	29 (100)	-	27	9 (33.3)	18 (66.7)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	1 (1.7)	58 (98.3)	-	55	14 (25.5)	41 (74.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Geographic region*											-
Region 1 [US, Canada, Europe]	33	0	33 (100)	-	28	7 (25.0)	21 (75.0)	-	-	-	
Region 2 [Rest of World]	30	0	30 (100)	-	27	3 (11.1)	24 (88.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of CDK4/6 inhibitor*											-
Yes	52	0	52 (100)	-	45	9 (20.0)	36 (80.0)	-	-	-	
No	11	0	11 (100)	-	10	1 (10.0)	9 (90.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Prior use of taxanes and/or anthracyclines*											-
Taxanes alone	19	0	19 (100)	-	13	1 (7.7)	12 (92.3)	-	-	-	
Anthracyclines alone	1	0	1 (100)	-	3	1 (33.3)	2 (66.7)	-	-	-	
Both taxanes and anthracyclines	32	0	32 (100)	-	30	6 (20.0)	24 (80.0)	-	-	-	
Neither taxanes nor anthracyclines	11	0	11 (100)	-	9	2 (22.2)	7 (77.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Age at randomization*											-
<65 years	52	0	52 (100)	-	41	9 (22.0)	32 (78.0)	-	-	-	
≥65 years	11	0	11 (100)	-	14	1 (7.1)	13 (92.9)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race Asian*											-
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Non-Asian	32	0	32 (100)	-	26	7 (26.9)	19 (73.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

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Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Pre-selected choice of chemotherapy*											-
Capecitabine	21	0	21 (100)	-	9	0	9 (100)	-	-	-	
Eribulin mesylate	31	0	31 (100)	-	41	9 (22.0)	32 (78.0)	-	-	-	
Vinorelbine	11	0	11 (100)	-	5	1 (20.0)	4 (80.0)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Brain metastases											0.9984
Yes	6	0	6 (100)	NE (NE, NE)	6	0	6 (100)	NE (NE, NE)	NE (NE, NE)	NE	
No	57	0	57 (100)	NE (NE, NE)	49	10 (20.4)	39 (79.6)	NE (NE, NE)	0.00 (0.00, NE)	0.0002	

N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Sex*											-
Male	1	0	1 (100)	-	1	0	1 (100)	-	-	-	
Female	62	0	62 (100)	-	54	10 (18.5)	44 (81.5)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Race*											-
White	31	0	31 (100)	-	24	5 (20.8)	19 (79.2)	-	-	-	
Asian	21	0	21 (100)	-	21	0	21 (100)	-	-	-	
Other*	1	0	1 (100)	-	2	2 (100)	0	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
* 'Black or African American' is included in this category.
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
ECOG PS at baseline*											-
0	35	0	35 (100)	-	33	5 (15.2)	28 (84.8)	-	-	-	
≥1	28	0	28 (100)	-	22	5 (22.7)	17 (77.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of endocrine therapy in the metastatic breast cancer setting*											-
<6 months	3	0	3 (100)	-	6	1 (16.7)	5 (83.3)	-	-	-	
≥6 months	49	0	49 (100)	-	42	7 (16.7)	35 (83.3)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Duration of prior use of breast cancer CDK4/6 inhibitor*											-
≤12 months	22	0	22 (100)	-	19	2 (10.5)	17 (89.5)	-	-	-	
>12 months	29	0	29 (100)	-	27	7 (25.9)	20 (74.1)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Table 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Time-to-event analysis - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: Blood and lymphatic system disorders, PT: Neutropenia

	Dato-DXd (N=63)				ICC (N=55)				Dato-DXd vs ICC		Interaction
	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	n	No. of subjects with events (%)	No. of subjects censored (%)	Median (95% CI) (months) [a]	Hazard Ratio (95% CI) [b]	Unstratified log-rank p-value [c]	P-value [d]
Early relapse*											-
Yes	4	0	4 (100)	-	0	0	0	-	-	-	
No	59	0	59 (100)	-	55	10 (18.2)	45 (81.8)	-	-	-	

* No summary displayed due to subgroup having less than 10 subjects
N: number of subjects in analysis set; n: number of subjects in subgroup category; %: proportion of number of subjects in n; CI: confidence interval; NE: not estimable; ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from unstratified Cox proportional hazards model with treatment as the only categorical variable in the model. Confidence limits are based on the Wald test.
[c] Two-sided p-value from unstratified log-rank test.
[d] Two-sided interaction p-value is for the interaction term from unstratified Cox proportional hazards model with treatment, subgroup, and treatment-by-subgroup interaction as categorical variables in the model. The p-value is based on the Wald test.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:10; Program name: t_4_67_2.sas; Output name: DE.T_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
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Figure 4.57.4 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) with incidence ≥ 5% in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 24-Jul-2024 - Modified Safety Analysis Set A

No data to be reported

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test
NE: not estimable , CI: confidence interval. ICC: Investigator's Choice of Chemotherapy.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 11:11; Program name: f_4_67_2.sas; Output name: DE.F_TEAESEVSOCPT2_SUB_mSASA_FA.rtf

Therapieabbruch aufgrund von UE nach SOC und PT

Therapieabbruch aufgrund von UE nach SOC und PT – Deskriptive Analysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01(DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 4.78.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) associated with treatment discontinuation - descriptive summary - DCO 24-Jul-2024 - Modified Safety Analysis Set A

SOC: System Organ Class PT: Perferred Term	Dato-DXd N=63 n (%)	ICC N=55 n (%)
Subjects with at least one any treatment-emergent adverse events associated with study drug discontinuation	2 (3.2)	4 (7.3)
SOC: Eye disorders	1 (1.6)	0
PT: Punctate keratitis	1 (1.6)	0
SOC: Gastrointestinal disorders	0	1 (1.8)
PT: Gastrointestinal haemorrhage	0	1 (1.8)
SOC: Hepatobiliary disorders	0	1 (1.8)
PT: Hepatic function abnormal	0	1 (1.8)
SOC: Infections and infestations	0	1 (1.8)
PT: COVID-19	0	1 (1.8)
SOC: Nervous system disorders	0	1 (1.8)
PT: Peripheral sensory neuropathy	0	1 (1.8)
SOC: Respiratory, thoracic and mediastinal disorders	1 (1.6)	0
PT: Pneumonitis	1 (1.6)	0

N: number of subjects in analysis set; %: Denominator is number of subjects in analysis set; NE: not estimable, ICC: Investigator's Choice of Chemotherapy.
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.
[b] Hazard ratio is from stratified Cox proportional hazards model, stratified by the randomization stratification factors. Confidence limits are based on the Wald test.
[c] Two-sided p-value from a stratified log-rank test using the same randomization stratification factors.

Data source: ADAM.ADAE
Run date: 06MAY2025 - 10:52; Program name: t_4_78_1.sas; Output name: DE.T_TEAEDISCDESC_mSASA_FA.rtf

Anhang 4-G: Weitere Analysen zum finalen Datenschnitt vom 24.07.2024

Therapieabbruch aufgrund von UE nach SOC und PT – Prüfung der Kriterien der Anhebungsregel

Die Analysen zum Therapieabbruch aufgrund von UE nach SOC und PT für die Anhebungsregel führten zu keinem verwertbaren Ergebnis. Es werden lediglich deskriptive Analysen dargestellt.

PRO-CTCAE

PRO-CTCAE – Rücklaufquoten

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Mouth/Throat Sores Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Mouth/Throat Sores Interference	Baseline	54	6 (11.1)	47	4 (8.5)
	Week 1	54	14 (25.9)	44	8 (18.2)
	Week 2	54	21 (38.9)	44	12 (27.3)
	Week 3	52	20 (38.5)	44	10 (22.7)
	Week 4	46	13 (28.3)	43	11 (25.6)
	Week 5	47	13 (27.7)	36	9 (25.0)
	Week 6	46	15 (32.6)	31	6 (19.4)
	Week 7	43	13 (30.2)	29	9 (31.0)
	Week 8	43	17 (39.5)	28	10 (35.7)
	Week 9	43	18 (41.9)	28	7 (25.0)
	Week 10	42	12 (28.6)	28	7 (25.0)
	Week 11	42	12 (28.6)	27	5 (18.5)
	Week 12	41	24 (58.5)	27	9 (33.3)
	Week 15	38	18 (47.4)	22	7 (31.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	13 (39.4)	16	5 (31.3)
	Week 21	32	13 (40.6)	16	8 (50.0)
	Week 24	28	12 (42.9)	13	5 (38.5)
	Week 27	26	13 (50.0)	10	4 (40.0)
	Week 30	25	12 (48.0)	10	4 (40.0)
	Week 33	23	11 (47.8)	8	5 (62.5)
	Week 36	24	13 (54.2)	8	6 (75.0)
	Week 39	21	10 (47.6)	7	3 (42.9)
	Week 42	17	4 (23.5)	6	4 (66.7)
	Week 45	13	4 (30.8)	6	3 (50.0)
	Week 48	11	3 (27.3)	5	2 (40.0)
	Week 51	11	1 (9.1)	5	1 (20.0)
	Week 54	10	3 (30.0)	4	2 (50.0)
	Week 57	10	2 (20.0)	4	0
	Week 60	9	3 (33.3)	3	1 (33.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	1 (16.7)	3	0
	Week 66	4	1 (25.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	0	2	1 (50.0)
	Week 75	2	1 (50.0)	2	0
	Week 78	2	1 (50.0)	2	1 (50.0)
	Week 81	2	1 (50.0)	2	1 (50.0)
	Week 84	1	0	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	55	11 (20.0)	45	8 (17.8)
	Baseline and at least one post baseline [c]		6 (9.5)		4 (7.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Decreased Appetite Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Decreased Appetite Interference	Baseline	54	10 (18.5)	47	9 (19.1)
	Week 1	55	21 (38.2)	44	14 (31.8)
	Week 2	55	20 (36.4)	44	18 (40.9)
	Week 3	53	16 (30.2)	44	18 (40.9)
	Week 4	47	22 (46.8)	43	18 (41.9)
	Week 5	47	11 (23.4)	36	18 (50.0)
	Week 6	46	12 (26.1)	31	11 (35.5)
	Week 7	43	18 (41.9)	30	14 (46.7)
	Week 8	43	13 (30.2)	28	14 (50.0)
	Week 9	43	13 (30.2)	28	12 (42.9)
	Week 10	42	18 (42.9)	29	14 (48.3)
	Week 11	42	12 (28.6)	27	13 (48.1)
	Week 12	41	11 (26.8)	27	10 (37.0)
	Week 15	38	10 (26.3)	22	11 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	8 (24.2)	16	4 (25.0)
	Week 21	32	9 (28.1)	16	6 (37.5)
	Week 24	28	11 (39.3)	13	3 (23.1)
	Week 27	26	8 (30.8)	10	4 (40.0)
	Week 30	25	10 (40.0)	10	2 (20.0)
	Week 33	23	7 (30.4)	8	3 (37.5)
	Week 36	24	8 (33.3)	8	5 (62.5)
	Week 39	21	7 (33.3)	7	2 (28.6)
	Week 42	17	4 (23.5)	6	4 (66.7)
	Week 45	13	5 (38.5)	6	1 (16.7)
	Week 48	11	4 (36.4)	5	1 (20.0)
	Week 51	11	3 (27.3)	5	1 (20.0)
	Week 54	10	3 (30.0)	4	1 (25.0)
	Week 57	10	3 (30.0)	4	0
	Week 60	9	3 (33.3)	3	0

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	2 (33.3)	3	0
	Week 66	4	1 (25.0)	2	1 (50.0)
	Week 69	3	1 (33.3)	2	0
	Week 72	2	0	2	1 (50.0)
	Week 75	2	1 (50.0)	2	1 (50.0)
	Week 78	2	1 (50.0)	2	1 (50.0)
	Week 81	2	1 (50.0)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	54	11 (20.4)	45	10 (22.2)
	Baseline and at least one post baseline [c]		10 (15.9)		9 (16.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Nausea Frequency	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Nausea Severity	Baseline	54	11 (20.4)	47	9 (19.1)
	Week 1	55	26 (47.3)	44	11 (25.0)
	Week 2	54	19 (35.2)	44	16 (36.4)
	Week 3	52	17 (32.7)	44	11 (25.0)
	Week 4	47	21 (44.7)	43	16 (37.2)
	Week 5	46	15 (32.6)	36	15 (41.7)
	Week 6	45	10 (22.2)	31	6 (19.4)
	Week 7	43	15 (34.9)	29	11 (37.9)
	Week 8	42	12 (28.6)	28	10 (35.7)
	Week 9	42	9 (21.4)	28	5 (17.9)
	Week 10	42	16 (38.1)	28	7 (25.0)
	Week 11	41	12 (29.3)	27	10 (37.0)
	Week 12	40	15 (37.5)	27	6 (22.2)
	Week 15	38	11 (28.9)	22	11 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	6 (18.8)	16	3 (18.8)
	Week 21	31	2 (6.5)	16	5 (31.3)
	Week 24	27	3 (11.1)	13	3 (23.1)
	Week 27	25	4 (16.0)	10	3 (30.0)
	Week 30	23	7 (30.4)	10	3 (30.0)
	Week 33	22	3 (13.6)	8	2 (25.0)
	Week 36	23	6 (26.1)	8	4 (50.0)
	Week 39	20	4 (20.0)	7	2 (28.6)
	Week 42	17	2 (11.8)	6	4 (66.7)
	Week 45	13	5 (38.5)	6	1 (16.7)
	Week 48	11	1 (9.1)	5	0
	Week 51	11	1 (9.1)	5	1 (20.0)
	Week 54	10	1 (10.0)	4	1 (25.0)
	Week 57	10	1 (10.0)	4	0
	Week 60	9	1 (11.1)	3	1 (33.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	2 (33.3)	3	0
	Week 66	4	1 (25.0)	2	1 (50.0)
	Week 69	3	1 (33.3)	2	1 (50.0)
	Week 72	2	0	2	1 (50.0)
	Week 75	2	1 (50.0)	2	1 (50.0)
	Week 78	2	1 (50.0)	2	1 (50.0)
	Week 81	2	1 (50.0)	2	1 (50.0)
	Week 84	1	0	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	54	12 (22.2)	45	6 (13.3)
	Baseline and at least one post baseline [c]		11 (17.5)		8 (14.5)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Vomiting Frequency	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Vomiting Severity	Baseline	54	7 (13.0)	47	4 (8.5)
	Week 1	54	11 (20.4)	44	3 (6.8)
	Week 2	54	7 (13.0)	44	4 (9.1)
	Week 3	52	6 (11.5)	44	3 (6.8)
	Week 4	46	10 (21.7)	43	4 (9.3)
	Week 5	46	7 (15.2)	36	6 (16.7)
	Week 6	45	4 (8.9)	31	0
	Week 7	42	9 (21.4)	29	0
	Week 8	42	6 (14.3)	28	2 (7.1)
	Week 9	42	3 (7.1)	28	0
	Week 10	41	8 (19.5)	28	1 (3.6)
	Week 11	41	7 (17.1)	27	1 (3.7)
	Week 12	40	5 (12.5)	27	2 (7.4)
	Week 15	37	3 (8.1)	22	2 (9.1)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	4 (12.5)	16	2 (12.5)
	Week 21	31	2 (6.5)	16	1 (6.3)
	Week 24	27	2 (7.4)	13	1 (7.7)
	Week 27	25	2 (8.0)	10	1 (10.0)
	Week 30	23	2 (8.7)	10	1 (10.0)
	Week 33	22	1 (4.5)	8	1 (12.5)
	Week 36	23	5 (21.7)	8	2 (25.0)
	Week 39	20	1 (5.0)	7	0
	Week 42	17	2 (11.8)	6	2 (33.3)
	Week 45	13	2 (15.4)	6	0
	Week 48	11	0	5	0
	Week 51	11	0	5	0
	Week 54	10	0	4	0
	Week 57	10	1 (10.0)	4	0
	Week 60	9	1 (11.1)	3	1 (33.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	1 (16.7)	3	0
	Week 66	4	0	2	0
	Week 69	3	0	2	0
	Week 72	2	0	2	0
	Week 75	2	0	2	0
	Week 78	2	0	2	0
	Week 81	2	0	2	0
	Week 84	1	0	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	54	8 (14.8)	45	5 (11.1)
	Baseline and at least one post baseline [c]		6 (9.5)		3 (5.5)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Constipation Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Diarrhea Frequency	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Abdominal Pain Frequency	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
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Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

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Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Abdominal Pain Severity	Baseline	54	13 (24.1)	47	10 (21.3)
	Week 1	55	15 (27.3)	44	8 (18.2)
	Week 2	54	10 (18.5)	44	16 (36.4)
	Week 3	52	13 (25.0)	44	19 (43.2)
	Week 4	46	12 (26.1)	43	16 (37.2)
	Week 5	46	8 (17.4)	36	15 (41.7)
	Week 6	45	9 (20.0)	31	8 (25.8)
	Week 7	42	8 (19.0)	30	10 (33.3)
	Week 8	42	11 (26.2)	28	12 (42.9)
	Week 9	42	9 (21.4)	28	9 (32.1)
	Week 10	41	11 (26.8)	29	10 (34.5)
	Week 11	41	8 (19.5)	27	9 (33.3)
	Week 12	40	14 (35.0)	27	10 (37.0)
	Week 15	37	10 (27.0)	22	11 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	10 (31.3)	16	5 (31.3)
	Week 21	31	8 (25.8)	16	8 (50.0)
	Week 24	27	8 (29.6)	13	6 (46.2)
	Week 27	25	5 (20.0)	10	6 (60.0)
	Week 30	23	5 (21.7)	10	6 (60.0)
	Week 33	22	4 (18.2)	8	5 (62.5)
	Week 36	22	5 (22.7)	8	8 (100)
	Week 39	20	4 (20.0)	7	5 (71.4)
	Week 42	17	1 (5.9)	6	4 (66.7)
	Week 45	13	3 (23.1)	6	4 (66.7)
	Week 48	11	1 (9.1)	5	2 (40.0)
	Week 51	11	1 (9.1)	5	2 (40.0)
	Week 54	10	1 (10.0)	4	1 (25.0)
	Week 57	10	1 (10.0)	4	1 (25.0)
	Week 60	9	1 (11.1)	3	1 (33.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 63	6	2 (33.3)	3	0
	Week 66	4	1 (25.0)	2	1 (50.0)
	Week 69	3	1 (33.3)	2	1 (50.0)
	Week 72	2	0	2	1 (50.0)
	Week 75	2	1 (50.0)	2	1 (50.0)
	Week 78	2	1 (50.0)	2	1 (50.0)
	Week 81	2	0	2	1 (50.0)
	Week 84	1	0	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	54	8 (14.8)	45	9 (20.0)
	Baseline and at least one post baseline [c]		13 (20.6)		10 (18.2)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Abdominal Pain Interference	Baseline	54	13 (24.1)	47	9 (19.1)
	Week 1	54	14 (25.9)	44	8 (18.2)
	Week 2	54	10 (18.5)	44	15 (34.1)
	Week 3	52	12 (23.1)	44	19 (43.2)
	Week 4	46	12 (26.1)	43	16 (37.2)
	Week 5	46	8 (17.4)	36	15 (41.7)
	Week 6	45	8 (17.8)	31	6 (19.4)
	Week 7	42	7 (16.7)	30	10 (33.3)
	Week 8	42	10 (23.8)	28	10 (35.7)
	Week 9	42	7 (16.7)	28	8 (28.6)
	Week 10	41	11 (26.8)	29	10 (34.5)
	Week 11	41	7 (17.1)	27	8 (29.6)
	Week 12	40	14 (35.0)	27	10 (37.0)
	Week 15	37	9 (24.3)	22	11 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	9 (28.1)	16	5 (31.3)
	Week 21	31	6 (19.4)	16	8 (50.0)
	Week 24	27	8 (29.6)	13	5 (38.5)
	Week 27	25	5 (20.0)	10	6 (60.0)
	Week 30	23	5 (21.7)	10	6 (60.0)
	Week 33	22	2 (9.1)	8	5 (62.5)
	Week 36	22	5 (22.7)	8	8 (100)
	Week 39	20	3 (15.0)	7	5 (71.4)
	Week 42	17	1 (5.9)	6	4 (66.7)
	Week 45	13	3 (23.1)	6	4 (66.7)
	Week 48	11	1 (9.1)	5	2 (40.0)
	Week 51	11	1 (9.1)	5	2 (40.0)
	Week 54	10	1 (10.0)	4	1 (25.0)
	Week 57	10	1 (10.0)	4	1 (25.0)
	Week 60	9	0	3	1 (33.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	1 (16.7)	3	0
	Week 66	4	0	2	1 (50.0)
	Week 69	3	0	2	1 (50.0)
	Week 72	2	0	2	1 (50.0)
	Week 75	2	0	2	1 (50.0)
	Week 78	2	1 (50.0)	2	1 (50.0)
	Week 81	2	0	2	1 (50.0)
	Week 84	1	0	2	0
	Week 87	1	0	2	0
	Week 90	0	0	2	0
	End of Treatment	54	8 (14.8)	45	9 (20.0)
	Baseline and at least one post baseline [c]		13 (20.6)		9 (16.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Shortness of Breath Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Shortness of Breath Interference	Baseline	54	12 (22.2)	47	9 (19.1)
	Week 1	54	10 (18.5)	44	12 (27.3)
	Week 2	54	9 (16.7)	44	14 (31.8)
	Week 3	52	12 (23.1)	44	18 (40.9)
	Week 4	46	8 (17.4)	43	16 (37.2)
	Week 5	46	6 (13.0)	36	14 (38.9)
	Week 6	45	7 (15.6)	31	11 (35.5)
	Week 7	42	7 (16.7)	30	10 (33.3)
	Week 8	42	10 (23.8)	28	10 (35.7)
	Week 9	42	10 (23.8)	28	7 (25.0)
	Week 10	41	9 (22.0)	29	7 (24.1)
	Week 11	41	4 (9.8)	27	9 (33.3)
	Week 12	40	16 (40.0)	27	9 (33.3)
	Week 15	37	8 (21.6)	22	10 (45.5)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	9 (28.1)	16	2 (12.5)
	Week 21	31	9 (29.0)	16	4 (25.0)
	Week 24	27	5 (18.5)	13	5 (38.5)
	Week 27	25	6 (24.0)	10	1 (10.0)
	Week 30	23	6 (26.1)	10	6 (60.0)
	Week 33	22	6 (27.3)	8	2 (25.0)
	Week 36	23	6 (26.1)	8	4 (50.0)
	Week 39	20	7 (35.0)	7	3 (42.9)
	Week 42	17	2 (11.8)	6	4 (66.7)
	Week 45	13	4 (30.8)	6	3 (50.0)
	Week 48	11	2 (18.2)	5	0
	Week 51	11	0	5	0
	Week 54	10	2 (20.0)	4	0
	Week 57	10	1 (10.0)	4	0
	Week 60	9	0	3	0

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	0	3	0
	Week 66	4	1 (25.0)	2	0
	Week 69	3	1 (33.3)	2	0
	Week 72	2	0	2	0
	Week 75	2	0	2	0
	Week 78	2	2 (100)	2	0
	Week 81	2	1 (50.0)	2	0
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	54	7 (13.0)	45	12 (26.7)
	Baseline and at least one post baseline [c]		11 (17.5)		9 (16.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Cough Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Cough Interference	Baseline	54	8 (14.8)	47	9 (19.1)
	Week 1	54	11 (20.4)	44	12 (27.3)
	Week 2	54	9 (16.7)	44	12 (27.3)
	Week 3	52	10 (19.2)	44	12 (27.3)
	Week 4	46	9 (19.6)	43	13 (30.2)
	Week 5	46	7 (15.2)	36	10 (27.8)
	Week 6	45	12 (26.7)	31	10 (32.3)
	Week 7	42	9 (21.4)	30	9 (30.0)
	Week 8	42	14 (33.3)	28	10 (35.7)
	Week 9	42	10 (23.8)	28	8 (28.6)
	Week 10	41	8 (19.5)	29	13 (44.8)
	Week 11	41	7 (17.1)	27	10 (37.0)
	Week 12	40	11 (27.5)	27	9 (33.3)
	Week 15	37	12 (32.4)	22	9 (40.9)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	32	11 (34.4)	16	3 (18.8)
	Week 21	31	9 (29.0)	16	5 (31.3)
	Week 24	27	5 (18.5)	13	4 (30.8)
	Week 27	25	5 (20.0)	10	2 (20.0)
	Week 30	23	6 (26.1)	10	5 (50.0)
	Week 33	22	5 (22.7)	8	3 (37.5)
	Week 36	22	8 (36.4)	8	3 (37.5)
	Week 39	20	6 (30.0)	7	2 (28.6)
	Week 42	17	3 (17.6)	6	3 (50.0)
	Week 45	13	5 (38.5)	6	2 (33.3)
	Week 48	11	3 (27.3)	5	0
	Week 51	11	3 (27.3)	5	0
	Week 54	10	1 (10.0)	4	0
	Week 57	10	2 (20.0)	4	0
	Week 60	9	2 (22.2)	3	0

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	1 (16.7)	3	0
	Week 66	4	0	2	0
	Week 69	3	0	2	0
	Week 72	2	0	2	0
	Week 75	2	0	2	0
	Week 78	2	1 (50.0)	2	0
	Week 81	2	0	2	1 (50.0)
	Week 84	1	0	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	54	6 (11.1)	45	7 (15.6)
	Baseline and at least one post baseline [c]		8 (12.7)		9 (16.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Rash Presence	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Hair Loss Amount	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Hand-Foot Syndrome Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Numbness & Tingling Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Numbness & Tingling Interference	Baseline	54	15 (27.8)	47	15 (31.9)
	Week 1	54	10 (18.5)	44	17 (38.6)
	Week 2	54	14 (25.9)	44	21 (47.7)
	Week 3	52	15 (28.8)	44	22 (50.0)
	Week 4	46	13 (28.3)	43	23 (53.5)
	Week 5	46	14 (30.4)	36	17 (47.2)
	Week 6	46	14 (30.4)	31	16 (51.6)
	Week 7	42	9 (21.4)	30	18 (60.0)
	Week 8	42	10 (23.8)	28	15 (53.6)
	Week 9	42	12 (28.6)	28	16 (57.1)
	Week 10	41	8 (19.5)	29	18 (62.1)
	Week 11	41	9 (22.0)	27	15 (55.6)
	Week 12	40	15 (37.5)	27	18 (66.7)
	Week 15	37	9 (24.3)	22	17 (77.3)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	32	12 (37.5)	16	7 (43.8)
	Week 21	31	8 (25.8)	16	8 (50.0)
	Week 24	27	7 (25.9)	13	7 (53.8)
	Week 27	25	6 (24.0)	10	6 (60.0)
	Week 30	23	8 (34.8)	10	7 (70.0)
	Week 33	22	5 (22.7)	8	5 (62.5)
	Week 36	22	5 (22.7)	8	7 (87.5)
	Week 39	20	4 (20.0)	7	4 (57.1)
	Week 42	17	4 (23.5)	6	5 (83.3)
	Week 45	13	5 (38.5)	6	4 (66.7)
	Week 48	11	3 (27.3)	5	1 (20.0)
	Week 51	11	3 (27.3)	5	2 (40.0)
	Week 54	10	3 (30.0)	4	2 (50.0)
	Week 57	10	3 (30.0)	4	1 (25.0)
	Week 60	9	4 (44.4)	4	1 (25.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	3 (50.0)	3	0
	Week 66	4	3 (75.0)	2	0
	Week 69	3	2 (66.7)	2	0
	Week 72	2	1 (50.0)	2	0
	Week 75	2	1 (50.0)	2	0
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	0
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	54	6 (11.1)	45	15 (33.3)
	Baseline and at least one post baseline [c]		14 (22.2)		13 (23.6)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Fatigue Severity	Baseline	55	44 (80.0)	47	32 (68.1)
	Week 1	55	34 (61.8)	44	30 (68.2)
	Week 2	55	37 (67.3)	44	31 (70.5)
	Week 3	53	42 (79.2)	44	34 (77.3)
	Week 4	47	31 (66.0)	43	34 (79.1)
	Week 5	47	29 (61.7)	36	27 (75.0)
	Week 6	46	35 (76.1)	31	22 (71.0)
	Week 7	43	29 (67.4)	30	24 (80.0)
	Week 8	43	29 (67.4)	28	23 (82.1)
	Week 9	43	35 (81.4)	28	20 (71.4)
	Week 10	42	25 (59.5)	29	22 (75.9)
	Week 11	42	26 (61.9)	27	19 (70.4)
	Week 12	41	36 (87.8)	27	22 (81.5)
	Week 15	39	33 (84.6)	22	18 (81.8)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63) Number of expected questionnaires [b]	Dato-DXd (N=63) Number of subjects with completed questionnaires n(%)	ICC (N=55) Number of expected questionnaires [b]	ICC (N=55) Number of subjects with completed questionnaires n(%)
	Week 18	33	26 (78.8)	16	9 (56.3)
	Week 21	32	23 (71.9)	16	12 (75.0)
	Week 24	28	23 (82.1)	13	9 (69.2)
	Week 27	26	19 (73.1)	10	7 (70.0)
	Week 30	25	21 (84.0)	10	8 (80.0)
	Week 33	23	18 (78.3)	8	6 (75.0)
	Week 36	24	19 (79.2)	8	8 (100)
	Week 39	21	16 (76.2)	7	6 (85.7)
	Week 42	17	9 (52.9)	6	6 (100)
	Week 45	13	10 (76.9)	6	5 (83.3)
	Week 48	11	8 (72.7)	5	3 (60.0)
	Week 51	11	7 (63.6)	5	3 (60.0)
	Week 54	10	6 (60.0)	4	2 (50.0)
	Week 57	10	7 (70.0)	4	1 (25.0)
	Week 60	9	6 (66.7)	4	2 (50.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	4 (66.7)	3	0
	Week 66	4	3 (75.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	16 (29.1)	45	19 (42.2)
	Baseline and at least one post baseline [c]		44 (69.8)		31 (56.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

Questionnaire - endpoint	Visit [a]	Dato-DXd (N=63)		ICC (N=55)	
		Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
PRO-CTCAE - PT01-Fatigue Interference	Baseline	55	32 (58.2)	47	20 (42.6)
	Week 1	55	26 (47.3)	44	22 (50.0)
	Week 2	55	23 (41.8)	44	28 (63.6)
	Week 3	53	31 (58.5)	44	26 (59.1)
	Week 4	47	27 (57.4)	43	28 (65.1)
	Week 5	47	19 (40.4)	36	25 (69.4)
	Week 6	46	24 (52.2)	31	19 (61.3)
	Week 7	43	22 (51.2)	30	20 (66.7)
	Week 8	43	22 (51.2)	28	19 (67.9)
	Week 9	43	23 (53.5)	28	16 (57.1)
	Week 10	42	20 (47.6)	29	20 (69.0)
	Week 11	42	17 (40.5)	27	17 (63.0)
	Week 12	41	29 (70.7)	27	20 (74.1)
	Week 15	38	21 (55.3)	22	16 (72.7)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 18	33	21 (63.6)	16	6 (37.5)
	Week 21	32	18 (56.3)	16	9 (56.3)
	Week 24	28	16 (57.1)	13	7 (53.8)
	Week 27	26	13 (50.0)	10	6 (60.0)
	Week 30	25	15 (60.0)	10	6 (60.0)
	Week 33	23	14 (60.9)	8	5 (62.5)
	Week 36	24	15 (62.5)	8	7 (87.5)
	Week 39	21	11 (52.4)	7	5 (71.4)
	Week 42	17	6 (35.3)	6	6 (100)
	Week 45	13	7 (53.8)	6	5 (83.3)
	Week 48	11	7 (63.6)	5	3 (60.0)
	Week 51	11	5 (45.5)	5	2 (40.0)
	Week 54	10	5 (50.0)	4	2 (50.0)
	Week 57	10	5 (50.0)	4	1 (25.0)
	Week 60	9	3 (33.3)	4	1 (25.0)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

Table 3.76.1 PRO-CTCAE - Compliance - DCO 24-Jul-2024 - Modified Safety Analysis Set A

		Dato-DXd (N=63)		ICC (N=55)	
Questionnaire - endpoint	Visit [a]	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)	Number of expected questionnaires [b]	Number of subjects with completed questionnaires n(%)
	Week 63	6	3 (50.0)	3	0
	Week 66	4	2 (50.0)	2	1 (50.0)
	Week 69	3	2 (66.7)	2	1 (50.0)
	Week 72	2	1 (50.0)	2	1 (50.0)
	Week 75	2	2 (100)	2	1 (50.0)
	Week 78	2	2 (100)	2	1 (50.0)
	Week 81	2	2 (100)	2	1 (50.0)
	Week 84	1	1 (100)	2	0
	Week 87	1	1 (100)	2	0
	Week 90	0	0	2	0
	End of Treatment	55	12 (21.8)	45	15 (33.3)
	Baseline and at least one post baseline [c]		32 (50.8)		20 (36.4)

N: number of subjects in analysis set; %: proportion of number of expected questionnaires (i.e. response rate); ICC: Investigator's Choice of Chemotherapy.
[a] Planned visits
[b] A questionnaire is expected if the patient is alive, under treatment, has not withdrawn from the study and the questionnaire is expected to be completed at the respective time point as per study protocol. Completed questionnaires are generally considered to be expected.
[c] Percentages are based on all subjects in the population.

Data source: ADAM.ADQS
Run date: 06MAY2025 - 11:04; Program name: t_3_76_1.sas; Output name: DE.T_PROCTCAE_COMP_mSASA_FA.rtf

PRO-CTCAE – Deskriptive Analysen

Daiichi Sankyo
Data Intelligence – Evidence Generation
D9268C00001 – TROPION-BREAST01 (DCO 24Jul2024)
Statistical analyses for AMNOG (HTA Germany)

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Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.1		1.1	
Standard Deviation	0.35		0.34	
Minimum	1		1	
Median	1.0		1.0	
Maximum	2		2	
Week 1				
n	34	32	30	23
Mean	1.9	0.7	1.4	0.3
Standard Deviation	1.36	1.40	0.72	0.75
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	5	4	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.9	0.8	1.5	0.3
Standard Deviation	1.05	1.10	0.68	0.47
Minimum	1	-1	1	0
Median	2.0	0.0	1.0	0.0
Maximum	5	4	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.6	0.5	1.5	0.3
Standard Deviation	0.76	0.82	0.93	0.75
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.5	0.3	1.4	0.3
Standard Deviation	0.68	0.66	0.70	0.82
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.6	0.5	1.4	0.4
Standard Deviation	0.90	0.93	0.85	1.05
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	5	4	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.7	0.5	1.4	0.3
Standard Deviation	0.90	0.85	0.73	0.60
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.7	0.6	1.5	0.3
Standard Deviation	0.85	0.76	0.72	0.69
Minimum	1	0	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	2.0	1.0	1.6	0.4
Standard Deviation	1.09	1.06	0.79	0.81
Minimum	1	0	1	-1
Median	2.0	1.0	1.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.9	0.7	1.4	0.2
Standard Deviation	1.05	0.96	0.49	0.43
Minimum	1	0	1	0
Median	2.0	0.0	1.0	0.0
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.8	0.7	1.4	0.2
Standard Deviation	0.96	0.81	0.58	0.54
Minimum	1	0	1	-1
Median	1.0	1.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.8	0.8	1.3	0.2
Standard Deviation	1.08	0.96	0.58	0.69
Minimum	1	0	1	-1
Median	1.0	0.5	1.0	0.0
Maximum	5	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	2.3	1.1	1.4	0.2
Standard Deviation	1.18	0.98	0.50	0.53
Minimum	1	0	1	-1
Median	2.0	1.0	1.0	0.0
Maximum	5	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	2.0	0.8	1.5	0.3
Standard Deviation	1.16	0.99	0.79	0.85
Minimum	1	0	1	0
Median	2.0	0.0	1.0	0.0
Maximum	5	3	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	2.0	0.8	1.7	0.3
Standard Deviation	1.08	0.97	0.71	0.52
Minimum	1	0	1	0
Median	1.5	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	2.1	0.9	1.7	0.4
Standard Deviation	1.20	1.08	0.49	0.52
Minimum	1	0	1	0
Median	2.0	1.0	2.0	0.0
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.8	0.8	1.8	0.4
Standard Deviation	1.03	1.06	0.83	0.53
Minimum	1	0	1	0
Median	2.0	0.5	2.0	0.0
Maximum	5	4	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	2.3	1.1	1.6	0.0
Standard Deviation	1.15	0.96	0.53	0.00
Minimum	1	0	1	0
Median	2.0	1.0	2.0	0.0
Maximum	5	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	2.0	0.8	1.6	0.3
Standard Deviation	1.07	1.01	0.74	0.52
Minimum	1	0	1	0
Median	2.0	1.0	1.5	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.8	0.8	1.8	0.3
Standard Deviation	0.73	0.75	0.41	0.58
Minimum	1	0	1	0
Median	2.0	1.0	2.0	0.0
Maximum	3	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	2.2	1.1	1.8	0.0
Standard Deviation	1.07	1.10	0.46	0.82
Minimum	1	0	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	5	4	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.9	0.9	1.5	0.0
Standard Deviation	0.81	0.83	0.55	0.00
Minimum	1	0	1	0
Median	2.0	1.0	1.5	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.4	0.4	1.7	0.0
Standard Deviation	0.53	0.53	0.52	0.00
Minimum	1	0	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.5	0.4	1.8	0.3
Standard Deviation	0.71	0.73	0.84	0.58
Minimum	1	0	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.4	0.4	2.0	0.0
Standard Deviation	0.52	0.52	1.00	-
Minimum	1	0	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.1	0.1	1.3	1.0
Standard Deviation	0.38	0.38	0.58	-
Minimum	1	0	1	1
Median	1.0	0.0	1.0	1.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.5	0.5	2.5	1.0
Standard Deviation	0.55	0.55	0.71	-
Minimum	1	0	2	1
Median	1.5	0.5	2.5	1.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.4	0.4	1.0	0.0
Standard Deviation	0.79	0.79	-	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.5	0.5	1.5	0.0
Standard Deviation	0.55	0.55	0.71	-
Minimum	1	0	1	0
Median	1.5	0.5	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.3	0.3	-	-
Standard Deviation	0.50	0.50	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	2.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	2.0	1.0	2.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	2	1	2	-
Median	2.0	1.0	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	1	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.5	3.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	3	-
Median	1.5	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.8	0.5	1.6	0.6
Standard Deviation	0.66	0.78	1.01	1.09
Minimum	1	-1	1	0
Median	2.0	0.0	1.0	0.0
Maximum	3	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	6		4	
Mean	1.5		1.5	
Standard Deviation	0.55		0.58	
Minimum	1		1	
Median	1.5		1.5	
Maximum	2		2	
Week 1				
n	14	3	8	2
Mean	2.7	1.7	1.6	0.0
Standard Deviation	1.54	1.15	0.74	1.41
Minimum	1	1	1	-1
Median	3.0	1.0	1.5	0.0
Maximum	5	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	21	3	12	3
Mean	2.0	0.7	1.8	0.7
Standard Deviation	1.18	1.15	0.72	1.15
Minimum	1	0	1	0
Median	2.0	0.0	2.0	0.0
Maximum	5	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	20	2	10	2
Mean	2.2	0.0	2.1	0.5
Standard Deviation	0.93	0.00	1.20	0.71
Minimum	1	0	1	0
Median	2.0	0.0	2.0	0.5
Maximum	4	0	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	13	4	11	0
Mean	1.9	0.3	2.0	-
Standard Deviation	0.49	0.50	1.00	-
Minimum	1	0	1	-
Median	2.0	0.0	2.0	-
Maximum	3	1	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	13	3	9	1
Mean	2.1	0.7	2.2	1.0
Standard Deviation	1.12	0.58	1.09	-
Minimum	1	0	1	1
Median	2.0	1.0	2.0	1.0
Maximum	5	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	15	4	6	2
Mean	1.9	0.8	2.2	1.5
Standard Deviation	0.88	0.96	1.17	0.71
Minimum	1	0	1	1
Median	2.0	0.5	2.0	1.5
Maximum	3	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	13	1	9	2
Mean	2.2	0.0	1.8	1.0
Standard Deviation	0.83	-	0.83	0.00
Minimum	1	0	1	1
Median	2.0	0.0	2.0	1.0
Maximum	3	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	17	2	10	2
Mean	2.5	1.5	1.8	1.5
Standard Deviation	0.94	0.71	0.92	0.71
Minimum	1	1	1	1
Median	2.0	1.5	2.0	1.5
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	18	4	7	1
Mean	2.4	1.0	1.6	1.0
Standard Deviation	0.98	0.82	0.53	-
Minimum	1	0	1	1
Median	2.5	1.0	2.0	1.0
Maximum	4	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	12	3	7	2
Mean	2.3	1.3	1.9	1.0
Standard Deviation	0.89	0.58	0.69	0.00
Minimum	1	1	1	1
Median	2.0	1.0	2.0	1.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	12	2	5	1
Mean	2.5	2.0	2.4	1.0
Standard Deviation	1.09	1.41	0.55	-
Minimum	1	1	2	1
Median	2.5	2.0	2.0	1.0
Maximum	5	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	24	4	9	2
Mean	2.4	1.5	1.7	0.5
Standard Deviation	1.21	1.29	0.50	0.71
Minimum	1	0	1	0
Median	2.0	1.5	2.0	0.5
Maximum	5	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	18	3	7	3
Mean	2.5	0.7	2.0	0.3
Standard Deviation	1.20	1.15	1.00	0.58
Minimum	1	0	1	0
Median	2.5	0.0	2.0	0.0
Maximum	5	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	13	3	5	1
Mean	2.7	0.7	1.8	1.0
Standard Deviation	0.63	1.15	0.84	-
Minimum	2	0	1	1
Median	3.0	0.0	2.0	1.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	13	2	8	2
Mean	2.7	1.5	1.6	0.5
Standard Deviation	1.38	0.71	0.52	0.71
Minimum	1	1	1	0
Median	2.0	1.5	2.0	0.5
Maximum	5	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	12	0	5	2
Mean	2.2	-	1.8	1.0
Standard Deviation	0.72	-	0.84	0.00
Minimum	1	-	1	1
Median	2.0	-	2.0	1.0
Maximum	4	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	13	0	4	2
Mean	2.5	-	2.0	1.0
Standard Deviation	0.88	-	0.82	0.00
Minimum	1	-	1	1
Median	2.0	-	2.0	1.0
Maximum	4	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	12	0	4	2
Mean	2.3	-	1.8	1.0
Standard Deviation	1.14	-	0.96	0.00
Minimum	1	-	1	1
Median	2.0	-	1.5	1.0
Maximum	4	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	11	0	5	1
Mean	1.5	-	1.6	0.0
Standard Deviation	0.69	-	0.55	-
Minimum	1	-	1	0
Median	1.0	-	2.0	0.0
Maximum	3	-	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	13	0	6	1
Mean	2.5	-	1.5	1.0
Standard Deviation	0.88	-	0.55	-
Minimum	1	-	1	1
Median	3.0	-	1.5	1.0
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	10	0	3	1
Mean	1.8	-	1.3	0.0
Standard Deviation	0.92	-	0.58	-
Minimum	1	-	1	0
Median	2.0	-	1.0	0.0
Maximum	4	-	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	4	0	4	2
Mean	1.3	-	2.0	0.5
Standard Deviation	0.50	-	0.00	0.71
Minimum	1	-	2	0
Median	1.0	-	2.0	0.5
Maximum	2	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	4	0	3	1
Mean	1.8	-	2.7	1.0
Standard Deviation	0.50	-	0.58	-
Minimum	1	-	2	1
Median	2.0	-	3.0	1.0
Maximum	2	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	3	0	2	0
Mean	1.3	-	2.5	-
Standard Deviation	0.58	-	0.71	-
Minimum	1	-	2	-
Median	1.0	-	2.5	-
Maximum	2	-	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	1	0	1	0
Mean	1.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	1	-
Median	1.0	-	1.0	-
Maximum	1	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	3	0	2	0
Mean	1.7	-	1.5	-
Standard Deviation	0.58	-	0.71	-
Minimum	1	-	1	-
Median	2.0	-	1.5	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	2	0	0	0
Mean	2.0	-	-	-
Standard Deviation	0.00	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	3	0	1	0
Mean	1.7	-	1.0	-
Standard Deviation	0.58	-	-	-
Minimum	1	-	1	-
Median	2.0	-	1.0	-
Maximum	2	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	0	1	0
Mean	2.0	-	3.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	-	3	-
Median	2.0	-	3.0	-
Maximum	2	-	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	0	0	1	0
Mean	-	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	1	-
Median	-	-	1.0	-
Maximum	-	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	1	0	1	0
Mean	1.0	-	3.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	3	-
Median	1.0	-	3.0	-
Maximum	1	-	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Mouth/Throat Sores Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	11	2	8	0
Mean	1.7	0.5	2.0	-
Standard Deviation	0.79	0.71	1.31	-
Minimum	1	0	1	-
Median	2.0	0.5	2.0	-
Maximum	3	1	5	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.4		1.6	
Standard Deviation	0.75		1.16	
Minimum	1		1	
Median	1.0		1.0	
Maximum	4		5	
Week 1				
n	34	32	30	23
Mean	2.3	1.0	1.7	0.4
Standard Deviation	1.36	1.18	0.84	0.78
Minimum	1	0	1	-1
Median	2.0	1.0	1.0	0.0
Maximum	5	4	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.8	0.4	1.9	0.3
Standard Deviation	0.93	0.61	0.92	0.88
Minimum	1	0	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.5	0.1	1.8	0.4
Standard Deviation	0.67	0.79	0.92	0.59
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	3	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	2.1	0.7	1.9	0.4
Standard Deviation	0.96	0.76	0.99	0.84
Minimum	1	0	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.6	0.4	2.3	0.9
Standard Deviation	0.83	0.65	1.20	0.97
Minimum	1	0	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	4	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.5	0.3	1.7	0.4
Standard Deviation	0.78	0.59	0.83	1.09
Minimum	1	-1	1	-3
Median	1.0	0.0	1.5	1.0
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.9	0.7	1.9	0.5
Standard Deviation	0.95	0.75	0.95	1.37
Minimum	1	0	1	-4
Median	2.0	1.0	2.0	1.0
Maximum	5	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.7	0.3	2.0	0.6
Standard Deviation	0.86	1.05	1.11	1.36
Minimum	1	-2	1	-4
Median	1.0	0.0	2.0	1.0
Maximum	4	3	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.6	0.3	2.1	0.7
Standard Deviation	0.91	1.08	1.29	1.33
Minimum	1	-2	1	-2
Median	1.0	0.0	2.0	1.0
Maximum	4	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	2.0	0.7	1.9	0.6
Standard Deviation	0.91	0.97	0.97	1.15
Minimum	1	-2	1	-3
Median	2.0	1.0	2.0	1.0
Maximum	5	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.7	0.5	2.1	0.6
Standard Deviation	0.85	0.72	1.10	1.04
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	1.0
Maximum	4	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.5	0.2	1.9	0.2
Standard Deviation	0.97	1.12	1.17	1.48
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	3	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.5	0.2	1.9	0.4
Standard Deviation	0.97	1.19	0.83	1.12
Minimum	1	-3	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	5	4	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.5	0.1	1.6	-0.2
Standard Deviation	0.91	1.21	0.73	0.98
Minimum	1	-3	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.6	0.4	1.7	0.3
Standard Deviation	0.79	0.83	0.78	1.28
Minimum	1	-1	1	-2
Median	1.0	0.0	1.5	0.5
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.7	0.5	1.7	-0.3
Standard Deviation	0.96	1.34	1.12	2.21
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	3	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.7	0.6	1.6	-0.2
Standard Deviation	1.05	1.45	0.53	1.10
Minimum	1	-3	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.9	0.6	1.4	-0.2
Standard Deviation	1.20	1.50	0.74	1.47
Minimum	1	-3	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	5	4	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.5	0.4	1.7	-0.3
Standard Deviation	0.71	1.11	0.82	1.53
Minimum	1	-3	1	-2
Median	1.0	0.0	1.5	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.7	0.3	1.8	0.0
Standard Deviation	1.06	1.59	0.71	1.41
Minimum	1	-3	1	-2
Median	1.0	0.0	2.0	0.5
Maximum	5	4	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.6	0.2	1.5	-0.7
Standard Deviation	0.81	1.25	0.84	2.08
Minimum	1	-3	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	2.0	0.9	2.2	0.3
Standard Deviation	1.32	1.21	1.17	2.50
Minimum	1	0	1	-3
Median	1.0	0.0	2.0	0.5
Maximum	4	3	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.8	0.0	1.4	-0.7
Standard Deviation	1.03	1.41	0.89	2.08
Minimum	1	-3	1	-3
Median	1.5	0.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.9	0.5	1.3	0.0
Standard Deviation	1.13	1.77	0.58	-
Minimum	1	-3	1	0
Median	1.5	0.5	1.0	0.0
Maximum	4	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.9	0.4	1.3	0.0
Standard Deviation	1.21	1.90	0.58	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	2.0	0.5	1.5	0.0
Standard Deviation	1.55	2.26	0.71	-
Minimum	1	-3	1	0
Median	1.5	0.5	1.5	0.0
Maximum	5	4	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.9	0.4	1.0	0.0
Standard Deviation	1.21	1.90	-	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.5	0.0	1.0	0.0
Standard Deviation	0.55	1.55	0.00	-
Minimum	1	-3	1	0
Median	1.5	0.5	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.8	0.0	-	-
Standard Deviation	0.96	0.82	-	-
Minimum	1	-1	-	-
Median	1.5	0.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	2.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	1	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	2.3	0.6	2.2	0.4
Standard Deviation	1.18	0.96	1.44	1.15
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	10		9	
Mean	2.2		2.3	
Standard Deviation	1.03		1.41	
Minimum	1		1	
Median	2.0		2.0	
Maximum	4		5	
Week 1				
n	21	6	14	3
Mean	2.7	0.8	1.9	0.0
Standard Deviation	1.10	0.41	1.03	0.00
Minimum	1	0	1	0
Median	2.0	1.0	1.5	0.0
Maximum	5	1	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	20	7	18	6
Mean	2.1	0.4	2.0	0.0
Standard Deviation	0.94	0.98	1.03	0.63
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	16	9	18	5
Mean	1.8	-0.4	1.9	0.6
Standard Deviation	0.54	0.88	0.83	1.14
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	1.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	22	3	18	6
Mean	2.3	0.7	2.1	-0.3
Standard Deviation	1.24	1.15	0.80	1.03
Minimum	1	0	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	11	2	18	5
Mean	2.2	2.0	2.4	-0.2
Standard Deviation	1.17	2.83	1.04	1.64
Minimum	1	0	1	-3
Median	2.0	2.0	2.0	0.0
Maximum	5	4	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	12	2	11	3
Mean	1.9	1.0	1.8	1.0
Standard Deviation	0.79	1.41	0.75	1.00
Minimum	1	0	1	0
Median	2.0	1.0	2.0	1.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	18	3	14	3
Mean	2.1	0.0	1.9	1.0
Standard Deviation	0.94	0.00	0.83	0.00
Minimum	1	0	1	1
Median	2.0	0.0	2.0	1.0
Maximum	4	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	13	3	14	2
Mean	2.1	-0.7	2.4	2.0
Standard Deviation	0.86	1.53	1.22	1.41
Minimum	1	-2	1	1
Median	2.0	-1.0	2.0	2.0
Maximum	4	1	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	13	4	12	2
Mean	2.1	-0.8	1.8	0.5
Standard Deviation	0.64	1.50	1.34	0.71
Minimum	1	-2	1	0
Median	2.0	-1.0	1.0	0.5
Maximum	3	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	18	4	14	3
Mean	2.2	0.3	1.9	1.0
Standard Deviation	1.04	1.71	1.07	1.00
Minimum	1	-2	1	0
Median	2.0	0.5	2.0	1.0
Maximum	5	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	12	3	13	3
Mean	2.0	0.3	2.0	0.3
Standard Deviation	0.95	1.15	1.22	0.58
Minimum	1	-1	1	0
Median	2.0	1.0	2.0	0.0
Maximum	4	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	11	2	10	3
Mean	2.3	1.0	2.4	1.7
Standard Deviation	1.01	0.00	1.17	0.58
Minimum	1	1	1	1
Median	2.0	1.0	2.0	2.0
Maximum	4	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	10	1	11	3
Mean	2.0	2.0	1.7	0.0
Standard Deviation	0.94	-	0.90	0.00
Minimum	1	2	1	0
Median	2.0	2.0	1.0	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	8	1	4	2
Mean	2.4	3.0	2.3	1.0
Standard Deviation	1.19	-	0.96	1.41
Minimum	1	3	1	0
Median	2.0	3.0	2.5	1.0
Maximum	4	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	9	3	6	1
Mean	1.9	0.7	1.7	1.0
Standard Deviation	1.05	1.15	0.52	-
Minimum	1	0	1	1
Median	1.0	0.0	2.0	1.0
Maximum	3	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	11	1	3	2
Mean	2.0	0.0	2.3	1.0
Standard Deviation	1.18	-	1.15	1.41
Minimum	1	0	1	0
Median	2.0	0.0	3.0	1.0
Maximum	4	0	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	8	1	4	2
Mean	2.3	1.0	1.8	0.5
Standard Deviation	1.16	-	0.50	0.71
Minimum	1	1	1	0
Median	2.0	1.0	2.0	0.5
Maximum	4	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	10	0	2	1
Mean	2.0	-	2.5	2.0
Standard Deviation	1.05	-	0.71	-
Minimum	1	-	2	2
Median	2.0	-	2.5	2.0
Maximum	4	-	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	7	0	3	2
Mean	1.9	-	2.0	1.0
Standard Deviation	0.90	-	1.00	1.41
Minimum	1	-	1	0
Median	2.0	-	2.0	1.0
Maximum	3	-	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	8	0	5	2
Mean	2.4	-	1.8	1.0
Standard Deviation	1.51	-	0.84	1.41
Minimum	1	-	1	0
Median	2.0	-	2.0	1.0
Maximum	5	-	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	7	1	2	1
Mean	2.0	0.0	2.0	2.0
Standard Deviation	1.15	-	1.41	-
Minimum	1	0	1	2
Median	2.0	0.0	2.0	2.0
Maximum	4	0	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	4	0	4	1
Mean	2.5	-	2.5	3.0
Standard Deviation	1.29	-	1.29	-
Minimum	1	-	1	3
Median	2.5	-	2.5	3.0
Maximum	4	-	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	5	1	1	1
Mean	1.8	0.0	4.0	3.0
Standard Deviation	0.84	-	-	-
Minimum	1	0	4	3
Median	2.0	0.0	4.0	3.0
Maximum	3	0	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	4	0	1	0
Mean	2.3	-	1.0	-
Standard Deviation	0.50	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	3	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	3	0	1	0
Mean	2.7	-	1.0	-
Standard Deviation	1.15	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	4	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	3	0	1	0
Mean	2.7	-	1.0	-
Standard Deviation	1.15	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	4	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	3	0	0	0
Mean	2.7	-	-	-
Standard Deviation	1.15	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	4	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	3	0	0	0
Mean	1.7	-	-	-
Standard Deviation	0.58	-	-	-
Minimum	1	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	2	1	0	0
Mean	1.5	-2.0	-	-
Standard Deviation	0.71	-	-	-
Minimum	1	-2	-	-
Median	1.5	-2.0	-	-
Maximum	2	-2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	1	0	1	0
Mean	2.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	2	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Decreased Appetite Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	11	4	10	5
Mean	2.7	0.5	2.5	0.2
Standard Deviation	1.35	0.58	1.27	0.45
Minimum	1	0	1	0
Median	2.0	0.5	2.0	0.0
Maximum	5	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.4		1.7	
Standard Deviation	0.85		1.23	
Minimum	1		1	
Median	1.0		1.0	
Maximum	4		5	
Week 1				
n	34	32	30	23
Mean	2.6	1.2	1.5	0.3
Standard Deviation	1.28	1.18	0.86	0.57
Minimum	1	0	1	0
Median	3.0	1.0	1.0	0.0
Maximum	5	4	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.8	0.3	1.9	0.4
Standard Deviation	0.86	0.73	1.06	0.73
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.5	0.1	1.4	0.2
Standard Deviation	0.77	0.89	0.70	0.52
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	2.4	1.1	1.8	0.5
Standard Deviation	1.34	1.38	0.99	0.99
Minimum	1	-2	1	-1
Median	2.0	1.0	1.0	0.0
Maximum	5	4	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.8	0.6	2.0	0.6
Standard Deviation	1.00	0.78	1.14	0.94
Minimum	1	0	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.5	0.2	1.3	-0.1
Standard Deviation	0.92	0.75	0.57	1.20
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	5	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	2.0	0.7	1.5	0.1
Standard Deviation	1.24	1.28	0.66	1.05
Minimum	1	-2	1	-3
Median	2.0	0.0	1.0	0.0
Maximum	5	4	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.7	0.3	1.6	0.1
Standard Deviation	1.04	0.93	0.84	1.00
Minimum	1	-2	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.3	0.1	1.4	-0.1
Standard Deviation	0.64	0.72	0.75	1.23
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	2.3	1.0	1.4	0.0
Standard Deviation	1.28	1.51	0.58	1.21
Minimum	1	-2	1	-4
Median	2.0	1.0	1.0	0.0
Maximum	5	4	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.7	0.5	1.6	-0.3
Standard Deviation	0.96	1.06	0.68	1.49
Minimum	1	-2	1	-4
Median	1.0	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.7	0.3	1.4	-0.4
Standard Deviation	0.95	0.98	0.66	1.46
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.4	0.2	1.8	0.3
Standard Deviation	0.66	0.82	0.79	1.60
Minimum	1	-2	1	-4
Median	1.0	0.0	2.0	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.4	0.0	1.6	-0.2
Standard Deviation	0.90	1.09	1.01	2.04
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.1	-0.1	1.6	-0.4
Standard Deviation	0.46	0.57	0.79	1.51
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.3	-0.1	1.3	-1.0
Standard Deviation	0.82	0.73	0.50	2.08
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.3	0.0	1.7	-0.2
Standard Deviation	0.56	0.63	1.11	2.28
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.5	0.1	1.5	-0.3
Standard Deviation	0.81	0.75	0.76	1.86
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.2	0.1	1.7	-1.0
Standard Deviation	0.55	0.75	1.03	2.65
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.6	0.1	1.6	-0.5
Standard Deviation	1.02	0.99	0.74	2.38
Minimum	1	-2	1	-4
Median	1.0	0.0	1.5	0.5
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.6	0.1	1.5	-1.0
Standard Deviation	1.09	0.95	0.84	2.65
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.6	0.3	1.8	-0.5
Standard Deviation	1.13	0.76	0.75	2.38
Minimum	1	0	1	-4
Median	1.0	0.0	2.0	0.5
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.7	0.2	1.6	-0.7
Standard Deviation	0.95	1.09	1.34	3.06
Minimum	1	-2	1	-4
Median	1.5	0.0	1.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.1	-0.3	1.0	0.0
Standard Deviation	0.35	0.89	0.00	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.1	-0.1	1.3	0.0
Standard Deviation	0.38	0.90	0.58	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.2	-0.2	1.5	0.0
Standard Deviation	0.41	0.98	0.71	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.1	-0.3	1.0	0.0
Standard Deviation	0.38	0.95	-	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.2	-0.2	1.5	0.0
Standard Deviation	0.41	0.98	0.71	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	2.0	0.5	-	-
Standard Deviation	1.41	0.58	-	-
Minimum	1	0	-	-
Median	1.5	0.5	-	-
Maximum	4	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	3.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	1	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	3.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	3	-
Median	1.5	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	2.3	0.2	1.6	0.0
Standard Deviation	1.13	0.80	0.96	1.36
Minimum	1	-1	1	-4
Median	2.0	0.0	1.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	11		9	
Mean	2.5		2.8	
Standard Deviation	0.69		1.09	
Minimum	2		1	
Median	2.0		3.0	
Maximum	4		4	
Week 1				
n	26	6	11	3
Mean	2.7	0.5	2.2	-0.7
Standard Deviation	1.00	0.84	0.40	1.15
Minimum	1	0	2	-2
Median	2.5	0.0	2.0	0.0
Maximum	5	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	19	7	16	5
Mean	2.4	0.3	2.3	0.4
Standard Deviation	0.68	0.49	1.20	1.14
Minimum	1	0	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	17	7	11	4
Mean	1.9	-0.4	2.0	-0.3
Standard Deviation	0.56	0.98	0.45	0.96
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	-0.5
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	21	2	16	4
Mean	2.9	0.0	2.3	0.5
Standard Deviation	0.96	0.00	0.86	1.29
Minimum	2	0	1	-1
Median	3.0	0.0	2.0	0.5
Maximum	5	0	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	15	1	15	4
Mean	2.2	0.0	2.6	0.0
Standard Deviation	0.68	-	0.91	1.15
Minimum	1	0	2	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	0	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	10	1	6	0
Mean	2.6	2.0	2.0	-
Standard Deviation	1.07	-	0.00	-
Minimum	1	2	2	-
Median	2.0	2.0	2.0	-
Maximum	4	2	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	15	2	11	3
Mean	2.8	0.0	1.9	-1.0
Standard Deviation	0.94	0.00	0.54	2.00
Minimum	2	0	1	-3
Median	2.0	0.0	2.0	-1.0
Maximum	4	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	12	3	10	3
Mean	2.6	0.0	2.4	-0.7
Standard Deviation	1.08	2.00	0.84	2.52
Minimum	2	-2	1	-3
Median	2.0	0.0	2.0	-1.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	9	3	5	0
Mean	2.0	-0.7	2.2	-
Standard Deviation	0.00	1.15	0.45	-
Minimum	2	-2	2	-
Median	2.0	0.0	2.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	16	2	7	1
Mean	2.6	-1.0	1.9	1.0
Standard Deviation	0.96	1.41	0.38	-
Minimum	1	-2	1	1
Median	2.0	-1.0	2.0	1.0
Maximum	5	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	12	2	10	3
Mean	2.2	0.5	2.0	-0.7
Standard Deviation	0.94	0.71	0.82	1.53
Minimum	1	0	1	-2
Median	2.0	0.5	2.0	-1.0
Maximum	4	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	15	2	6	3
Mean	2.2	0.0	2.0	0.0
Standard Deviation	0.77	0.00	0.00	1.00
Minimum	1	0	2	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	11	2	11	1
Mean	2.2	0.5	1.9	-1.0
Standard Deviation	0.60	0.71	0.30	-
Minimum	1	0	1	-1
Median	2.0	0.5	2.0	-1.0
Maximum	3	1	2	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	6	0	3	1
Mean	2.8	-	2.0	1.0
Standard Deviation	0.98	-	0.00	-
Minimum	2	-	2	1
Median	2.5	-	2.0	1.0
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	2	1	5	1
Mean	2.0	0.0	1.8	0.0
Standard Deviation	0.00	-	0.45	-
Minimum	2	0	1	0
Median	2.0	0.0	2.0	0.0
Maximum	2	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	3	0	3	1
Mean	2.3	-	2.0	1.0
Standard Deviation	0.58	-	0.00	-
Minimum	2	-	2	1
Median	2.0	-	2.0	1.0
Maximum	3	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	4	0	3	1
Mean	2.0	-	2.3	2.0
Standard Deviation	0.00	-	0.58	-
Minimum	2	-	2	2
Median	2.0	-	2.0	2.0
Maximum	2	-	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	7	0	3	1
Mean	2.4	-	2.0	1.0
Standard Deviation	0.79	-	0.00	-
Minimum	2	-	2	1
Median	2.0	-	2.0	1.0
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	3	1	2	1
Mean	1.7	-1.0	2.0	1.0
Standard Deviation	0.58	-	0.00	-
Minimum	1	-1	2	1
Median	2.0	-1.0	2.0	1.0
Maximum	2	-1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	6	1	4	1
Mean	2.5	1.0	2.0	1.0
Standard Deviation	0.55	-	0.00	-
Minimum	2	1	2	1
Median	2.5	1.0	2.0	1.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	4	2	2	1
Mean	2.0	-0.5	2.0	1.0
Standard Deviation	0.82	0.71	0.00	-
Minimum	1	-1	2	1
Median	2.0	-0.5	2.0	1.0
Maximum	3	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	2	0	4	1
Mean	3.0	-	1.8	1.0
Standard Deviation	1.41	-	0.50	-
Minimum	2	-	1	1
Median	3.0	-	2.0	1.0
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	5	2	1	1
Mean	2.2	0.0	3.0	2.0
Standard Deviation	0.45	0.00	-	-
Minimum	2	0	3	2
Median	2.0	0.0	3.0	2.0
Maximum	3	0	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	1	0	1	0
Mean	1.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	1	-
Median	1.0	-	1.0	-
Maximum	1	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	1	0	1	0
Mean	2.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	2	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	2	1	0	0
Mean	2.0	-1.0	-	-
Standard Deviation	1.41	-	-	-
Minimum	1	-1	-	-
Median	2.0	-1.0	-	-
Maximum	3	-1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Nausea Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	12	7	6	3
Mean	2.6	0.4	2.7	0.7
Standard Deviation	1.16	0.79	0.82	1.15
Minimum	1	0	2	0
Median	2.0	0.0	2.5	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.3		1.3	
Standard Deviation	0.76		0.97	
Minimum	1		1	
Median	1.0		1.0	
Maximum	4		5	
Week 1				
n	34	32	30	23
Mean	1.6	0.4	1.2	0.1
Standard Deviation	1.07	0.88	0.73	0.42
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	5	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.4	0.1	1.2	0.0
Standard Deviation	0.82	0.65	0.54	0.37
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.2	-0.2	1.1	0.0
Standard Deviation	0.44	0.59	0.41	0.21
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.7	0.3	1.1	0.1
Standard Deviation	1.18	0.78	0.44	0.34
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.3	0.2	1.4	0.3
Standard Deviation	0.53	0.51	0.79	0.55
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.2	-0.1	1.0	-0.3
Standard Deviation	0.77	0.44	0.00	1.00
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	5	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.4	0.2	1.0	0.0
Standard Deviation	0.78	0.54	0.00	0.00
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	2	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.3	0.0	1.1	0.1
Standard Deviation	0.77	0.77	0.29	0.25
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.1	-0.2	1.0	-0.3
Standard Deviation	0.40	0.68	0.00	1.07
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.5	0.2	1.0	-0.3
Standard Deviation	0.77	0.89	0.21	1.00
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.4	0.3	1.1	-0.3
Standard Deviation	0.75	0.74	0.23	1.11
Minimum	1	-1	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.2	-0.1	1.1	-0.2
Standard Deviation	0.52	0.66	0.47	1.01
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.1	-0.2	1.2	-0.2
Standard Deviation	0.42	0.74	0.51	1.28
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.3	0.0	1.2	-0.5
Standard Deviation	0.84	0.98	0.44	1.76
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.1	0.1	1.1	-0.5
Standard Deviation	0.29	0.40	0.29	1.41
Minimum	1	-1	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.1	-0.2	1.1	-0.4
Standard Deviation	0.46	0.73	0.33	1.62
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.1	-0.1	1.1	-0.6
Standard Deviation	0.32	0.85	0.38	1.95
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.1	-0.3	1.1	-0.5
Standard Deviation	0.30	0.92	0.35	1.76
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.1	-0.2	1.2	-1.3
Standard Deviation	0.47	0.75	0.41	2.31
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.3	-0.1	1.3	-0.8
Standard Deviation	0.58	0.92	0.46	2.22
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.1	-0.3	1.0	-1.3
Standard Deviation	0.25	0.83	0.00	2.31
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	2	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.2	0.1	1.3	-0.5
Standard Deviation	0.44	0.38	0.52	2.38
Minimum	1	0	1	-4
Median	1.0	0.0	1.0	0.5
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.3	-0.3	1.0	-1.3
Standard Deviation	0.67	1.12	0.00	2.31
Minimum	1	-3	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.0	-0.5	1.0	0.0
Standard Deviation	0.00	1.07	0.00	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.0	-0.4	1.0	0.0
Standard Deviation	0.00	1.13	0.00	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.0	-0.5	1.0	0.0
Standard Deviation	0.00	1.22	0.00	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.1	-0.4	1.0	0.0
Standard Deviation	0.38	1.27	-	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.2	-0.3	1.5	0.0
Standard Deviation	0.41	1.37	0.71	-
Minimum	1	-3	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.5	-0.3	-	-
Standard Deviation	1.00	0.50	-	-
Minimum	1	-1	-	-
Median	1.0	0.0	-	-
Maximum	3	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.9	0.3	1.5	0.0
Standard Deviation	1.24	1.03	0.90	1.30
Minimum	1	-1	1	-4
Median	1.5	0.0	1.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	7		4	
Mean	2.7		3.3	
Standard Deviation	0.95		0.96	
Minimum	2		2	
Median	2.0		3.5	
Maximum	4		4	
Week 1				
n	11	3	3	2
Mean	2.7	0.7	2.3	-1.0
Standard Deviation	1.27	0.58	0.58	0.00
Minimum	1	0	2	-1
Median	3.0	1.0	2.0	-1.0
Maximum	5	1	3	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	7	2	4	2
Mean	2.7	1.0	2.3	-0.5
Standard Deviation	0.76	0.00	1.26	0.71
Minimum	2	1	1	-1
Median	3.0	1.0	2.0	-0.5
Maximum	4	1	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	6	5	3	1
Mean	2.2	-0.4	2.0	-1.0
Standard Deviation	0.41	0.55	0.00	-
Minimum	2	-1	2	-1
Median	2.0	0.0	2.0	-1.0
Maximum	3	0	2	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	10	3	4	1
Mean	3.2	0.0	2.3	0.0
Standard Deviation	1.03	0.00	0.50	-
Minimum	2	0	2	0
Median	3.0	0.0	2.0	0.0
Maximum	5	0	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	7	1	6	1
Mean	2.0	0.0	2.8	-1.0
Standard Deviation	0.58	-	0.98	-
Minimum	1	0	2	-1
Median	2.0	0.0	2.5	-1.0
Maximum	3	0	4	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	4	1	0	0
Mean	2.8	0.0	-	-
Standard Deviation	0.96	-	-	-
Minimum	2	0	-	-
Median	2.5	0.0	-	-
Maximum	4	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	9	3	0	0
Mean	2.3	-0.3	-	-
Standard Deviation	0.71	0.58	-	-
Minimum	2	-1	-	-
Median	2.0	0.0	-	-
Maximum	4	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	6	1	2	0
Mean	2.7	0.0	2.0	-
Standard Deviation	1.03	-	0.00	-
Minimum	2	0	2	-
Median	2.0	0.0	2.0	-
Maximum	4	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	3	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	8	1	1	0
Mean	1.9	0.0	2.0	-
Standard Deviation	0.35	-	-	-
Minimum	1	0	2	-
Median	2.0	0.0	2.0	-
Maximum	2	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	7	1	1	0
Mean	2.1	0.0	2.0	-
Standard Deviation	1.07	-	-	-
Minimum	1	0	2	-
Median	2.0	0.0	2.0	-
Maximum	4	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	5	1	2	0
Mean	2.2	-1.0	1.5	-
Standard Deviation	0.84	-	0.71	-
Minimum	1	-1	1	-
Median	2.0	-1.0	1.5	-
Maximum	3	-1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	3	0	2	0
Mean	2.7	-	2.0	-
Standard Deviation	0.58	-	0.00	-
Minimum	2	-	2	-
Median	3.0	-	2.0	-
Maximum	3	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	4	1	2	0
Mean	3.0	0.0	1.5	-
Standard Deviation	1.15	-	0.71	-
Minimum	2	0	1	-
Median	3.0	0.0	1.5	-
Maximum	4	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	2	0	1	0
Mean	1.5	-	2.0	-
Standard Deviation	0.71	-	-	-
Minimum	1	-	2	-
Median	1.5	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	2	1	1	0
Mean	2.0	-2.0	2.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	-2	2	-
Median	2.0	-2.0	2.0	-
Maximum	2	-2	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	2	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	2	0	1	0
Mean	2.5	-	2.0	-
Standard Deviation	0.71	-	-	-
Minimum	2	-	2	-
Median	2.5	-	2.0	-
Maximum	3	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	1	1	1	0
Mean	3.0	-1.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	3	-1	1	-
Median	3.0	-1.0	1.0	-
Maximum	3	-1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	5	1	2	0
Mean	2.0	-1.0	1.5	-
Standard Deviation	0.71	-	0.71	-
Minimum	1	-1	1	-
Median	2.0	-1.0	1.5	-
Maximum	3	-1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	2	0	2	0
Mean	1.5	-	1.5	-
Standard Deviation	0.71	-	0.71	-
Minimum	1	-	1	-
Median	1.5	-	1.5	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	2	0	0	0
Mean	2.0	-	-	-
Standard Deviation	0.00	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	1	0	1	0
Mean	2.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	1	-
Median	2.0	-	1.0	-
Maximum	2	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	1	1	0	0
Mean	2.0	-2.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	-2	-	-
Median	2.0	-2.0	-	-
Maximum	2	-2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Vomiting Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	8	2	5	2
Mean	2.6	0.0	3.0	0.5
Standard Deviation	1.41	0.00	0.71	2.12
Minimum	1	0	2	-1
Median	2.5	0.0	3.0	0.5
Maximum	5	0	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.4		1.5	
Standard Deviation	0.57		0.84	
Minimum	1		1	
Median	1.0		1.0	
Maximum	3		4	
Week 1				
n	34	32	30	23
Mean	1.8	0.4	1.7	0.3
Standard Deviation	1.01	1.04	1.12	0.98
Minimum	1	-1	1	-1
Median	1.5	0.0	1.0	0.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.6	0.2	1.9	0.3
Standard Deviation	0.83	0.85	1.02	0.70
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.5	0.1	1.6	0.3
Standard Deviation	0.92	0.73	0.65	0.69
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	2.0	0.6	1.9	0.3
Standard Deviation	1.10	1.01	0.96	0.63
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	3	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.7	0.2	1.9	0.7
Standard Deviation	0.89	0.66	1.06	0.88
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	4	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.5	0.1	1.8	0.3
Standard Deviation	0.92	0.57	0.80	0.93
Minimum	1	-1	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	5	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.7	0.5	1.8	0.6
Standard Deviation	0.84	0.91	0.93	1.12
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.6	0.2	2.0	0.3
Standard Deviation	0.87	0.69	0.93	1.25
Minimum	1	-1	1	-3
Median	1.0	0.0	2.0	1.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.4	0.1	1.8	0.5
Standard Deviation	0.69	0.62	0.79	0.85
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.8	0.7	1.9	0.6
Standard Deviation	1.03	0.93	0.71	0.81
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.5
Maximum	4	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	2.0	0.8	1.7	0.1
Standard Deviation	1.04	0.88	0.67	1.38
Minimum	1	0	1	-2
Median	2.0	1.0	2.0	0.0
Maximum	4	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.8	0.4	1.7	0.4
Standard Deviation	1.16	1.04	0.84	1.22
Minimum	1	-1	1	-2
Median	1.0	0.0	1.5	0.0
Maximum	5	4	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.5	0.1	1.8	0.3
Standard Deviation	0.97	0.63	0.71	1.38
Minimum	1	-1	1	-3
Median	1.0	0.0	2.0	1.0
Maximum	5	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.8	0.4	1.7	0.0
Standard Deviation	0.90	0.73	0.71	1.10
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.7	0.4	2.0	0.6
Standard Deviation	0.92	0.76	0.85	1.41
Minimum	1	-1	1	-2
Median	1.0	0.0	2.0	1.0
Maximum	4	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.8	0.4	1.8	0.0
Standard Deviation	0.85	0.86	0.67	1.41
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	1.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.7	0.4	1.7	0.0
Standard Deviation	0.75	0.73	0.76	1.73
Minimum	1	-1	1	-3
Median	2.0	0.0	2.0	1.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.9	0.5	2.1	0.7
Standard Deviation	1.00	0.87	0.99	1.51
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	1.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.2	-0.1	1.8	0.0
Standard Deviation	0.51	0.33	0.98	1.00
Minimum	1	-1	1	-1
Median	1.0	0.0	1.5	0.0
Maximum	3	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.7	0.3	2.1	0.5
Standard Deviation	0.93	0.62	0.83	1.73
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	1.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.9	0.5	1.7	-0.3
Standard Deviation	1.00	0.76	0.82	1.53
Minimum	1	0	1	-2
Median	2.0	0.0	1.5	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.6	0.3	1.8	-0.3
Standard Deviation	1.01	0.49	0.75	1.26
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.9	0.3	2.0	-0.3
Standard Deviation	1.29	0.87	0.71	1.15
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	-1.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.5	0.1	1.7	1.0
Standard Deviation	0.76	0.35	0.58	-
Minimum	1	0	1	1
Median	1.0	0.0	2.0	1.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.6	0.4	2.0	1.0
Standard Deviation	0.53	0.53	1.00	-
Minimum	1	0	1	1
Median	2.0	0.0	2.0	1.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.3	0.2	1.5	0.0
Standard Deviation	0.52	0.41	0.71	-
Minimum	1	0	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.6	0.1	2.0	1.0
Standard Deviation	0.79	0.38	-	-
Minimum	1	0	2	1
Median	1.0	0.0	2.0	1.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.3	0.2	1.0	0.0
Standard Deviation	0.52	0.41	0.00	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.5	0.3	-	-
Standard Deviation	0.58	0.50	-	-
Minimum	1	0	-	-
Median	1.5	0.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.7	0.3	3.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	2.0	0.5	2.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	2	0	2	-
Median	2.0	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	2.0	1.0	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	1	2	-
Median	2.0	1.0	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.0	2.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	1	0	2	-
Median	1.5	0.0	2.0	-
Maximum	2	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.0	2.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	1	0	2	-
Median	1.5	0.0	2.0	-
Maximum	2	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.0	3.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	1	0	3	-
Median	1.5	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Constipation Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	2.1	0.3	1.7	0.1
Standard Deviation	1.29	1.32	1.10	0.95
Minimum	1	-1	1	-2
Median	2.0	0.0	1.0	0.0
Maximum	5	4	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.3		1.3	
Standard Deviation	0.76		0.62	
Minimum	1		1	
Median	1.0		1.0	
Maximum	5		3	
Week 1				
n	34	32	30	23
Mean	1.5	0.1	1.4	0.1
Standard Deviation	0.79	1.07	0.81	0.46
Minimum	1	-4	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.1	-0.2	1.4	0.2
Standard Deviation	0.35	0.84	0.71	0.80
Minimum	1	-4	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.2	-0.1	1.5	0.3
Standard Deviation	0.55	0.60	0.86	0.88
Minimum	1	-3	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.3	0.1	1.4	0.3
Standard Deviation	0.54	0.62	0.82	0.97
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.2	-0.2	1.7	0.2
Standard Deviation	0.49	1.09	0.91	0.77
Minimum	1	-4	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.1	-0.2	1.6	0.3
Standard Deviation	0.28	0.87	0.73	0.70
Minimum	1	-4	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.3	0.1	1.3	0.0
Standard Deviation	0.71	0.91	0.46	0.61
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.3	0.0	1.5	0.3
Standard Deviation	0.76	1.25	0.59	0.45
Minimum	1	-4	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.1	-0.2	1.4	0.2
Standard Deviation	0.40	0.93	0.59	0.43
Minimum	1	-4	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.3	-0.1	1.7	0.6
Standard Deviation	0.63	1.14	0.78	0.81
Minimum	1	-4	1	0
Median	1.0	0.0	1.5	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.2	-0.1	1.8	0.9
Standard Deviation	0.51	1.02	1.08	1.19
Minimum	1	-4	1	0
Median	1.0	0.0	1.0	1.0
Maximum	3	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.2	-0.1	1.7	0.4
Standard Deviation	0.47	0.73	0.72	0.86
Minimum	1	-3	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.1	-0.2	1.4	0.2
Standard Deviation	0.42	0.98	0.61	0.44
Minimum	1	-4	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.3	0.0	1.6	0.3
Standard Deviation	0.53	1.11	0.88	0.82
Minimum	1	-4	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.3	-0.2	1.7	0.9
Standard Deviation	0.65	1.26	0.78	0.83
Minimum	1	-4	1	0
Median	1.0	0.0	1.5	1.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.3	0.1	1.7	0.7
Standard Deviation	0.63	0.90	1.00	1.11
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.2	-0.1	1.9	0.6
Standard Deviation	0.50	0.62	1.21	0.89
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.2	-0.1	1.6	0.3
Standard Deviation	0.51	0.60	1.06	0.52
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.1	0.1	1.7	0.0
Standard Deviation	0.32	0.43	0.82	0.00
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.1	-0.1	1.6	0.5
Standard Deviation	0.23	0.35	0.74	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	0.5
Maximum	2	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.5	0.3	1.5	0.3
Standard Deviation	0.82	0.83	0.84	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.1	0.1	2.0	0.8
Standard Deviation	0.33	0.38	0.89	0.96
Minimum	1	0	1	0
Median	1.0	0.0	2.0	0.5
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.0	-0.1	1.8	0.3
Standard Deviation	0.00	0.33	0.84	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	1	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.5	0.5	1.7	0.0
Standard Deviation	0.76	0.76	1.15	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.6	0.6	1.7	0.0
Standard Deviation	0.79	0.79	1.15	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.7	0.7	1.0	0.0
Standard Deviation	0.82	0.82	0.00	-
Minimum	1	0	1	0
Median	1.5	0.5	1.0	0.0
Maximum	3	2	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.7	0.7	1.0	0.0
Standard Deviation	1.25	1.25	-	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.3	0.3	1.5	0.0
Standard Deviation	0.52	0.52	0.71	-
Minimum	1	0	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.5	0.5	-	-
Standard Deviation	1.00	1.00	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	3	2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	3.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	3.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	3	-
Median	1.5	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	3.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	1	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.5	3.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	3	-
Median	1.5	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	3.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	3	-
Median	1.5	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.0	0.0	3.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	1	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Diarrhea Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.2	-0.2	1.6	0.2
Standard Deviation	0.40	0.38	0.96	0.70
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	0	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.5		1.8	
Standard Deviation	0.98		1.30	
Minimum	1		1	
Median	1.0		1.0	
Maximum	5		5	
Week 1				
n	34	32	30	23
Mean	1.7	0.3	1.4	0.1
Standard Deviation	0.88	0.57	0.82	0.51
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.4	0.0	1.8	0.3
Standard Deviation	0.80	0.58	0.91	0.75
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.5	0.0	1.7	0.4
Standard Deviation	0.89	0.63	0.79	1.04
Minimum	1	-2	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	5	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.6	0.0	1.7	0.2
Standard Deviation	0.92	0.85	0.84	0.83
Minimum	1	-3	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.3	0.0	2.0	0.5
Standard Deviation	0.45	0.46	1.09	1.05
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	2	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.3	-0.1	1.5	-0.2
Standard Deviation	0.64	0.63	0.67	1.28
Minimum	1	-2	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.3	0.0	1.6	0.2
Standard Deviation	0.54	0.63	0.82	1.07
Minimum	1	-2	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.6	0.0	1.8	0.3
Standard Deviation	0.78	0.66	0.94	1.24
Minimum	1	-2	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.3	-0.2	1.8	0.1
Standard Deviation	0.64	0.86	1.02	1.10
Minimum	1	-3	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.5	0.0	1.7	0.3
Standard Deviation	0.59	0.77	0.89	1.25
Minimum	1	-3	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.4	0.1	1.6	-0.1
Standard Deviation	0.70	0.72	0.76	1.44
Minimum	1	-2	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.6	-0.2	1.6	-0.1
Standard Deviation	0.87	1.13	0.85	1.34
Minimum	1	-4	1	-4
Median	1.0	0.0	1.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.4	-0.2	1.9	0.0
Standard Deviation	0.60	1.09	0.94	1.58
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	3	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.6	-0.1	1.9	-0.2
Standard Deviation	0.86	1.23	0.93	1.47
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.4	-0.2	1.8	0.4
Standard Deviation	0.58	0.76	0.72	1.60
Minimum	1	-2	1	-3
Median	1.0	0.0	2.0	0.5
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.5	-0.2	1.9	-0.1
Standard Deviation	0.79	1.34	0.78	1.46
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.4	0.0	2.1	0.2
Standard Deviation	0.76	1.15	0.90	1.92
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	1.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.3	-0.4	1.9	-0.2
Standard Deviation	0.56	1.18	0.64	1.47
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.2	-0.4	2.0	-1.0
Standard Deviation	0.43	1.22	0.63	1.73
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.4	-0.5	2.1	0.0
Standard Deviation	0.68	1.30	0.35	2.16
Minimum	1	-4	2	-3
Median	1.0	0.0	2.0	0.5
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.3	-0.6	2.0	-0.7
Standard Deviation	0.60	1.22	0.63	2.08
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	3	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.2	0.0	1.8	-0.5
Standard Deviation	0.67	0.00	0.75	2.38
Minimum	1	0	1	-4
Median	1.0	0.0	2.0	0.5
Maximum	3	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.5	-0.8	2.2	-0.7
Standard Deviation	0.85	1.64	0.84	2.08
Minimum	1	-4	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.1	-0.8	1.7	0.0
Standard Deviation	0.35	1.49	0.58	-
Minimum	1	-4	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.1	-0.4	1.7	0.0
Standard Deviation	0.38	1.62	0.58	-
Minimum	1	-4	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.2	-0.5	2.0	0.0
Standard Deviation	0.41	1.76	1.41	-
Minimum	1	-4	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.1	-0.9	2.0	1.0
Standard Deviation	0.38	1.86	-	-
Minimum	1	-4	2	1
Median	1.0	0.0	2.0	1.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.2	-0.5	1.5	0.0
Standard Deviation	0.41	1.76	0.71	-
Minimum	1	-4	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.8	-0.3	-	-
Standard Deviation	0.96	1.26	-	-
Minimum	1	-2	-	-
Median	1.5	0.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	2.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	3.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	1	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	2.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	2	-
Median	1.5	0.5	2.0	-
Maximum	2	1	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.0	0.0	2.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	2	-
Median	1.0	0.0	2.0	-
Maximum	1	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Frequency

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.7	0.2	1.7	0.0
Standard Deviation	0.79	0.83	0.99	0.96
Minimum	1	-1	1	-3
Median	1.5	0.0	1.0	0.0
Maximum	3	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	13		10	
Mean	2.7		3.0	
Standard Deviation	1.11		1.15	
Minimum	2		1	
Median	2.0		3.0	
Maximum	5		5	
Week 1				
n	15	7	8	4
Mean	2.3	0.3	2.4	-0.8
Standard Deviation	0.70	0.49	0.52	0.96
Minimum	1	0	2	-2
Median	2.0	0.0	2.0	-0.5
Maximum	4	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	10	4	16	5
Mean	2.4	0.3	2.5	-0.4
Standard Deviation	0.70	0.50	0.82	1.34
Minimum	2	0	1	-2
Median	2.0	0.0	2.0	-1.0
Maximum	4	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	13	8	19	4
Mean	2.2	-0.4	2.3	-0.5
Standard Deviation	0.83	0.74	0.56	1.29
Minimum	1	-2	2	-2
Median	2.0	0.0	2.0	-0.5
Maximum	4	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	12	4	16	4
Mean	2.5	-0.5	2.4	-0.3
Standard Deviation	0.80	2.08	0.63	1.26
Minimum	2	-3	2	-2
Median	2.0	-0.5	2.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	8	2	15	5
Mean	2.0	0.0	2.8	-0.2
Standard Deviation	0.00	0.00	0.68	0.84
Minimum	2	0	2	-1
Median	2.0	0.0	3.0	0.0
Maximum	2	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	9	3	8	4
Mean	2.3	-0.3	2.1	-1.0
Standard Deviation	0.87	1.15	0.83	1.15
Minimum	1	-1	1	-2
Median	2.0	-1.0	2.0	-1.0
Maximum	4	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	8	3	10	2
Mean	2.0	-1.3	2.3	-1.0
Standard Deviation	0.53	1.15	0.48	0.00
Minimum	1	-2	2	-1
Median	2.0	-2.0	2.0	-1.0
Maximum	3	0	3	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	11	4	12	3
Mean	2.1	-1.0	2.2	0.0
Standard Deviation	0.54	1.83	0.72	1.00
Minimum	1	-3	1	-1
Median	2.0	-1.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	9	4	9	3
Mean	1.9	-1.0	2.3	-0.7
Standard Deviation	0.60	1.15	0.87	1.15
Minimum	1	-2	1	-2
Median	2.0	-1.0	2.0	0.0
Maximum	3	0	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	11	6	10	3
Mean	2.0	-0.5	2.4	-0.7
Standard Deviation	0.00	1.22	0.52	1.53
Minimum	2	-3	2	-2
Median	2.0	0.0	2.0	-1.0
Maximum	2	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	8	4	9	4
Mean	2.3	-0.5	2.3	0.0
Standard Deviation	0.89	1.00	1.12	1.83
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	0	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	14	6	10	3
Mean	2.4	-0.5	2.3	-0.3
Standard Deviation	0.65	1.22	0.48	1.15
Minimum	2	-2	2	-1
Median	2.0	0.0	2.0	-1.0
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	10	4	11	3
Mean	2.1	-0.5	2.3	-0.7
Standard Deviation	0.57	1.29	0.65	1.53
Minimum	1	-2	2	-2
Median	2.0	-0.5	2.0	-1.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	10	4	5	2
Mean	2.2	-0.3	2.2	-0.5
Standard Deviation	0.63	1.26	0.45	2.12
Minimum	1	-2	2	-2
Median	2.0	0.0	2.0	-0.5
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	8	4	8	2
Mean	2.0	-1.0	2.3	-0.5
Standard Deviation	0.76	1.83	0.46	2.12
Minimum	1	-3	2	-2
Median	2.0	-1.0	2.0	-0.5
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	8	2	6	2
Mean	2.3	-1.0	2.2	-1.0
Standard Deviation	0.71	1.41	0.98	2.83
Minimum	2	-2	1	-3
Median	2.0	-1.0	2.0	-1.0
Maximum	4	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	5	0	6	2
Mean	2.4	-	2.0	-0.5
Standard Deviation	0.89	-	0.00	2.12
Minimum	2	-	2	-2
Median	2.0	-	2.0	-0.5
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	5	2	6	2
Mean	2.2	-1.0	2.0	-0.5
Standard Deviation	0.45	1.41	0.00	2.12
Minimum	2	-2	2	-2
Median	2.0	-1.0	2.0	-0.5
Maximum	3	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	4	2	5	2
Mean	1.8	-1.0	2.2	-0.5
Standard Deviation	0.96	2.83	0.45	2.12
Minimum	1	-3	2	-2
Median	1.5	-1.0	2.0	-0.5
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	5	2	8	2
Mean	2.6	-1.0	2.0	-0.5
Standard Deviation	0.89	1.41	0.00	2.12
Minimum	2	-2	2	-2
Median	2.0	-1.0	2.0	-0.5
Maximum	4	0	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	4	3	5	2
Mean	2.3	-1.3	2.0	-0.5
Standard Deviation	0.96	0.58	0.00	2.12
Minimum	1	-2	2	-2
Median	2.5	-1.0	2.0	-0.5
Maximum	3	-1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	1	0	4	1
Mean	2.0	-	2.0	1.0
Standard Deviation	-	-	0.00	-
Minimum	2	-	2	1
Median	2.0	-	2.0	1.0
Maximum	2	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	3	1	4	2
Mean	2.3	-2.0	2.3	-0.5
Standard Deviation	0.58	-	0.50	2.12
Minimum	2	-2	2	-2
Median	2.0	-2.0	2.0	-0.5
Maximum	3	-2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	1	1	2	0
Mean	2.0	-2.0	2.0	-
Standard Deviation	-	-	0.00	-
Minimum	2	-2	2	-
Median	2.0	-2.0	2.0	-
Maximum	2	-2	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	1	0	2	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	0.00	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	1	0	1	0
Mean	2.0	-	3.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	3	-
Median	2.0	-	3.0	-
Maximum	2	-	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	1	0	1	0
Mean	1.0	-	3.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	3	-
Median	1.0	-	3.0	-
Maximum	1	-	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	2	1	0	0
Mean	2.0	-2.0	-	-
Standard Deviation	1.41	-	-	-
Minimum	1	-2	-	-
Median	2.0	-2.0	-	-
Maximum	3	-2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	1	0	1	0
Mean	1.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	2	-
Median	1.0	-	2.0	-
Maximum	1	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	8	3	9	3
Mean	2.1	0.3	2.6	-0.3
Standard Deviation	0.35	0.58	0.88	1.53
Minimum	2	0	2	-2
Median	2.0	0.0	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	13		9	
Mean	2.2		2.9	
Standard Deviation	1.07		1.54	
Minimum	1		1	
Median	2.0		3.0	
Maximum	4		5	
Week 1				
n	14	7	8	4
Mean	2.3	0.6	2.1	0.3
Standard Deviation	0.91	0.79	0.99	0.96
Minimum	1	0	1	-1
Median	2.0	0.0	2.0	0.5
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	10	4	15	5
Mean	2.0	0.3	2.1	-0.4
Standard Deviation	0.82	0.50	0.96	1.14
Minimum	1	0	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	12	8	19	3
Mean	1.7	-0.4	1.7	-0.3
Standard Deviation	0.89	1.19	0.58	0.58
Minimum	1	-2	1	-1
Median	1.5	0.0	2.0	0.0
Maximum	4	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	12	4	16	4
Mean	2.3	0.3	1.9	-0.3
Standard Deviation	1.23	1.50	0.72	0.96
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	-0.5
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	8	2	15	5
Mean	1.4	-0.5	2.1	-1.0
Standard Deviation	0.52	0.71	0.99	1.22
Minimum	1	-1	1	-3
Median	1.0	-0.5	2.0	-1.0
Maximum	2	0	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	8	2	6	2
Mean	2.0	0.0	2.2	0.0
Standard Deviation	1.07	0.00	0.41	1.41
Minimum	1	0	2	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	7	3	10	2
Mean	1.9	-1.3	2.0	0.0
Standard Deviation	0.69	1.53	0.82	0.00
Minimum	1	-3	1	0
Median	2.0	-1.0	2.0	0.0
Maximum	3	0	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	10	4	10	2
Mean	1.9	-0.8	2.1	0.5
Standard Deviation	0.57	0.96	0.74	0.71
Minimum	1	-2	1	0
Median	2.0	-0.5	2.0	0.5
Maximum	3	0	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	7	4	8	3
Mean	1.4	-0.8	1.8	-0.7
Standard Deviation	0.79	0.96	1.16	2.89
Minimum	1	-2	1	-4
Median	1.0	-0.5	1.0	1.0
Maximum	3	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	11	6	10	2
Mean	1.7	0.0	2.0	-2.0
Standard Deviation	0.47	1.10	0.67	2.83
Minimum	1	-2	1	-4
Median	2.0	0.0	2.0	-2.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	7	4	8	3
Mean	1.7	-0.3	1.9	-1.0
Standard Deviation	1.11	0.96	1.46	2.65
Minimum	1	-1	1	-4
Median	1.0	-0.5	1.0	0.0
Maximum	4	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	14	6	10	2
Mean	2.1	-0.3	1.9	0.0
Standard Deviation	0.86	1.03	0.74	0.00
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	0.0
Maximum	4	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	9	3	11	2
Mean	1.6	0.3	1.9	-2.0
Standard Deviation	0.73	1.15	0.83	2.83
Minimum	1	-1	1	-4
Median	1.0	1.0	2.0	-2.0
Maximum	3	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	9	4	5	1
Mean	2.0	0.0	1.4	-4.0
Standard Deviation	0.00	0.82	0.55	-
Minimum	2	-1	1	-4
Median	2.0	0.0	1.0	-4.0
Maximum	2	1	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	6	3	8	1
Mean	1.7	-0.3	1.5	-4.0
Standard Deviation	0.82	1.53	0.53	-
Minimum	1	-2	1	-4
Median	1.5	0.0	1.5	-4.0
Maximum	3	1	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	8	2	5	0
Mean	2.0	-0.5	2.0	-
Standard Deviation	0.93	0.71	1.00	-
Minimum	1	-1	1	-
Median	2.0	-0.5	2.0	-
Maximum	4	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	5	0	6	1
Mean	1.6	-	1.7	-4.0
Standard Deviation	0.55	-	0.82	-
Minimum	1	-	1	-4
Median	2.0	-	1.5	-4.0
Maximum	2	-	3	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	5	2	6	1
Mean	1.8	-0.5	1.8	-4.0
Standard Deviation	0.45	0.71	0.75	-
Minimum	1	-1	1	-4
Median	2.0	-0.5	2.0	-4.0
Maximum	2	0	3	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	2	1	5	1
Mean	2.0	0.0	1.6	-4.0
Standard Deviation	0.00	-	0.55	-
Minimum	2	0	1	-4
Median	2.0	0.0	2.0	-4.0
Maximum	2	0	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	5	2	8	1
Mean	2.0	-1.0	1.5	-4.0
Standard Deviation	0.00	0.00	0.53	-
Minimum	2	-1	1	-4
Median	2.0	-1.0	1.5	-4.0
Maximum	2	-1	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	3	2	5	1
Mean	1.7	-1.5	1.6	-4.0
Standard Deviation	0.58	0.71	0.55	-
Minimum	1	-2	1	-4
Median	2.0	-1.5	2.0	-4.0
Maximum	2	-1	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	1	0	4	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	0.00	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	3	1	4	1
Mean	2.3	-1.0	1.8	-4.0
Standard Deviation	0.58	-	0.50	-
Minimum	2	-1	1	-4
Median	2.0	-1.0	2.0	-4.0
Maximum	3	-1	2	-4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	1	1	2	0
Mean	1.0	-2.0	2.0	-
Standard Deviation	-	-	0.00	-
Minimum	1	-2	2	-
Median	1.0	-2.0	2.0	-
Maximum	1	-2	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	1	0	2	0
Mean	2.0	-	1.5	-
Standard Deviation	-	-	0.71	-
Minimum	2	-	1	-
Median	2.0	-	1.5	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	1	0	1	0
Mean	1.0	-	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	-	1	-
Median	1.0	-	1.0	-
Maximum	1	-	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	1	1	0	0
Mean	3.0	-1.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	-1	-	-
Median	3.0	-1.0	-	-
Maximum	3	-1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	1	0
Mean	2.0	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	2	-	2	-
Median	2.0	-	2.0	-
Maximum	2	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	0	0	1	0
Mean	-	-	2.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	2	-
Median	-	-	2.0	-
Maximum	-	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Abdominal Pain Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	8	3	9	3
Mean	1.8	0.3	2.0	-0.3
Standard Deviation	0.46	0.58	1.22	3.21
Minimum	1	0	1	-4
Median	2.0	0.0	2.0	1.0
Maximum	2	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.3		1.4	
Standard Deviation	0.61		0.71	
Minimum	1		1	
Median	1.0		1.0	
Maximum	3		4	
Week 1				
n	34	32	30	23
Mean	1.4	0.0	1.5	0.1
Standard Deviation	0.70	0.54	0.78	0.51
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.2	-0.1	1.6	0.3
Standard Deviation	0.43	0.51	0.80	0.76
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.3	0.0	1.7	0.4
Standard Deviation	0.52	0.49	0.80	0.66
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.3	-0.1	1.6	0.3
Standard Deviation	0.53	0.60	0.70	0.54
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.2	-0.1	1.6	0.4
Standard Deviation	0.51	0.45	0.74	0.59
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.2	-0.1	1.7	0.3
Standard Deviation	0.41	0.50	0.78	0.60
Minimum	1	-1	1	-1
Median	1.0	0.0	1.5	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.3	-0.1	1.5	0.2
Standard Deviation	0.53	0.56	0.59	0.64
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.3	0.0	1.4	0.2
Standard Deviation	0.48	0.66	0.51	0.40
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.3	0.0	1.4	0.1
Standard Deviation	0.53	0.54	0.49	0.53
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.4	-0.1	1.4	0.1
Standard Deviation	0.49	0.69	0.58	0.34
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.2	-0.2	1.6	0.3
Standard Deviation	0.37	0.59	0.69	0.63
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.5	0.1	1.4	0.2
Standard Deviation	0.61	0.61	0.50	0.44
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.3	-0.1	1.8	0.6
Standard Deviation	0.52	0.74	0.88	0.96
Minimum	1	-2	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.3	0.0	1.2	-0.2
Standard Deviation	0.49	0.58	0.44	0.41
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.4	0.0	1.4	0.3
Standard Deviation	0.50	0.58	0.67	0.89
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.3	0.1	1.7	0.4
Standard Deviation	0.70	0.90	0.71	0.53
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.4	0.3	1.1	0.0
Standard Deviation	0.60	0.68	0.38	0.00
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.3	0.1	1.8	0.5
Standard Deviation	0.58	0.66	0.46	0.55
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.5
Maximum	3	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.3	0.2	1.3	0.0
Standard Deviation	0.49	0.53	0.52	0.00
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.5	0.2	1.5	0.5
Standard Deviation	0.84	0.94	0.53	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	0.5
Maximum	4	3	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.5	0.1	1.5	0.7
Standard Deviation	0.63	0.53	0.55	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	1.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.6	0.0	1.7	0.5
Standard Deviation	1.33	0.58	0.52	1.00
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	5	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.5	0.1	1.6	0.3
Standard Deviation	0.71	0.60	0.55	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.3	0.1	1.0	0.0
Standard Deviation	0.46	0.64	0.00	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.0	-0.1	1.0	0.0
Standard Deviation	0.00	0.38	0.00	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.3	0.2	1.0	0.0
Standard Deviation	0.52	0.75	0.00	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.1	0.0	1.0	0.0
Standard Deviation	0.38	0.58	-	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.0	-0.2	1.0	0.0
Standard Deviation	0.00	0.41	0.00	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.0	-0.3	-	-
Standard Deviation	0.00	0.50	-	-
Minimum	1	-1	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.0	1.0	-
Standard Deviation	0.58	1.00	-	-
Minimum	1	-1	1	-
Median	1.0	0.0	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	2.0	1.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	2	1	1	-
Median	2.0	1.0	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.8	0.4	1.8	0.4
Standard Deviation	1.22	1.33	0.71	0.74
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	5	4	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	12		9	
Mean	1.8		2.1	
Standard Deviation	0.58		1.17	
Minimum	1		1	
Median	2.0		2.0	
Maximum	3		5	
Week 1				
n	10	5	12	5
Mean	2.2	0.8	1.9	0.2
Standard Deviation	0.79	0.45	1.00	1.48
Minimum	1	0	1	-2
Median	2.0	1.0	2.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	9	6	14	6
Mean	2.0	0.2	1.7	0.0
Standard Deviation	0.50	0.41	0.73	1.10
Minimum	1	0	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	12	8	18	5
Mean	1.8	0.1	2.2	0.8
Standard Deviation	0.39	0.64	0.92	0.84
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	1.0
Maximum	2	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	8	3	16	6
Mean	2.0	0.3	1.9	0.2
Standard Deviation	0.76	1.15	0.50	0.75
Minimum	1	-1	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	6	4	14	4
Mean	2.0	0.3	2.0	0.3
Standard Deviation	0.00	0.96	1.04	0.50
Minimum	2	-1	1	0
Median	2.0	0.5	2.0	0.0
Maximum	2	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	7	5	11	5
Mean	1.7	0.0	2.0	0.0
Standard Deviation	0.49	1.00	0.63	0.00
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	7	3	10	3
Mean	2.0	0.7	1.8	0.3
Standard Deviation	0.00	0.58	0.63	0.58
Minimum	2	0	1	0
Median	2.0	1.0	2.0	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	10	4	10	5
Mean	1.7	-0.3	1.8	0.2
Standard Deviation	0.48	0.96	0.63	0.45
Minimum	1	-1	1	0
Median	2.0	-0.5	2.0	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	10	6	7	2
Mean	1.8	0.2	1.4	-0.5
Standard Deviation	0.63	0.98	0.53	0.71
Minimum	1	-1	1	-1
Median	2.0	0.5	1.0	-0.5
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	9	4	7	4
Mean	1.8	0.5	1.7	0.0
Standard Deviation	0.67	0.58	0.49	0.00
Minimum	1	0	1	0
Median	2.0	0.5	2.0	0.0
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	4	3	9	4
Mean	2.0	0.0	1.9	0.5
Standard Deviation	0.00	1.00	0.78	0.58
Minimum	2	-1	1	0
Median	2.0	0.0	2.0	0.5
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	16	6	9	3
Mean	1.9	0.5	1.8	0.0
Standard Deviation	0.62	0.55	0.67	0.00
Minimum	1	0	1	0
Median	2.0	0.5	2.0	0.0
Maximum	3	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	8	3	10	4
Mean	1.8	0.3	2.3	0.0
Standard Deviation	0.71	1.15	0.82	0.82
Minimum	1	-1	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	9	5	2	1
Mean	1.8	-0.2	2.5	0.0
Standard Deviation	0.44	0.84	0.71	-
Minimum	1	-1	2	0
Median	2.0	0.0	2.5	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	9	6	4	1
Mean	1.7	-0.2	2.0	0.0
Standard Deviation	0.71	0.75	0.00	-
Minimum	1	-1	2	0
Median	2.0	0.0	2.0	0.0
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	5	1	5	2
Mean	2.2	1.0	1.8	0.5
Standard Deviation	1.10	-	0.84	0.71
Minimum	1	1	1	0
Median	2.0	1.0	2.0	0.5
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	6	2	1	1
Mean	1.7	0.5	3.0	1.0
Standard Deviation	0.82	0.71	-	-
Minimum	1	0	3	1
Median	1.5	0.5	3.0	1.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	6	2	6	2
Mean	1.8	0.5	1.3	-0.5
Standard Deviation	0.75	0.71	0.52	0.71
Minimum	1	0	1	-1
Median	2.0	0.5	1.0	-0.5
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	6	2	2	1
Mean	1.8	0.5	2.0	0.0
Standard Deviation	0.41	0.71	0.00	-
Minimum	1	0	2	0
Median	2.0	0.5	2.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	6	1	4	1
Mean	2.0	0.0	2.0	0.0
Standard Deviation	1.26	-	0.00	-
Minimum	1	0	2	0
Median	1.5	0.0	2.0	0.0
Maximum	4	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	7	3	3	1
Mean	2.0	0.3	1.7	1.0
Standard Deviation	1.00	0.58	1.15	-
Minimum	1	0	1	1
Median	2.0	0.0	1.0	1.0
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	2	0	4	0
Mean	3.0	-	1.5	-
Standard Deviation	2.83	-	0.58	-
Minimum	1	-	1	-
Median	3.0	-	1.5	-
Maximum	5	-	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	4	1	3	1
Mean	2.0	0.0	2.0	0.0
Standard Deviation	0.82	-	0.00	-
Minimum	1	0	2	0
Median	2.0	0.0	2.0	0.0
Maximum	3	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	2	0	0	0
Mean	1.5	-	-	-
Standard Deviation	0.71	-	-	-
Minimum	1	-	-	-
Median	1.5	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	2	0	0	0
Mean	2.0	-	-	-
Standard Deviation	0.00	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	0	0	0
Mean	1.5	-	-	-
Standard Deviation	0.71	-	-	-
Minimum	1	-	-	-
Median	1.5	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Shortness of Breath Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	7	4	12	5
Mean	2.9	0.8	1.9	0.0
Standard Deviation	1.46	0.96	0.51	0.71
Minimum	1	0	1	-1
Median	2.0	0.5	2.0	0.0
Maximum	5	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.2		1.4	
Standard Deviation	0.52		0.66	
Minimum	1		1	
Median	1.0		1.0	
Maximum	3		3	
Week 1				
n	34	32	30	23
Mean	1.4	0.3	1.5	0.1
Standard Deviation	0.70	0.64	0.73	0.69
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.4	0.2	1.5	0.3
Standard Deviation	0.79	0.76	0.72	0.62
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	5	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.3	0.0	1.5	0.1
Standard Deviation	0.50	0.54	0.71	0.55
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.4	0.2	1.4	0.2
Standard Deviation	0.61	0.70	0.61	0.52
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.3	0.2	1.4	0.3
Standard Deviation	0.53	0.70	0.64	0.72
Minimum	1	-2	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.3	0.1	1.6	0.4
Standard Deviation	0.48	0.67	0.85	0.96
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	2	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.3	0.2	1.6	0.5
Standard Deviation	0.55	0.83	0.97	1.12
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.5	0.3	1.6	0.6
Standard Deviation	0.57	0.69	0.94	1.09
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.4	0.1	1.6	0.4
Standard Deviation	0.65	0.66	0.83	0.84
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.4	0.1	1.7	0.4
Standard Deviation	0.57	0.63	0.70	0.62
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.4	0.3	1.6	0.3
Standard Deviation	0.70	0.74	0.68	0.48
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.4	0.3	1.6	0.2
Standard Deviation	0.69	0.83	0.85	0.90
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	3	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.5	0.3	1.6	0.1
Standard Deviation	0.83	0.98	0.70	0.49
Minimum	1	-2	1	-1
Median	1.0	0.0	1.5	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.6	0.3	1.4	0.0
Standard Deviation	0.81	1.09	0.73	0.63
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.4	0.2	1.6	0.0
Standard Deviation	0.59	0.79	0.90	0.53
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.3	0.1	1.4	0.1
Standard Deviation	0.54	0.64	0.53	0.38
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.4	0.1	1.3	-0.2
Standard Deviation	0.76	0.72	0.49	0.45
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.4	0.4	1.8	0.2
Standard Deviation	0.81	1.06	0.71	0.41
Minimum	1	-2	1	0
Median	1.0	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.3	0.2	1.5	0.0
Standard Deviation	0.46	0.73	0.55	0.00
Minimum	1	-2	1	0
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.5	0.3	1.4	0.0
Standard Deviation	0.61	0.90	0.52	0.82
Minimum	1	-2	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.4	0.5	1.3	0.0
Standard Deviation	0.63	0.65	0.52	0.00
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.3	0.1	1.5	-0.3
Standard Deviation	0.50	1.07	0.55	0.50
Minimum	1	-2	1	-1
Median	1.0	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.7	0.8	1.4	0.0
Standard Deviation	0.82	0.83	0.55	0.00
Minimum	1	0	1	0
Median	1.5	1.0	1.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.4	0.1	1.0	0.0
Standard Deviation	0.52	0.99	0.00	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.4	0.1	1.0	0.0
Standard Deviation	0.53	1.07	0.00	-
Minimum	1	-2	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.2	-0.2	1.0	0.0
Standard Deviation	0.41	0.41	0.00	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.3	0.0	1.0	0.0
Standard Deviation	0.49	0.58	-	-
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.3	0.3	1.0	0.0
Standard Deviation	0.52	0.52	0.00	-
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	2	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.3	0.3	-	-
Standard Deviation	0.50	0.50	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.0	0.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	1	-
Median	1.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.0	0.0	5.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	5	-
Median	1.0	0.0	5.0	-
Maximum	1	0	5	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.8	0.6	1.5	0.2
Standard Deviation	1.13	0.96	0.77	0.43
Minimum	1	0	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	8		9	
Mean	1.8		1.7	
Standard Deviation	0.89		0.71	
Minimum	1		1	
Median	1.5		2.0	
Maximum	3		3	
Week 1				
n	11	3	12	3
Mean	1.7	0.3	1.7	0.3
Standard Deviation	1.01	1.15	0.89	1.53
Minimum	1	-1	1	-1
Median	1.0	1.0	1.5	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	9	4	12	6
Mean	1.8	0.5	1.5	0.0
Standard Deviation	1.30	1.29	0.80	1.26
Minimum	1	-1	1	-1
Median	1.0	0.5	1.0	-0.5
Maximum	5	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	10	4	12	4
Mean	1.5	0.0	1.8	0.8
Standard Deviation	0.71	0.82	0.87	0.50
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	1.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	9	2	13	3
Mean	1.7	1.0	1.6	0.3
Standard Deviation	0.71	0.00	0.51	0.58
Minimum	1	1	1	0
Median	2.0	1.0	2.0	0.0
Maximum	3	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	7	1	10	4
Mean	1.4	1.0	1.7	0.3
Standard Deviation	0.53	-	0.48	0.50
Minimum	1	1	1	0
Median	1.0	1.0	2.0	0.0
Maximum	2	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	12	3	10	4
Mean	1.6	0.7	1.5	-0.5
Standard Deviation	0.51	0.58	0.97	0.58
Minimum	1	0	1	-1
Median	2.0	1.0	1.0	-0.5
Maximum	2	1	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	9	1	9	4
Mean	1.7	1.0	1.9	0.3
Standard Deviation	0.50	-	1.36	0.96
Minimum	1	1	1	-1
Median	2.0	1.0	1.0	0.5
Maximum	2	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	14	4	10	4
Mean	1.6	-0.3	2.1	0.3
Standard Deviation	0.65	0.96	1.37	1.26
Minimum	1	-1	1	-1
Median	1.5	-0.5	2.0	0.0
Maximum	3	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	10	3	8	3
Mean	1.6	0.3	1.4	0.0
Standard Deviation	0.52	0.58	0.74	1.00
Minimum	1	0	1	-1
Median	2.0	0.0	1.0	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	8	3	13	6
Mean	1.3	0.0	1.7	0.5
Standard Deviation	0.46	1.00	0.75	0.84
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	7	2	10	4
Mean	1.7	0.0	1.4	0.0
Standard Deviation	0.95	1.41	0.70	0.82
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	11	1	9	5
Mean	2.1	1.0	2.0	0.6
Standard Deviation	0.83	-	1.12	0.89
Minimum	1	1	1	-1
Median	2.0	1.0	2.0	1.0
Maximum	4	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	12	2	9	6
Mean	1.9	0.0	1.8	0.5
Standard Deviation	1.08	1.41	0.83	1.05
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.5
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	11	2	3	1
Mean	1.8	0.0	1.7	0.0
Standard Deviation	0.75	1.41	0.58	-
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	0.0
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	9	2	5	3
Mean	1.8	-0.5	1.8	0.7
Standard Deviation	0.83	0.71	0.84	1.15
Minimum	1	-1	1	0
Median	2.0	-0.5	2.0	0.0
Maximum	3	0	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	5	0	4	3
Mean	1.8	-	1.8	0.7
Standard Deviation	0.84	-	0.96	0.58
Minimum	1	-	1	0
Median	2.0	-	1.5	1.0
Maximum	3	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	5	0	2	2
Mean	2.0	-	2.0	0.5
Standard Deviation	1.22	-	1.41	0.71
Minimum	1	-	1	0
Median	2.0	-	2.0	0.5
Maximum	4	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	6	0	5	3
Mean	1.8	-	1.6	0.3
Standard Deviation	1.17	-	0.55	0.58
Minimum	1	-	1	0
Median	1.5	-	2.0	0.0
Maximum	4	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	5	0	3	2
Mean	1.2	-	1.7	0.0
Standard Deviation	0.45	-	0.58	0.00
Minimum	1	-	1	0
Median	1.0	-	2.0	0.0
Maximum	2	-	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	8	0	3	2
Mean	1.5	-	1.3	0.0
Standard Deviation	0.53	-	0.58	0.00
Minimum	1	-	1	0
Median	1.5	-	1.0	0.0
Maximum	2	-	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	6	0	2	2
Mean	1.3	-	2.0	0.5
Standard Deviation	0.52	-	1.41	0.71
Minimum	1	-	1	0
Median	1.0	-	2.0	0.5
Maximum	2	-	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	3	0	3	2
Mean	1.0	-	1.7	0.0
Standard Deviation	0.00	-	0.58	0.00
Minimum	1	-	1	0
Median	1.0	-	2.0	0.0
Maximum	1	-	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	5	0	2	2
Mean	2.0	-	2.0	0.5
Standard Deviation	0.71	-	0.00	0.71
Minimum	1	-	2	0
Median	2.0	-	2.0	0.5
Maximum	3	-	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	3	0	0	0
Mean	1.7	-	-	-
Standard Deviation	0.58	-	-	-
Minimum	1	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	3	0	0	0
Mean	1.0	-	-	-
Standard Deviation	0.00	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	1	1	0	0
Mean	1.0	-1.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	-1	-	-
Median	1.0	-1.0	-	-
Maximum	1	-1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	2	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	2	0	0	0
Mean	1.5	-	-	-
Standard Deviation	0.71	-	-	-
Minimum	1	-	-	-
Median	1.5	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	1	0	0	0
Mean	2.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	2	-	-	-
Median	2.0	-	-	-
Maximum	2	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	0	0	1	0
Mean	-	-	4.0	-
Standard Deviation	-	-	-	-
Minimum	-	-	4	-
Median	-	-	4.0	-
Maximum	-	-	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	0	0	0
Mean	1.0	-	-	-
Standard Deviation	-	-	-	-
Minimum	1	-	-	-
Median	1.0	-	-	-
Maximum	1	-	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Cough Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	6	4	7	3
Mean	2.5	0.5	1.9	0.7
Standard Deviation	1.38	0.58	0.69	1.15
Minimum	1	0	1	0
Median	2.5	0.5	2.0	0.0
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	0.2		0.1	
Standard Deviation	0.42		0.34	
Minimum	0		0	
Median	0.0		0.0	
Maximum	1		1	
Week 1				
n	34	32	30	23
Mean	0.4	0.1	0.1	-0.1
Standard Deviation	0.49	0.55	0.25	0.29
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	0.3	0.1	0.2	0.1
Standard Deviation	0.47	0.45	0.40	0.51
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	0.3	0.0	0.2	0.0
Standard Deviation	0.45	0.49	0.43	0.37
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	0.1	-0.1	0.1	-0.1
Standard Deviation	0.30	0.51	0.33	0.42
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	0.2	-0.1	0.3	0.2
Standard Deviation	0.44	0.50	0.45	0.59
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	0.2	-0.1	0.2	0.0
Standard Deviation	0.38	0.54	0.39	0.52
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	0.1	-0.1	0.2	-0.1
Standard Deviation	0.35	0.48	0.41	0.56
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	0.2	0.0	0.1	-0.1
Standard Deviation	0.44	0.57	0.34	0.34
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	0.1	-0.1	0.1	-0.1
Standard Deviation	0.36	0.47	0.31	0.27
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	0.1	-0.1	0.2	-0.1
Standard Deviation	0.33	0.42	0.39	0.34
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	0.3	0.0	0.1	-0.1
Standard Deviation	0.45	0.62	0.32	0.49
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	0.2	-0.1	0.1	-0.1
Standard Deviation	0.38	0.52	0.29	0.33
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	0.2	-0.1	0.2	-0.2
Standard Deviation	0.36	0.42	0.43	0.38
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	0.2	0.0	0.1	-0.2
Standard Deviation	0.43	0.49	0.33	0.41
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	0.1	-0.2	0.2	-0.1
Standard Deviation	0.34	0.50	0.39	0.35
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	0.1	-0.1	0.2	0.0
Standard Deviation	0.34	0.47	0.44	0.58
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	0.1	-0.1	0.3	0.0
Standard Deviation	0.32	0.57	0.49	0.71
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	0.1	-0.2	0.3	0.0
Standard Deviation	0.30	0.53	0.46	0.63
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	0.1	-0.2	0.2	-0.3
Standard Deviation	0.24	0.44	0.41	0.58
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	0.2	-0.1	0.3	0.0
Standard Deviation	0.37	0.46	0.46	0.82
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	0.1	-0.2	0.2	-0.3
Standard Deviation	0.34	0.43	0.41	0.58
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	0.2	-0.3	0.3	0.0
Standard Deviation	0.44	0.76	0.52	0.82
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	0.1	-0.3	0.6	0.0
Standard Deviation	0.32	0.50	0.55	0.00
Minimum	0	-1	0	0
Median	0.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	0.0	-0.4	0.7	0.0
Standard Deviation	0.00	0.52	0.58	-
Minimum	0	-1	0	0
Median	0.0	0.0	1.0	0.0
Maximum	0	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	0.0	-0.3	0.7	0.0
Standard Deviation	0.00	0.49	0.58	-
Minimum	0	-1	0	0
Median	0.0	0.0	1.0	0.0
Maximum	0	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	0.0	-0.2	0.5	0.0
Standard Deviation	0.00	0.41	0.71	-
Minimum	0	-1	0	0
Median	0.0	0.0	0.5	0.0
Maximum	0	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	0.1	-0.1	1.0	0.0
Standard Deviation	0.38	0.38	-	-
Minimum	0	-1	1	0
Median	0.0	0.0	1.0	0.0
Maximum	1	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	0.0	-0.3	0.5	0.0
Standard Deviation	0.00	0.52	0.71	-
Minimum	0	-1	0	0
Median	0.0	0.0	0.5	0.0
Maximum	0	0	1	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	0.0	-0.3	-	-
Standard Deviation	0.00	0.50	-	-
Minimum	0	-1	-	-
Median	0.0	0.0	-	-
Maximum	0	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	0.3	0.0	1.0	-
Standard Deviation	0.58	0.00	-	-
Minimum	0	0	1	-
Median	0.0	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	0.0	-0.5	1.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	0	-1	1	-
Median	0.0	-0.5	1.0	-
Maximum	0	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	0.0	-1.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	0	-1	1	-
Median	0.0	-1.0	1.0	-
Maximum	0	-1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	0.5	0.0	1.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	0	0	1	-
Median	0.5	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	0.5	0.0	1.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	0	0	1	-
Median	0.5	0.0	1.0	-
Maximum	1	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	0.5	0.0	0.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	0	0	0	-
Median	0.5	0.0	0.0	-
Maximum	1	0	0	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	0.0	-1.0	-	-
Standard Deviation	-	-	-	-
Minimum	0	-1	-	-
Median	0.0	-1.0	-	-
Maximum	0	-1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Rash Presence

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	0.3	0.0	0.1	0.0
Standard Deviation	0.45	0.41	0.32	0.39
Minimum	0	-1	0	-1
Median	0.0	0.0	0.0	0.0
Maximum	1	1	1	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.3		1.2	
Standard Deviation	0.64		0.40	
Minimum	1		1	
Median	1.0		1.0	
Maximum	4		2	
Week 1				
n	34	32	30	23
Mean	1.3	0.1	1.2	0.0
Standard Deviation	0.59	0.50	0.46	0.37
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.5	0.2	1.5	0.3
Standard Deviation	0.96	1.21	0.89	0.82
Minimum	1	-3	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	5	4	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	2.6	1.2	2.4	0.9
Standard Deviation	1.45	1.51	1.69	1.47
Minimum	1	-1	1	-1
Median	2.0	1.0	1.5	0.0
Maximum	5	4	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	2.5	1.1	2.4	0.9
Standard Deviation	1.26	1.22	1.64	1.41
Minimum	1	0	1	-1
Median	3.0	1.0	2.0	0.0
Maximum	5	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	2.2	0.8	2.3	1.1
Standard Deviation	0.95	1.18	1.48	1.50
Minimum	1	-2	1	-1
Median	2.0	0.5	2.0	0.0
Maximum	4	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	2.3	0.8	2.7	1.3
Standard Deviation	1.10	1.31	1.45	1.24
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	4	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	2.3	0.8	2.4	1.1
Standard Deviation	1.11	1.26	1.53	1.36
Minimum	1	-2	1	0
Median	2.0	0.5	2.0	0.0
Maximum	5	4	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	2.1	0.5	2.3	1.3
Standard Deviation	1.10	1.10	1.50	1.40
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	2.0	0.4	2.2	1.1
Standard Deviation	1.01	0.98	1.31	1.23
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	2.2	0.6	2.3	1.2
Standard Deviation	1.00	1.08	1.46	1.28
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	2.3	0.7	1.8	0.8
Standard Deviation	1.28	1.23	0.90	0.99
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	4	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	2.1	0.6	2.2	0.9
Standard Deviation	1.08	0.89	1.31	1.03
Minimum	1	-1	1	0
Median	2.0	0.5	2.0	1.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.9	0.3	2.4	1.0
Standard Deviation	1.13	1.17	1.38	1.15
Minimum	1	-3	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	2.0	0.5	1.9	0.3
Standard Deviation	1.37	1.57	1.27	0.82
Minimum	1	-3	1	-1
Median	1.5	0.0	2.0	0.5
Maximum	5	4	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	2.1	0.6	2.3	0.8
Standard Deviation	1.29	1.34	1.67	1.04
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	0.5
Maximum	5	4	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	2.0	0.4	1.8	0.6
Standard Deviation	1.33	1.42	0.97	0.79
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	0.0
Maximum	5	4	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.8	0.3	1.9	0.6
Standard Deviation	1.03	1.13	1.46	1.34
Minimum	1	-2	1	0
Median	2.0	0.0	1.0	0.0
Maximum	5	3	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	2.0	0.4	1.8	0.7
Standard Deviation	1.40	1.33	1.04	0.82
Minimum	1	-1	1	0
Median	1.0	0.0	1.5	0.5
Maximum	5	4	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.6	0.2	1.7	0.7
Standard Deviation	1.04	1.19	0.52	0.58
Minimum	1	-2	1	0
Median	1.0	0.0	2.0	1.0
Maximum	5	4	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.8	0.1	2.0	1.3
Standard Deviation	1.12	0.83	1.31	1.89
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	0.5
Maximum	5	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	2.3	0.8	1.8	0.7
Standard Deviation	1.58	1.58	0.75	1.15
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	0.0
Maximum	5	4	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	2.1	-0.4	2.2	1.0
Standard Deviation	1.45	1.40	0.98	0.82
Minimum	1	-3	1	0
Median	2.0	0.0	2.0	1.0
Maximum	5	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.6	0.1	1.4	0.3
Standard Deviation	1.07	0.78	0.55	0.58
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	4	2	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.8	0.1	1.7	0.0
Standard Deviation	0.46	1.13	0.58	-
Minimum	1	-2	1	0
Median	2.0	0.5	2.0	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	2.0	0.3	1.7	0.0
Standard Deviation	0.58	0.95	0.58	-
Minimum	1	-1	1	0
Median	2.0	1.0	2.0	0.0
Maximum	3	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	2.0	0.2	3.0	0.0
Standard Deviation	0.63	0.98	1.41	-
Minimum	1	-1	2	0
Median	2.0	0.5	3.0	0.0
Maximum	3	1	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	2.0	0.3	2.0	0.0
Standard Deviation	0.82	1.50	-	-
Minimum	1	-2	2	0
Median	2.0	0.0	2.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.7	0.3	2.5	0.0
Standard Deviation	0.52	0.82	0.71	-
Minimum	1	-1	2	0
Median	2.0	0.5	2.5	0.0
Maximum	2	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	2.0	0.5	-	-
Standard Deviation	0.82	1.29	-	-
Minimum	1	-1	-	-
Median	2.0	0.5	-	-
Maximum	3	2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	2.3	0.7	1.0	-
Standard Deviation	0.58	1.53	-	-
Minimum	2	-1	1	-
Median	2.0	1.0	1.0	-
Maximum	3	2	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	2.5	1.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	2	1	1	-
Median	2.5	1.5	1.0	-
Maximum	3	2	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	3.0	2.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	3	2	1	-
Median	3.0	2.0	1.0	-
Maximum	3	2	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	2.0	1.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	2	1	1	-
Median	2.0	1.0	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	2.0	1.0	1.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	2	1	1	-
Median	2.0	1.0	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.5	0.5	1.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	1	-
Median	1.5	0.5	1.0	-
Maximum	2	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	1	-	-
Median	2.0	1.0	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hair Loss Amount

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	2.6	1.3	1.5	0.1
Standard Deviation	1.50	1.65	1.02	0.53
Minimum	1	-1	1	-1
Median	2.0	1.0	1.0	0.0
Maximum	5	4	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.3		1.4	
Standard Deviation	0.63		0.91	
Minimum	1		1	
Median	1.0		1.0	
Maximum	4		4	
Week 1				
n	34	32	30	23
Mean	1.2	-0.1	1.3	0.0
Standard Deviation	0.39	0.49	0.55	0.60
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.2	-0.2	1.5	0.0
Standard Deviation	0.44	0.52	0.81	1.02
Minimum	1	-2	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.2	-0.2	1.4	-0.1
Standard Deviation	0.38	0.63	0.60	0.85
Minimum	1	-2	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	2	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.3	0.0	1.5	0.1
Standard Deviation	0.59	0.52	0.86	0.87
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.3	0.0	1.9	0.5
Standard Deviation	0.61	0.51	1.28	1.19
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.4	0.1	1.6	0.2
Standard Deviation	0.74	0.57	0.96	0.98
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.2	0.0	1.5	-0.1
Standard Deviation	0.51	0.40	0.83	1.34
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.6	0.3	1.5	0.0
Standard Deviation	0.91	0.75	0.95	1.15
Minimum	1	-1	1	-2
Median	1.0	0.0	1.0	0.0
Maximum	4	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.3	0.0	1.8	0.2
Standard Deviation	0.63	0.54	1.02	1.12
Minimum	1	-1	1	-2
Median	1.0	0.0	1.5	0.0
Maximum	3	1	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.4	0.0	1.6	0.4
Standard Deviation	0.70	0.71	1.05	1.41
Minimum	1	-2	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	3	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.5	0.2	1.7	0.5
Standard Deviation	0.76	0.51	1.05	1.13
Minimum	1	-1	1	-1
Median	1.0	0.0	1.0	0.0
Maximum	4	1	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.6	0.2	1.7	0.2
Standard Deviation	0.91	0.66	1.03	1.39
Minimum	1	-1	1	-2
Median	1.0	0.0	1.5	0.0
Maximum	5	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.4	0.1	1.5	-0.2
Standard Deviation	0.75	0.52	0.86	1.41
Minimum	1	-1	1	-3
Median	1.0	0.0	1.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.4	0.1	1.7	0.3
Standard Deviation	0.75	0.64	0.71	1.03
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.4	0.1	1.7	-0.1
Standard Deviation	0.73	0.46	0.78	1.25
Minimum	1	-1	1	-2
Median	1.0	0.0	1.5	0.0
Maximum	4	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.4	0.2	1.9	-0.1
Standard Deviation	0.84	0.65	1.05	1.46
Minimum	1	0	1	-3
Median	1.0	0.0	2.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.3	0.2	2.4	0.0
Standard Deviation	0.56	0.54	1.27	1.41
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	1.0
Maximum	3	2	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.4	0.2	2.1	-0.2
Standard Deviation	0.68	0.66	1.36	1.17
Minimum	1	-1	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	3	2	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.3	0.1	2.3	0.3
Standard Deviation	0.57	0.75	1.03	1.15
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	3	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.2	0.2	2.0	-0.5
Standard Deviation	0.54	0.56	0.76	1.73
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	-0.5
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.3	0.0	2.3	0.3
Standard Deviation	0.45	0.68	1.03	1.15
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	2	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.1	0.0	2.3	-0.3
Standard Deviation	0.33	0.00	1.03	1.26
Minimum	1	0	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	2	0	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.3	0.1	2.2	0.3
Standard Deviation	0.67	0.33	0.45	1.15
Minimum	1	0	2	-1
Median	1.0	0.0	2.0	1.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.1	0.1	3.0	1.0
Standard Deviation	0.35	0.35	1.00	-
Minimum	1	0	2	1
Median	1.0	0.0	3.0	1.0
Maximum	2	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.3	0.3	2.7	1.0
Standard Deviation	0.76	0.76	0.58	-
Minimum	1	0	2	1
Median	1.0	0.0	3.0	1.0
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.3	0.3	2.5	1.0
Standard Deviation	0.52	0.52	0.71	-
Minimum	1	0	2	1
Median	1.0	0.0	2.5	1.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.4	0.4	3.0	1.0
Standard Deviation	0.53	0.53	-	-
Minimum	1	0	3	1
Median	1.0	0.0	3.0	1.0
Maximum	2	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.2	0.2	3.0	2.0
Standard Deviation	0.41	0.41	1.41	-
Minimum	1	0	2	2
Median	1.0	0.0	3.0	2.0
Maximum	2	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	1.5	0.5	-	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	-	-
Median	1.5	0.5	-	-
Maximum	2	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.3	0.3	3.0	-
Standard Deviation	0.58	0.58	-	-
Minimum	1	0	3	-
Median	1.0	0.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	1.5	0.5	4.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	4	-
Median	1.5	0.5	4.0	-
Maximum	2	1	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	2.0	1.0	3.0	-
Standard Deviation	-	-	-	-
Minimum	2	1	3	-
Median	2.0	1.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	1.0	0.0	4.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	4	-
Median	1.0	0.0	4.0	-
Maximum	1	0	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	1.5	0.5	5.0	-
Standard Deviation	0.71	0.71	-	-
Minimum	1	0	5	-
Median	1.5	0.5	5.0	-
Maximum	2	1	5	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	1.0	0.0	4.0	-
Standard Deviation	0.00	0.00	-	-
Minimum	1	0	4	-
Median	1.0	0.0	4.0	-
Maximum	1	0	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	1.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	1	0	-	-
Median	1.0	0.0	-	-
Maximum	1	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Hand-Foot Syndrome Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.3	0.1	2.0	0.8
Standard Deviation	0.60	0.49	1.33	1.31
Minimum	1	-1	1	0
Median	1.0	0.0	1.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	1.5		1.6	
Standard Deviation	0.73		0.76	
Minimum	1		1	
Median	1.0		1.0	
Maximum	3		4	
Week 1				
n	34	32	30	23
Mean	1.3	-0.1	1.7	0.3
Standard Deviation	0.53	0.53	0.87	0.97
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.4	-0.1	2.0	0.4
Standard Deviation	0.60	0.65	1.00	1.27
Minimum	1	-2	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	1.4	0.0	1.9	0.5
Standard Deviation	0.63	0.69	0.84	0.99
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	1.5	0.0	1.9	0.4
Standard Deviation	0.68	0.62	0.79	0.95
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	4	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.6	0.1	2.2	0.7
Standard Deviation	0.63	0.78	1.30	1.57
Minimum	1	-2	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	1.5	-0.1	2.1	0.7
Standard Deviation	0.61	0.57	0.97	1.20
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	1.3	-0.1	2.1	0.7
Standard Deviation	0.55	0.63	0.95	1.10
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	1.4	-0.1	1.9	0.4
Standard Deviation	0.56	0.59	0.85	1.15
Minimum	1	-1	1	-2
Median	1.0	0.0	2.0	0.0
Maximum	3	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	1.4	-0.1	2.3	0.9
Standard Deviation	0.65	0.61	1.07	1.38
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.5
Maximum	4	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	1.4	-0.1	2.3	0.9
Standard Deviation	0.65	0.60	1.04	1.39
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.4	0.0	2.2	0.8
Standard Deviation	0.64	0.62	0.98	1.34
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	1.6	0.1	2.4	1.1
Standard Deviation	0.81	0.73	1.05	1.27
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	4	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	1.4	-0.1	2.3	0.8
Standard Deviation	0.70	0.71	0.77	0.99
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	1.7	0.2	2.0	0.7
Standard Deviation	0.93	0.69	0.71	1.21
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.5
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	1.7	0.1	2.0	0.6
Standard Deviation	1.11	0.88	0.95	1.30
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.5
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	1.5	0.1	2.3	0.9
Standard Deviation	0.95	1.00	1.00	1.21
Minimum	1	-2	1	-1
Median	1.0	0.0	2.0	1.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	1.5	0.1	2.6	1.2
Standard Deviation	0.90	0.77	0.98	1.30
Minimum	1	-1	1	-1
Median	1.0	0.0	3.0	2.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	1.5	-0.2	2.4	0.7
Standard Deviation	0.68	0.73	0.92	1.21
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.5
Maximum	3	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	1.5	0.0	2.2	1.3
Standard Deviation	0.92	0.71	0.75	0.58
Minimum	1	-1	1	1
Median	1.0	0.0	2.0	1.0
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	1.5	0.1	2.3	1.3
Standard Deviation	0.96	0.99	0.71	0.96
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	1.5
Maximum	4	3	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	1.4	-0.1	2.0	1.3
Standard Deviation	0.81	0.53	0.89	1.15
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	2.0
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	1.6	-0.1	2.2	1.0
Standard Deviation	0.73	0.69	0.98	0.82
Minimum	1	-1	1	0
Median	1.0	0.0	2.0	1.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	1.7	0.0	2.2	1.3
Standard Deviation	0.95	0.71	1.10	1.53
Minimum	1	-1	1	0
Median	1.5	0.0	2.0	1.0
Maximum	4	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	1.5	-0.4	1.7	2.0
Standard Deviation	0.76	0.52	1.15	-
Minimum	1	-1	1	2
Median	1.0	0.0	1.0	2.0
Maximum	3	0	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	1.7	-0.1	1.7	1.0
Standard Deviation	1.11	0.69	0.58	-
Minimum	1	-1	1	1
Median	1.0	0.0	2.0	1.0
Maximum	4	1	2	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	1.8	0.2	3.5	3.0
Standard Deviation	1.17	0.75	0.71	-
Minimum	1	-1	3	3
Median	1.5	0.0	3.5	3.0
Maximum	4	1	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	1.7	0.0	3.0	2.0
Standard Deviation	1.11	0.82	-	-
Minimum	1	-1	3	2
Median	1.0	0.0	3.0	2.0
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	2.0	0.2	2.0	2.0
Standard Deviation	1.10	0.75	1.41	-
Minimum	1	-1	1	2
Median	2.0	0.0	2.0	2.0
Maximum	4	1	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	2.3	0.5	-	-
Standard Deviation	1.26	0.58	-	-
Minimum	1	0	-	-
Median	2.0	0.5	-	-
Maximum	4	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	2.7	0.7	1.0	-
Standard Deviation	1.15	0.58	-	-
Minimum	2	0	1	-
Median	2.0	1.0	1.0	-
Maximum	4	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	2.5	0.0	1.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	2	0	1	-
Median	2.5	0.0	1.0	-
Maximum	3	0	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	4.0	1.0	1.0	-
Standard Deviation	-	-	-	-
Minimum	4	1	1	-
Median	4.0	1.0	1.0	-
Maximum	4	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	2.5	0.0	1.0	-
Standard Deviation	2.12	1.41	-	-
Minimum	1	-1	1	-
Median	2.5	0.0	1.0	-
Maximum	4	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	3.0	0.5	5.0	-
Standard Deviation	1.41	0.71	-	-
Minimum	2	0	5	-
Median	3.0	0.5	5.0	-
Maximum	4	1	5	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	3.0	0.5	1.0	-
Standard Deviation	1.41	0.71	-	-
Minimum	2	0	1	-
Median	3.0	0.5	1.0	-
Maximum	4	1	1	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	4.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	4	1	-	-
Median	4.0	1.0	-	-
Maximum	4	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	3.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	0	-	-
Median	3.0	0.0	-	-
Maximum	3	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	1.4	0.2	2.5	0.8
Standard Deviation	0.63	0.80	1.12	1.42
Minimum	1	-1	1	-1
Median	1.0	0.0	3.0	0.0
Maximum	3	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	15		15	
Mean	1.5		1.7	
Standard Deviation	0.64		0.80	
Minimum	1		1	
Median	1.0		2.0	
Maximum	3		3	
Week 1				
n	10	6	17	10
Mean	1.7	-0.2	1.6	-0.2
Standard Deviation	0.48	0.75	0.86	0.79
Minimum	1	-1	1	-2
Median	2.0	0.0	1.0	0.0
Maximum	2	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	14	7	21	9
Mean	1.6	0.3	1.9	0.0
Standard Deviation	0.65	0.76	1.11	0.50
Minimum	1	-1	1	-1
Median	1.5	0.0	2.0	0.0
Maximum	3	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	15	7	22	11
Mean	1.4	-0.1	1.8	-0.1
Standard Deviation	0.63	0.69	0.73	0.54
Minimum	1	-1	1	-1
Median	1.0	0.0	2.0	0.0
Maximum	3	1	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	13	7	23	9
Mean	1.9	0.4	2.0	0.0
Standard Deviation	0.86	1.27	0.88	1.00
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	14	5	17	8
Mean	1.7	0.2	2.5	0.8
Standard Deviation	0.61	1.10	1.33	0.89
Minimum	1	-1	1	0
Median	2.0	1.0	2.0	0.5
Maximum	3	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	14	9	16	7
Mean	1.6	0.3	1.9	0.6
Standard Deviation	0.74	0.71	1.09	1.13
Minimum	1	-1	1	-1
Median	1.5	0.0	1.5	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	9	4	18	8
Mean	1.4	-0.3	1.9	0.0
Standard Deviation	0.73	0.96	0.96	1.07
Minimum	1	-1	1	-2
Median	1.0	-0.5	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	10	6	15	5
Mean	1.6	0.0	2.1	0.2
Standard Deviation	0.70	0.89	0.92	0.45
Minimum	1	-1	1	0
Median	1.5	0.0	2.0	0.0
Maximum	3	1	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	12	8	16	7
Mean	1.9	0.3	2.0	0.1
Standard Deviation	0.79	1.04	1.21	0.90
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	8	5	18	7
Mean	1.8	0.4	1.9	0.1
Standard Deviation	0.71	0.89	1.11	1.46
Minimum	1	-1	1	-2
Median	2.0	1.0	2.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	9	5	15	5
Mean	2.0	0.4	2.1	0.0
Standard Deviation	1.12	1.14	0.88	1.00
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	15	6	18	7
Mean	2.0	0.3	2.1	0.4
Standard Deviation	1.00	1.21	1.21	0.79
Minimum	1	-1	1	0
Median	2.0	0.5	2.0	0.0
Maximum	4	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	9	5	17	7
Mean	1.9	0.2	2.1	0.7
Standard Deviation	0.78	1.10	0.93	0.95
Minimum	1	-1	1	0
Median	2.0	1.0	2.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	12	7	7	3
Mean	2.2	0.6	2.0	-0.3
Standard Deviation	1.11	0.79	0.58	0.58
Minimum	1	0	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	8	5	8	4
Mean	2.4	0.6	2.1	0.0
Standard Deviation	1.19	1.14	0.64	0.82
Minimum	1	-1	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	7	5	7	4
Mean	2.1	0.2	2.4	0.5
Standard Deviation	1.35	1.10	0.98	1.00
Minimum	1	-1	1	0
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	6	3	6	3
Mean	1.8	0.3	2.7	0.3
Standard Deviation	0.75	0.58	1.03	1.53
Minimum	1	0	1	-1
Median	2.0	0.0	3.0	0.0
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	8	5	7	4
Mean	1.9	-0.2	2.4	0.3
Standard Deviation	1.13	0.84	1.13	1.26
Minimum	1	-1	1	-1
Median	1.5	0.0	2.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	5	4	5	1
Mean	2.2	0.0	2.8	0.0
Standard Deviation	1.30	1.41	0.84	-
Minimum	1	-1	2	0
Median	2.0	-0.5	3.0	0.0
Maximum	4	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	5	3	7	2
Mean	2.4	0.7	2.3	0.0
Standard Deviation	1.52	1.53	0.76	1.41
Minimum	1	-1	1	-1
Median	2.0	1.0	2.0	0.0
Maximum	4	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	4	4	4	1
Mean	2.3	0.3	2.5	0.0
Standard Deviation	1.26	1.50	0.58	-
Minimum	1	-1	2	0
Median	2.0	0.0	2.5	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	4	2	5	2
Mean	2.0	0.5	2.4	0.5
Standard Deviation	0.82	0.71	1.14	2.12
Minimum	1	0	1	-1
Median	2.0	0.5	2.0	0.5
Maximum	3	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	5	3	4	1
Mean	2.2	0.7	2.8	0.0
Standard Deviation	1.10	1.53	0.50	-
Minimum	1	-1	2	0
Median	2.0	1.0	3.0	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	3	3	1	0
Mean	2.0	0.3	3.0	-
Standard Deviation	1.00	1.15	-	-
Minimum	1	-1	3	-
Median	2.0	1.0	3.0	-
Maximum	3	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	3	3	2	0
Mean	2.3	0.7	2.5	-
Standard Deviation	1.53	1.53	0.71	-
Minimum	1	-1	2	-
Median	2.0	1.0	2.5	-
Maximum	4	2	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	3	2	2	0
Mean	2.3	1.0	2.5	-
Standard Deviation	0.58	0.00	0.71	-
Minimum	2	1	2	-
Median	2.0	1.0	2.5	-
Maximum	3	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	3	2	1	0
Mean	1.7	0.5	3.0	-
Standard Deviation	1.15	0.71	-	-
Minimum	1	0	3	-
Median	1.0	0.5	3.0	-
Maximum	3	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	4	3	1	0
Mean	1.8	0.3	3.0	-
Standard Deviation	0.96	1.15	-	-
Minimum	1	-1	3	-
Median	1.5	1.0	3.0	-
Maximum	3	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	3	2	0	0
Mean	2.0	1.0	-	-
Standard Deviation	1.73	1.41	-	-
Minimum	1	0	-	-
Median	1.0	1.0	-	-
Maximum	4	2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	2	0	0
Mean	2.0	1.0	-	-
Standard Deviation	1.00	0.00	-	-
Minimum	1	1	-	-
Median	2.0	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	0	0
Mean	2.5	1.0	-	-
Standard Deviation	0.71	0.00	-	-
Minimum	2	1	-	-
Median	2.5	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	0	0
Mean	3.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	1	-	-
Median	3.0	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	1	1	0	0
Mean	3.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	1	-	-
Median	3.0	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	2.5	1.0	4.0	-
Standard Deviation	0.71	0.00	-	-
Minimum	2	1	4	-
Median	2.5	1.0	4.0	-
Maximum	3	1	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	0	0
Mean	3.0	1.5	-	-
Standard Deviation	1.41	0.71	-	-
Minimum	2	1	-	-
Median	3.0	1.5	-	-
Maximum	4	2	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	3.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	1	-	-
Median	3.0	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	3.0	1.0	-	-
Standard Deviation	-	-	-	-
Minimum	3	1	-	-
Median	3.0	1.0	-	-
Maximum	3	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Numbness & Tingling Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	6	2	15	7
Mean	1.5	0.0	2.1	0.4
Standard Deviation	0.84	0.00	1.28	0.79
Minimum	1	0	1	0
Median	1.0	0.0	2.0	0.0
Maximum	3	0	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	44		32	
Mean	2.1		2.0	
Standard Deviation	0.93		1.03	
Minimum	1		1	
Median	2.0		2.0	
Maximum	5		4	
Week 1				
n	34	32	30	23
Mean	2.7	0.6	2.0	0.2
Standard Deviation	1.32	0.98	0.83	0.80
Minimum	1	-1	1	-1
Median	3.0	0.5	2.0	0.0
Maximum	5	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	37	34	31	23
Mean	1.9	-0.1	2.4	0.5
Standard Deviation	0.98	0.81	0.81	0.90
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	42	39	34	23
Mean	2.0	0.0	2.3	0.5
Standard Deviation	0.77	0.71	1.03	0.90
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	31	27	34	23
Mean	2.6	0.5	2.3	0.4
Standard Deviation	1.02	1.09	0.84	0.99
Minimum	1	-2	1	-2
Median	3.0	1.0	2.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	29	24	27	20
Mean	1.9	0.1	2.5	0.5
Standard Deviation	0.82	0.88	0.85	1.05
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	35	31	22	16
Mean	2.1	0.1	2.3	0.4
Standard Deviation	0.91	0.65	0.77	1.03
Minimum	1	-1	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	29	26	24	17
Mean	2.4	0.5	2.6	0.6
Standard Deviation	1.15	0.99	1.18	1.46
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	1.0
Maximum	5	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	29	26	23	16
Mean	2.3	0.4	2.6	0.7
Standard Deviation	1.04	1.02	1.16	1.54
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.5
Maximum	5	3	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	35	32	20	14
Mean	2.1	0.1	2.1	0.2
Standard Deviation	1.00	0.89	0.79	0.97
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	25	23	22	16
Mean	2.4	0.3	2.2	0.4
Standard Deviation	0.95	0.83	0.66	1.02
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	26	24	19	13
Mean	1.8	0.1	2.4	0.3
Standard Deviation	0.88	0.65	0.96	1.18
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	36	30	22	17
Mean	2.2	0.1	2.5	0.4
Standard Deviation	0.82	1.01	0.86	0.86
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	4	3	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	33	28	18	13
Mean	2.0	-0.1	2.4	0.3
Standard Deviation	0.95	1.15	0.86	1.18
Minimum	1	-4	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	26	22	9	6
Mean	2.2	0.1	1.8	-0.2
Standard Deviation	0.86	1.39	0.67	0.98
Minimum	1	-4	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	3	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	23	19	12	8
Mean	2.0	0.0	1.9	-0.5
Standard Deviation	0.71	0.82	0.67	1.20
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	-0.5
Maximum	3	2	3	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	23	18	9	7
Mean	2.1	0.1	2.6	-0.3
Standard Deviation	1.00	1.30	1.13	1.25
Minimum	1	-4	1	-3
Median	2.0	0.0	3.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	19	16	7	5
Mean	2.0	0.2	2.6	-0.6
Standard Deviation	0.88	1.47	1.13	0.89
Minimum	1	-4	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	21	17	8	6
Mean	2.1	-0.1	2.5	0.0
Standard Deviation	1.06	1.54	1.20	1.10
Minimum	1	-4	1	-2
Median	2.0	0.0	2.5	0.0
Maximum	5	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	18	17	6	3
Mean	2.1	0.1	2.3	-0.7
Standard Deviation	0.73	1.25	1.03	1.15
Minimum	1	-3	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	3	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	19	15	8	4
Mean	2.3	0.1	2.4	-0.5
Standard Deviation	0.93	1.33	0.74	1.00
Minimum	1	-3	1	-2
Median	2.0	0.0	2.5	0.0
Maximum	4	3	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	16	14	6	3
Mean	2.3	0.2	2.3	-1.0
Standard Deviation	1.00	0.97	0.82	0.00
Minimum	1	-2	1	-1
Median	2.5	0.0	2.5	-1.0
Maximum	4	2	3	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	9	7	6	4
Mean	2.3	0.6	2.5	-0.5
Standard Deviation	1.41	1.13	0.84	1.29
Minimum	1	-1	2	-2
Median	2.0	0.0	2.0	-0.5
Maximum	5	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	10	9	5	3
Mean	2.2	-0.1	2.4	-0.7
Standard Deviation	1.23	1.17	0.55	1.15
Minimum	1	-3	2	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	8	8	3	1
Mean	2.3	0.3	2.7	0.0
Standard Deviation	0.71	1.49	1.15	-
Minimum	1	-3	2	0
Median	2.0	0.5	2.0	0.0
Maximum	3	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	7	7	3	1
Mean	2.1	0.1	2.0	0.0
Standard Deviation	1.07	1.77	1.00	-
Minimum	1	-3	1	0
Median	2.0	0.0	2.0	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	6	6	2	1
Mean	2.5	0.3	2.0	0.0
Standard Deviation	1.38	2.16	0.00	-
Minimum	1	-3	2	0
Median	2.0	0.5	2.0	0.0
Maximum	5	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	7	7	1	1
Mean	2.0	-0.1	2.0	0.0
Standard Deviation	0.82	1.57	-	-
Minimum	1	-3	2	0
Median	2.0	0.0	2.0	0.0
Maximum	3	2	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	6	6	2	1
Mean	1.5	-0.5	1.5	0.0
Standard Deviation	0.55	1.87	0.71	-
Minimum	1	-4	1	0
Median	1.5	0.0	1.5	0.0
Maximum	2	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	4	4	0	0
Mean	2.3	-0.3	-	-
Standard Deviation	1.26	0.96	-	-
Minimum	1	-1	-	-
Median	2.0	-0.5	-	-
Maximum	4	1	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	3	3	1	0
Mean	1.7	0.0	3.0	-
Standard Deviation	0.58	1.00	-	-
Minimum	1	-1	3	-
Median	2.0	0.0	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	2	1	0
Mean	2.0	0.5	3.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	2	0	3	-
Median	2.0	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	2.0	0.0	3.0	-
Standard Deviation	-	-	-	-
Minimum	2	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	2	1	0
Mean	2.0	0.5	3.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	2	0	3	-
Median	2.0	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	2	1	0
Mean	2.0	0.5	3.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	2	0	3	-
Median	2.0	0.5	3.0	-
Maximum	2	1	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	2	1	0
Mean	2.0	0.5	4.0	-
Standard Deviation	0.00	0.71	-	-
Minimum	2	0	4	-
Median	2.0	0.5	4.0	-
Maximum	2	1	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Severity

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	16	13	19	14
Mean	2.3	-0.1	2.6	0.4
Standard Deviation	1.20	1.04	1.30	0.93
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Baseline				
n	32		20	
Mean	2.5		2.6	
Standard Deviation	1.02		1.14	
Minimum	1		1	
Median	2.0		2.0	
Maximum	5		5	
Week 1				
n	26	19	22	12
Mean	2.9	0.3	2.2	-0.2
Standard Deviation	1.02	0.87	0.87	0.72
Minimum	2	-2	1	-1
Median	3.0	0.0	2.0	0.0
Maximum	5	2	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 2				
n	23	19	28	15
Mean	2.3	-0.2	2.3	0.2
Standard Deviation	0.88	0.79	1.04	0.86
Minimum	1	-2	1	-1
Median	2.0	0.0	2.0	0.0
Maximum	5	2	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 3				
n	31	25	26	13
Mean	2.2	-0.4	2.6	0.2
Standard Deviation	0.90	0.91	0.86	0.44
Minimum	1	-2	1	0
Median	2.0	0.0	2.0	0.0
Maximum	4	2	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 4				
n	27	16	28	13
Mean	2.6	0.3	2.3	-0.1
Standard Deviation	0.97	1.01	0.59	1.12
Minimum	1	-2	1	-3
Median	2.0	0.0	2.0	0.0
Maximum	5	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 5				
n	19	13	25	15
Mean	2.2	-0.2	2.6	0.4
Standard Deviation	0.90	1.07	1.08	1.59
Minimum	1	-2	1	-4
Median	2.0	0.0	2.0	0.0
Maximum	4	2	5	4

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 6				
n	24	18	19	10
Mean	2.3	-0.1	2.0	-0.5
Standard Deviation	0.79	0.94	0.88	1.08
Minimum	1	-2	1	-3
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 7				
n	22	14	20	10
Mean	2.7	0.6	2.6	-0.2
Standard Deviation	1.13	0.94	1.10	1.55
Minimum	1	0	1	-4
Median	2.0	0.0	2.0	0.0
Maximum	5	3	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 8				
n	22	15	19	9
Mean	2.7	0.2	3.0	0.1
Standard Deviation	1.03	0.86	1.11	1.45
Minimum	1	-1	2	-3
Median	3.0	0.0	3.0	0.0
Maximum	5	1	5	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 9				
n	23	18	16	7
Mean	2.5	0.1	2.4	0.0
Standard Deviation	0.79	1.11	0.81	1.29
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 10				
n	20	15	20	10
Mean	2.6	0.3	2.4	0.2
Standard Deviation	0.88	0.90	0.75	1.40
Minimum	1	-1	1	-3
Median	2.0	0.0	2.0	0.5
Maximum	4	2	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 11				
n	17	11	17	8
Mean	2.2	0.0	2.6	-0.1
Standard Deviation	0.73	0.63	1.23	1.25
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	1	5	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 12				
n	29	18	20	11
Mean	2.3	-0.2	2.5	0.0
Standard Deviation	0.80	0.79	0.89	1.18
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	1	4	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 15				
n	21	17	16	9
Mean	2.5	0.1	2.4	0.1
Standard Deviation	0.87	1.05	0.89	1.45
Minimum	1	-2	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	5	2	4	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 18				
n	21	13	6	4
Mean	2.3	0.1	2.2	-0.8
Standard Deviation	1.01	0.95	0.41	0.96
Minimum	1	-2	2	-2
Median	2.0	0.0	2.0	-0.5
Maximum	5	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 21				
n	18	12	9	4
Mean	2.2	0.0	2.2	0.0
Standard Deviation	0.73	0.85	0.67	1.63
Minimum	1	-1	1	-2
Median	2.0	0.0	2.0	0.0
Maximum	4	2	3	2

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 24				
n	16	9	7	5
Mean	2.5	0.2	3.1	0.0
Standard Deviation	1.03	0.83	1.07	0.00
Minimum	1	-1	2	0
Median	2.0	0.0	3.0	0.0
Maximum	4	2	5	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 27				
n	13	6	6	4
Mean	2.5	0.5	2.7	-1.3
Standard Deviation	0.78	1.05	1.21	1.26
Minimum	1	-1	1	-3
Median	2.0	0.5	2.5	-1.0
Maximum	4	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 30				
n	15	7	6	5
Mean	2.7	0.1	2.7	-0.6
Standard Deviation	1.16	0.90	1.03	1.52
Minimum	1	-1	1	-3
Median	2.0	0.0	3.0	0.0
Maximum	5	2	4	1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 33				
n	14	10	5	3
Mean	2.2	-0.6	2.2	-1.7
Standard Deviation	0.58	1.17	1.30	1.15
Minimum	1	-3	1	-3
Median	2.0	0.0	2.0	-1.0
Maximum	3	1	4	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 36				
n	15	10	7	4
Mean	2.5	-0.2	1.9	-1.5
Standard Deviation	0.74	1.23	0.38	1.29
Minimum	2	-3	1	-3
Median	2.0	0.0	2.0	-1.5
Maximum	4	1	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 39				
n	11	8	5	2
Mean	2.5	-0.4	2.4	-1.5
Standard Deviation	0.82	0.92	0.55	0.71
Minimum	1	-2	2	-2
Median	2.0	0.0	2.0	-1.5
Maximum	4	1	3	-1

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 42				
n	6	2	6	4
Mean	2.3	0.5	2.0	-1.5
Standard Deviation	1.03	0.71	0.89	1.29
Minimum	1	0	1	-3
Median	2.0	0.5	2.0	-1.5
Maximum	4	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 45				
n	7	5	5	3
Mean	2.7	-0.2	2.2	-1.0
Standard Deviation	1.11	1.10	0.45	1.00
Minimum	2	-2	2	-2
Median	2.0	0.0	2.0	-1.0
Maximum	5	1	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 48				
n	7	5	3	1
Mean	2.3	-0.2	2.7	0.0
Standard Deviation	0.95	1.92	1.15	-
Minimum	1	-3	2	0
Median	2.0	0.0	2.0	0.0
Maximum	4	2	4	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 51				
n	5	3	2	1
Mean	2.4	-0.3	2.5	0.0
Standard Deviation	0.89	2.52	0.71	-
Minimum	2	-3	2	0
Median	2.0	0.0	2.5	0.0
Maximum	4	2	3	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 54				
n	5	3	2	1
Mean	2.8	0.3	2.0	0.0
Standard Deviation	1.30	2.52	0.00	-
Minimum	2	-2	2	0
Median	2.0	0.0	2.0	0.0
Maximum	5	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 57				
n	5	4	1	1
Mean	3.0	0.3	2.0	0.0
Standard Deviation	1.22	2.50	-	-
Minimum	2	-3	2	0
Median	3.0	0.5	2.0	0.0
Maximum	5	3	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 60				
n	3	1	1	1
Mean	2.0	0.0	2.0	0.0
Standard Deviation	0.00	-	-	-
Minimum	2	0	2	0
Median	2.0	0.0	2.0	0.0
Maximum	2	0	2	0

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 63				
n	3	2	0	0
Mean	2.7	-0.5	-	-
Standard Deviation	1.15	0.71	-	-
Minimum	2	-1	-	-
Median	2.0	-0.5	-	-
Maximum	4	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 66				
n	2	1	1	0
Mean	2.0	0.0	2.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	2	-
Median	2.0	0.0	2.0	-
Maximum	2	0	2	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 69				
n	2	1	1	0
Mean	2.0	0.0	3.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 72				
n	1	1	1	0
Mean	2.0	0.0	3.0	-
Standard Deviation	-	-	-	-
Minimum	2	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 75				
n	2	1	1	0
Mean	2.0	0.0	3.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 78				
n	2	1	1	0
Mean	2.0	0.0	3.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	3	-
Median	2.0	0.0	3.0	-
Maximum	2	0	3	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 81				
n	2	1	1	0
Mean	2.0	0.0	4.0	-
Standard Deviation	0.00	-	-	-
Minimum	2	0	4	-
Median	2.0	0.0	4.0	-
Maximum	2	0	4	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 84				
n	1	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
Week 87				
n	1	1	0	0
Mean	2.0	0.0	-	-
Standard Deviation	-	-	-	-
Minimum	2	0	-	-
Median	2.0	0.0	-	-
Maximum	2	0	-	-

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf

Table 3.75.1 PRO-CTCAE - Description by visit - DCO 24-Jul-2024 - Modified Safety Analysis Set A

PT01-Fatigue Interference

	Dato-DXd (N=63)		ICC (N=55)	
	Value	Change from baseline	Value	Change from baseline
End of Treatment				
n	12	9	15	9
Mean	2.7	0.1	2.6	0.2
Standard Deviation	1.23	1.27	1.24	1.48
Minimum	1	-2	1	-2
Median	2.5	0.0	2.0	0.0
Maximum	5	2	5	3

Baseline is defined as the last available assessment prior to randomization or, if missing, prior (≤) first dose.

Data source: ADAM.ADQS
Run date: 21FEB2025 - 11:37; Program name: T_3_21_1.sas; Output name: DE.T_PROCTCAE_DESCVIS_mSASA.rtf