2024 ASCO® ANNUAL MEETING

A Randomized Study Comparing Electronic Patient-Reported Outcomes Monitoring With Routine Follow-Up During Trastuzumab Deruxtecan Treatment for Inoperable or Metastatic Breast Cancer Patients: PRO-DUCE Study

Yuichiro Kikawa, Yukari Uemura, Tetsuhiko Taira, Chiyoe Kitagawa, Hideki Maeda, Hiroaki Kato, Naoki Hashimoto, Mitsuchika Hosoda, Yohei Hamanaka, Yuko Tanabe, Tatsuya Yoshida, Kaori Tane, Daisuke Takabatake, Takashi Ishikawa, Takayuki Iwamoto, Takeshi Yamaguchi, Daisuke Takiguchi, Hirofumi Mukai, Naruto Taira, and Takafumi Sangai

On behalf of the PRO-DUCE Investigators

PRESENTED BY: Yuichiro Kikawa, MD, PhD

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Key Takeaways

The results of this study suggest that ePRO monitoring may be associated with maintenance/improvement of QoL in T-DXd-treated patients with HER2-positive metastatic breast cancer

The following outcomes were better in the ePRO monitoring group vs usual routine care group:

1. The change from baseline in Global QoL score at week 24 (primary endpoint)
2. The changes in role, cognitive, social functioning, and fatigue scores from baseline at week 24 (secondary endpoint)
3. Time to deterioration of cognitive functioning score (secondary endpoint)

ePRO, electronic patient-reported outcome; HER2, human epidermal growth factor receptor 2; QoL, quality of life; T-DXd, trastuzumab deruxtecan.

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Background

- T-DXd has been associated with some specific TEAEs, the most common being nausea and vomiting[1-3], but fatigue is also frequently observed and was reported in 49% of patients in DB-03[3]. ILD has been identified as a specific AE of interest[1-3]
- Use of PRO data can improve symptom control and QoL; some instruments are even associated with extended survival[4]
- Digital symptom monitoring in routine clinical care during systemic cancer treatment is recommended in the ESMO guidelines[5]

1. Modi S, et al. N Engl J Med. 2020 Feb 13;382(7):610-621. 2. Andre F, et al. Lancet. 2023 May 27;401(10390):1773-1785. 3. Cortés J, et al. N Engl J Med. 2022 Mar 24;386(12):1143-1154.
4. Basch E, et al. J Clin Oncol. 2016 Feb 20; 34(6):557-565. 5. Di Maio M, et al. Ann Oncol. 2022 Sep;33(9):878-892.
AE, adverse event; ESMO, European Society for Medical Oncology; ILD, interstitial lung disease; PRO, patient-reported outcome; QoL, quality of life; T-DXd, trastuzumab deruxtecan; TEAE, treatment-emergent adverse event.

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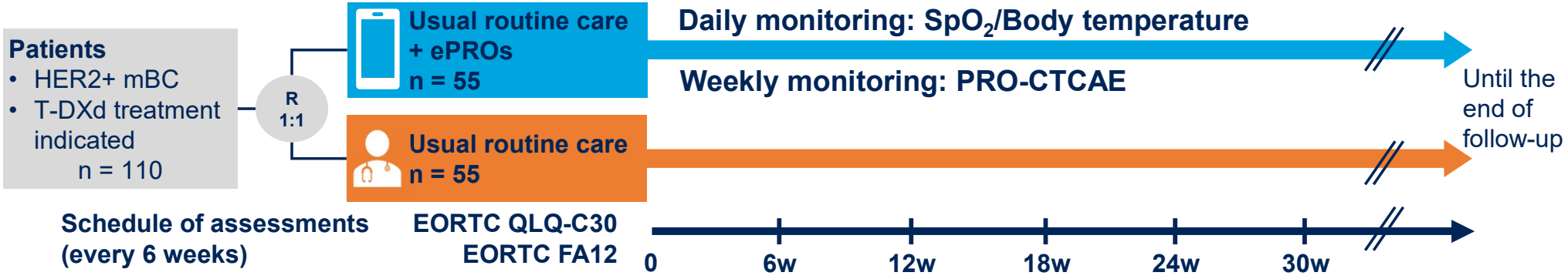
PRO-DUCE Study Design

A Multicenter, Randomized, Open-Label, Parallel-Group, Exploratory Study (Study ID: jRCTs031200387)

Study Aim: To evaluate the impact of ePRO monitoring compared with routine follow-up care on the quality of life of patients with HER2-positive metastatic breast cancer treated with T-DXd



Stratification factors:

- ECOG PS (0/1–2)
- Age (≤ 59 years/ ≥ 60 years)
- Line of treatment after recurrence (≤ third line/ fourth or subsequent line)

Primary endpoint

- Change in global health status/quality of life from baseline at week 24

Secondary PRO endpoints

- Change in each domain from baseline at week 24 and from baseline to the end of the entire observation period
- Cancer-related fatigue
- Time to deterioration in the EORTC QLQ-C30
- Adherence with ePRO

ECOG PS, Eastern Cooperative Oncology Group performance status; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; HER2, human epidermal growth factor receptor 2; mBC, metastatic breast cancer; PRO, patient-reported outcome; PRO-CTCAE, PRO version of the Common Terminology Criteria for Adverse Events; QLQ-C30, Quality of Life Core 30 questionnaire; R, randomization; SpO_2, oxygen saturation; T-DXd, trastuzumab deruxtecan; w, weeks.

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ePRO Monitoring Procedures

- Participants use the “Hibilog app” on personal devices for daily logging of body temperature and SpO_2 and weekly reporting of selected PRO-CTCAE symptoms (a pulse oximeter is provided for home SpO_2 monitoring)
- Investigators and healthcare providers have real-time access to PRO data via the app
- Alert notifications are triggered based on predefined symptom thresholds established by expert consensus

No	Daily PRO data collection		Threshold for alert notification
1	**Body temperature**		≥ 37.5°C
2	**SpO_2**		≤ 95%
No	**Weekly PRO data collection (PRO-CTCAE symptom)**		**Threshold for alert notification**
1	**Decreased appetite**	Severity	Severe
2		Interference with daily activities	Quite a bit
3	**Nausea**	Frequency	Frequent
4		Severity	Severe
5	**Vomiting**	Frequency	Frequent
6		Severity	Severe
7	**Diarrhea**	Frequency	Almost always
8	**Shortness of breath**	Severity	Moderate
9		Interference with daily activities	To a certain extent
10	**General pain**	Frequency	Frequent
11		Severity	Severe
12		Interference with daily activities	Quite a bit
13	**Fatigue**	Severity	Severe
14		Interference with daily activities	Quite a bit
15	**Cough**	Severity	Moderate
16		Interference with daily activities	To a certain extent

PRO-CTCAE, version 1.0 (Japanese version)
http://www.jcog.jp/doctor/tool/PRO_CTCAE.html

ePRO, electronic patient-reported outcome; PRO, patient-reported outcome; PRO-CTCAE, PRO version of the Common Terminology Criteria for Adverse Events; SpO_2, oxygen saturation.

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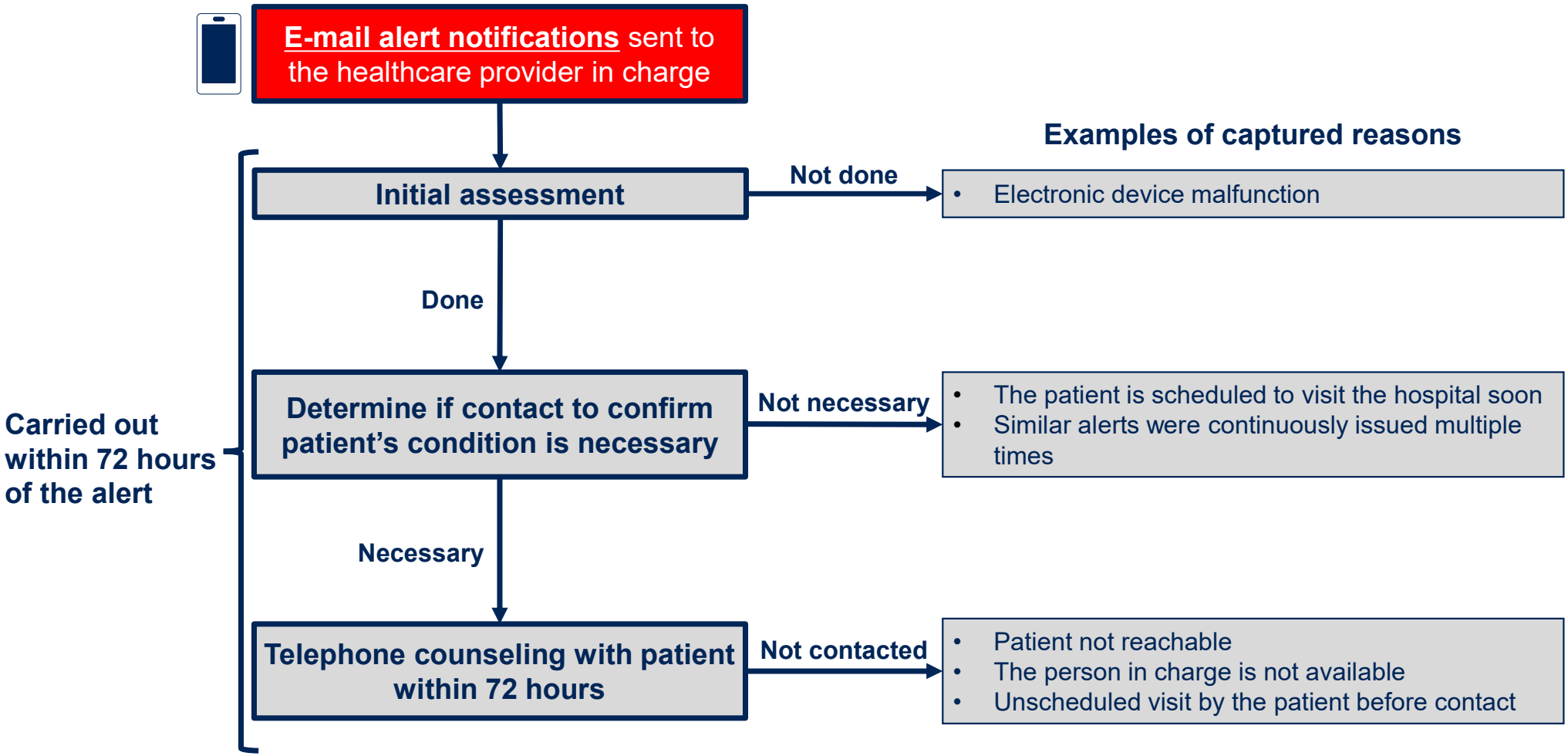
Flowchart of Actions Taken in Response to Alert Notifications



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Statistical Analysis

Primary Endpoint Analysis:

- A mixed-effects model for repeated measures (MMRM) was used for change in global health status/quality of life from baseline at week 24
- A two-sided alpha error < 0.10 was considered to be statistically significant (power 87%), considering the exploratory nature
- The required sample size was 55 in each group

Secondary Endpoint Analysis:

- MMRM was used for analyzing functional and symptom domains, FA12
- The Kaplan–Meier method was used to analyze the time to a 10-point decline in EORTC QLQ-C30

EORTC, European Organisation for Research and Treatment of Cancer; QLQ-C30, Quality of Life Core 30 questionnaire.

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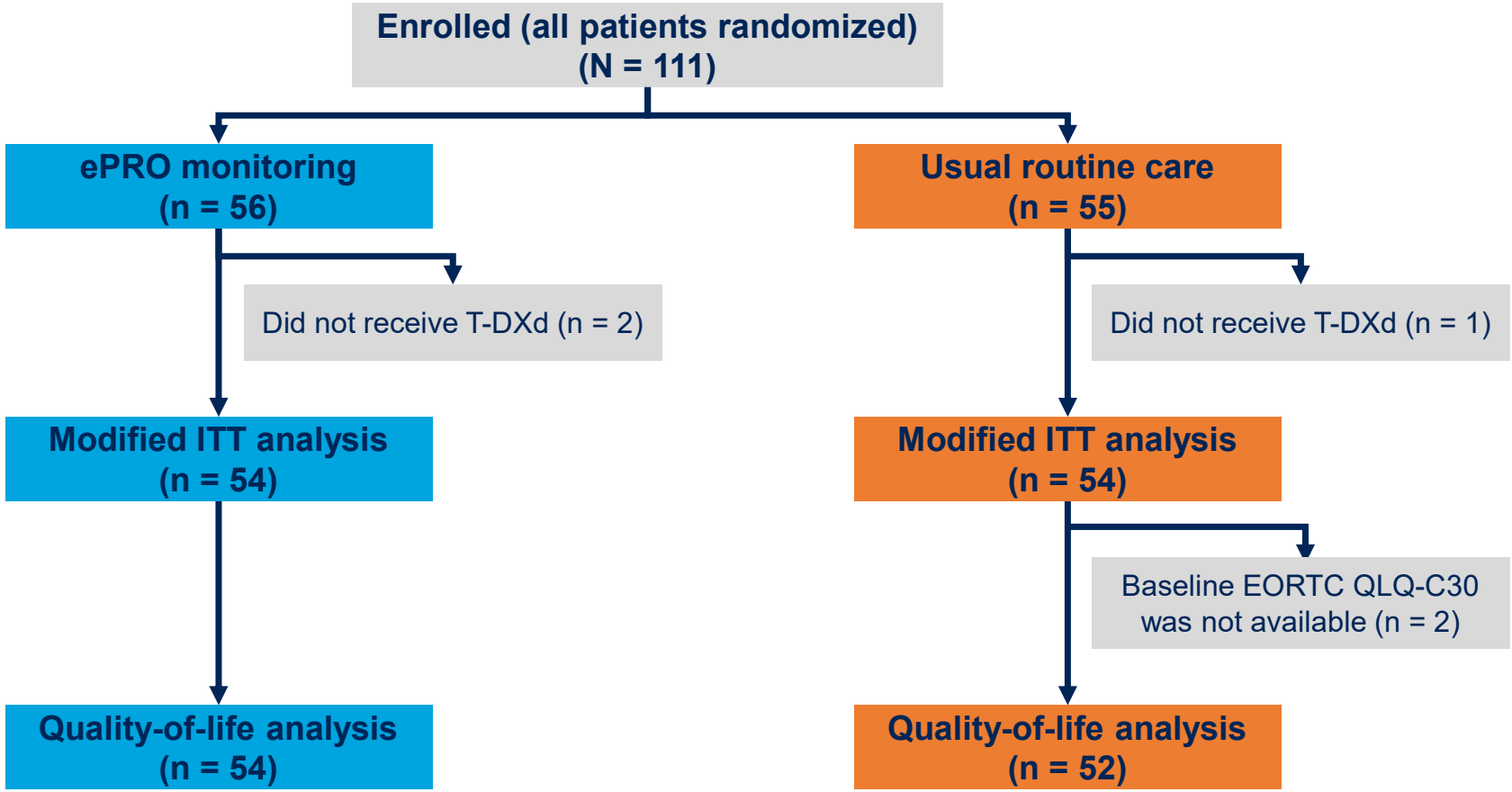
CONSORT Diagram



EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; ITT, intention-to-treat; QLQ-C30, Quality of Life Core 30 questionnaire; T-DXd, trastuzumab deruxtecan.

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Baseline Patient Characteristics

Between March 2021 and January 2023, patients who enrolled across 38 hospitals in Japan were randomized into two treatment groups; baseline characteristics were similar between the two cohorts

Characteristic		Modified ITT population (n = 108)	
		ePRO monitoring (n = 54)	Usual routine care (n = 54)
Age, years (SD)	Mean	57.1 (9.7)	57.2 (12.3)
ECOG PS, n (%)	0	33 (61.1)	32 (59.3)
	1	21 (38.9)	19 (35.2)
	2	0 (0.0)	3 (5.6)
T-DXd treatment line, n (%)	≤ 3	32 (59.3)	34 (63.0)
	≥ 4	22 (40.7)	20 (37.0)
Starting dose of T-DXd, n (%)	5.4 mg/kg	52 (96.3)	53 (98.1)
	4.4 mg/kg	2 (3.7)	1 (1.9)
Hormone receptor status, n (%)	ER positive	35 (64.8)	33 (61.1)
	ER negative	19 (35.2)	21 (38.9)
Education level, n (%)	Lower than college	47 (87.0)	48 (88.9)
	College and above	7 (13.0)	6 (11.1)

ECOG PS, Eastern Cooperative Oncology Group performance status; ePRO, electronic patient-reported outcome; ER, estrogen receptor; ITT, intention to treat; SD, standard deviation; T-DXd, trastuzumab deruxtecan.

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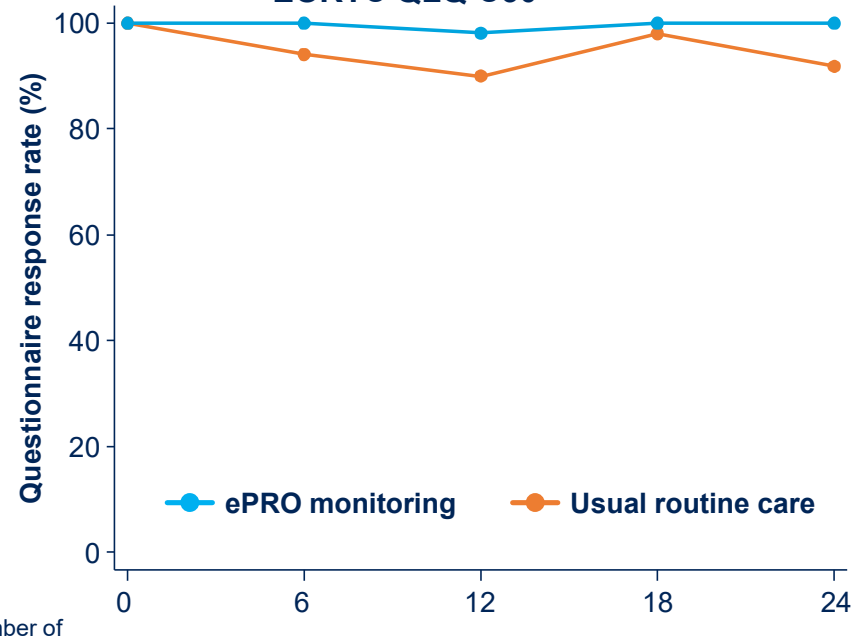
Data Availability

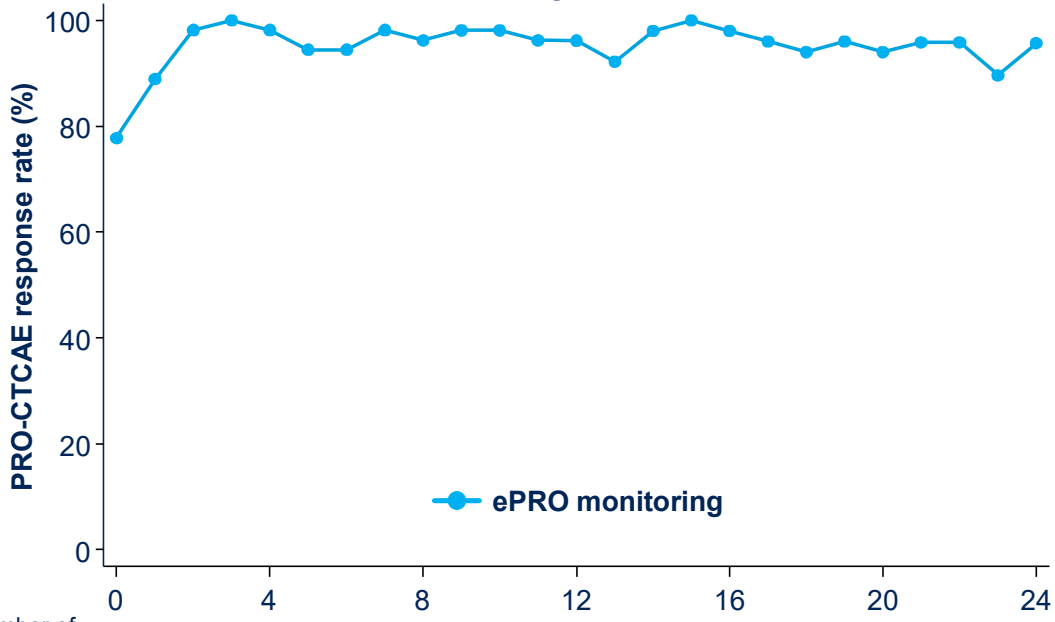
Questionnaire response rates remained high throughout the observation period

Proportion of patients completing expected questionnaire
EORTC QLQ-C30



Number of evaluable patients					
ePRO monitoring	54	54	53	50	47
Usual routine care	52	51	50	50	49

Proportion of patients completing expected questionnaire
PRO-CTCAE



Number of evaluable patients																								
ePRO monitoring	54	54	54	54	54	54	54	54	53	53	53	53	52	51	50	50	50	50	50	50	50	48	48	48	46

EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; PRO-CTCAE, patient-related outcome version of the Common Terminology Criteria for Adverse Events; QLQ-C30, Quality of Life Core 30 questionnaire.

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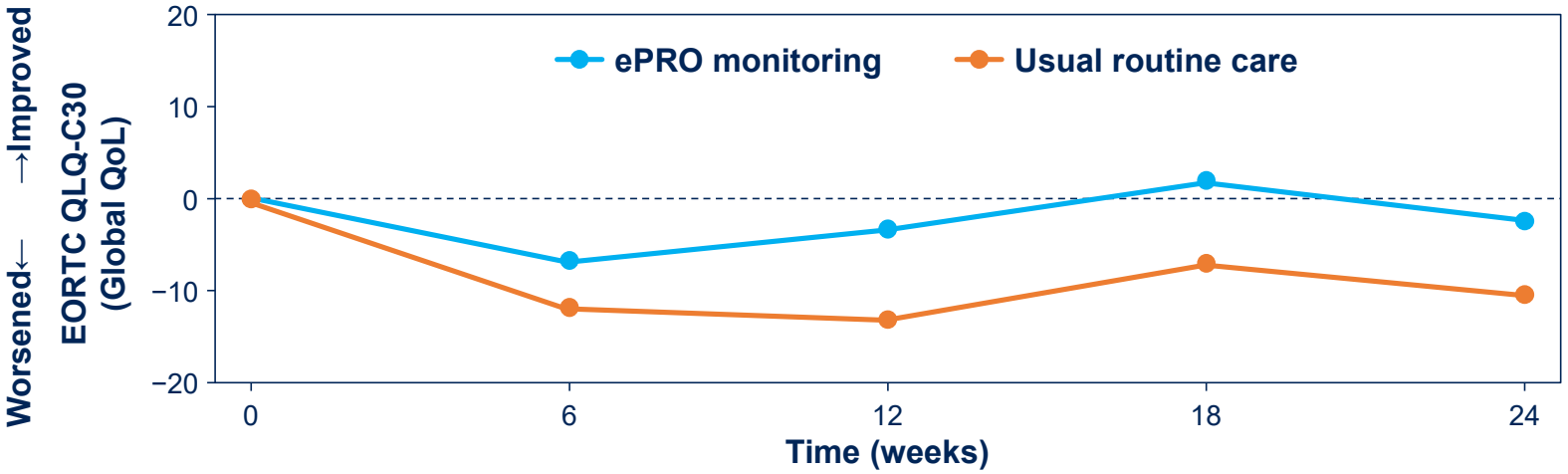
Primary Endpoint: Change in Global QoL From Baseline Using EORTC QLQ-C30

At 24 weeks, the change from baseline in GHS/QoL scores (primary endpoint) was significantly better ($p < 0.10$) in the ePRO monitoring group compared with the usual routine care group based on MMRM analysis



ePRO monitoring	Estimated value*	−6.7	−3.3	1.6	−2.4
Usual routine care	Estimated value*	−11.8	−13.1	−7.0	−10.4
Difference between groups (ePRO monitoring − usual routine care)	Estimated value*	5.2	9.8	8.6	8.0
	90% CI	−1.9, 12.2	2.7, 16.9	2.6, 14.5	0.2, 15.8
	p value				0.091

*Change from baseline

CI, confidence interval; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; GHS, global health status; MMRM, mixed-effects model for repeated measures; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life.

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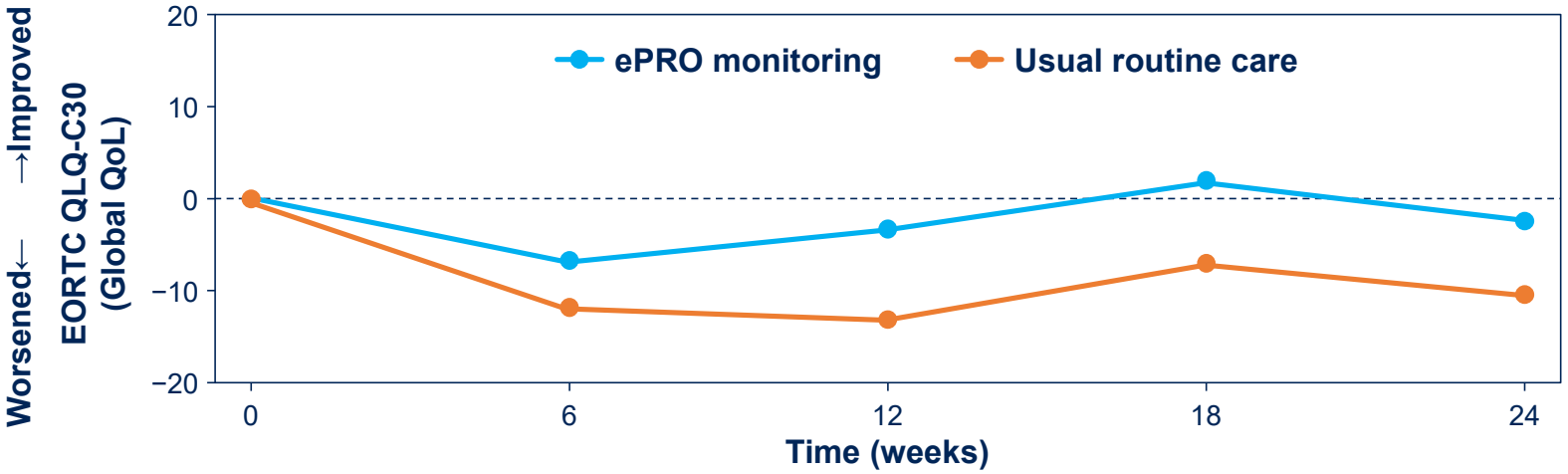

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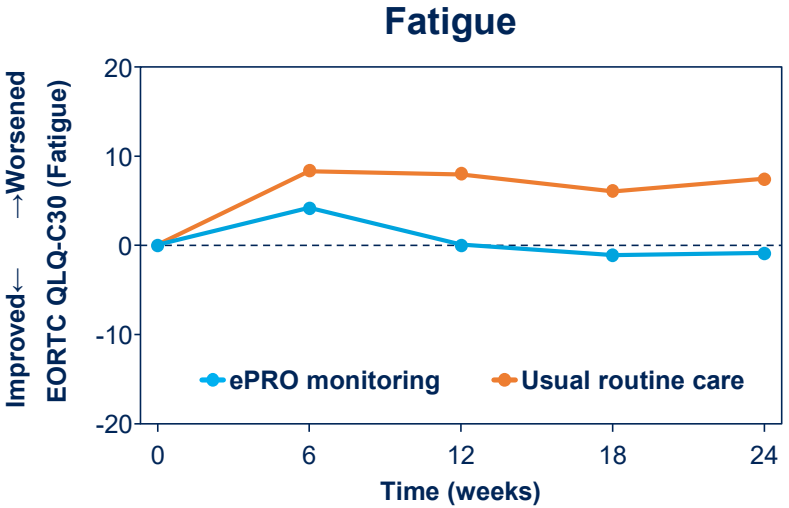
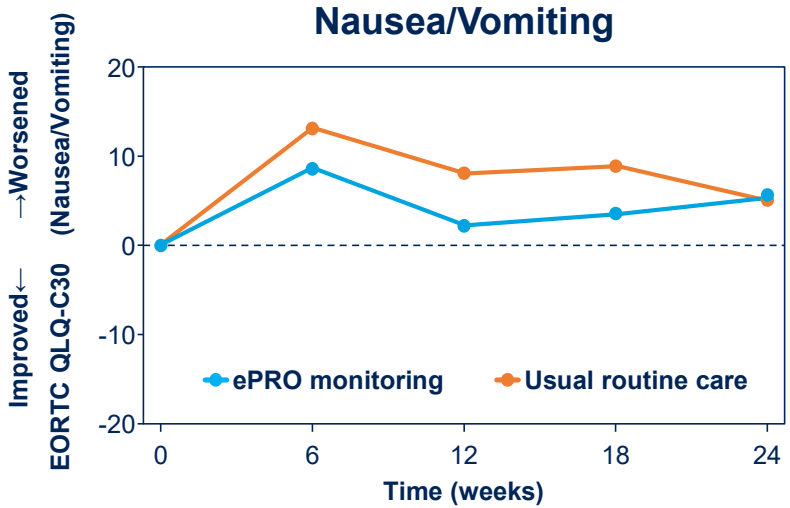
Secondary Endpoints: Fatigue and Nausea/Vomiting (QLQ-C30)

- Fatigue score was better in the ePRO monitoring group at 24 weeks (−8.4 [95% CI −16.1, −0.6])
- There was no difference in nausea/vomiting scores (0.5 [95% CI −6.2, 7.1])





ePRO monitoring	Estimated value*	4.2	0.1	-1.2	-0.9
Usual routine care	Estimated value*	8.3	8	6.1	7.5
Difference between groups (ePRO monitoring − usual routine care)	Estimated value*	-4.1	-7.9	-7.2	-8.4
	95% CI	-12.2, 4.0	-15.3, -0.4	-14.5, 0.1	-16.1, -0.6

ePRO monitoring	Estimated value*	8.7	2.2	3.5	5.4
Usual routine care	Estimated value*	13.2	8.1	8.9	4.9
Difference between groups (ePRO monitoring − usual routine care)	Estimated value*	-4.5	-5.8	-5.4	0.5
	95% CI	-12.1, 3.2	-11.5, -0.2	-10.4, -0.3	-6.2, 7.1

*Change from baseline

CI, confidence interval; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; QLQ-C30, Quality of Life Core 30 questionnaire.

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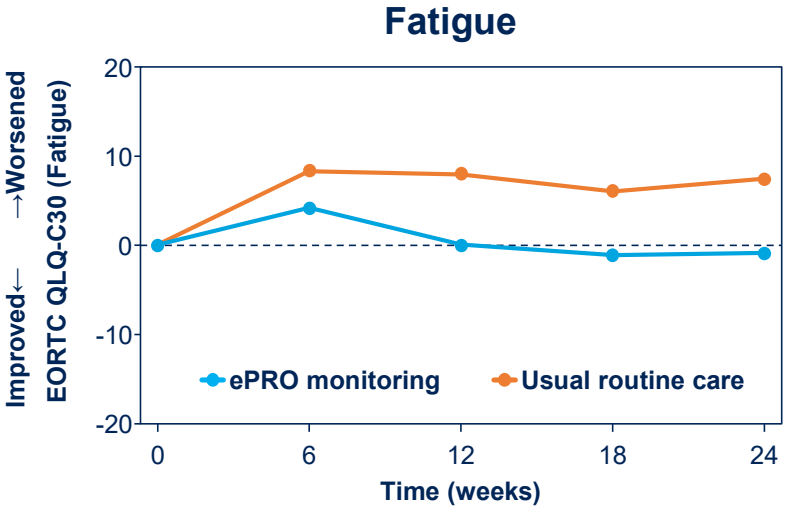

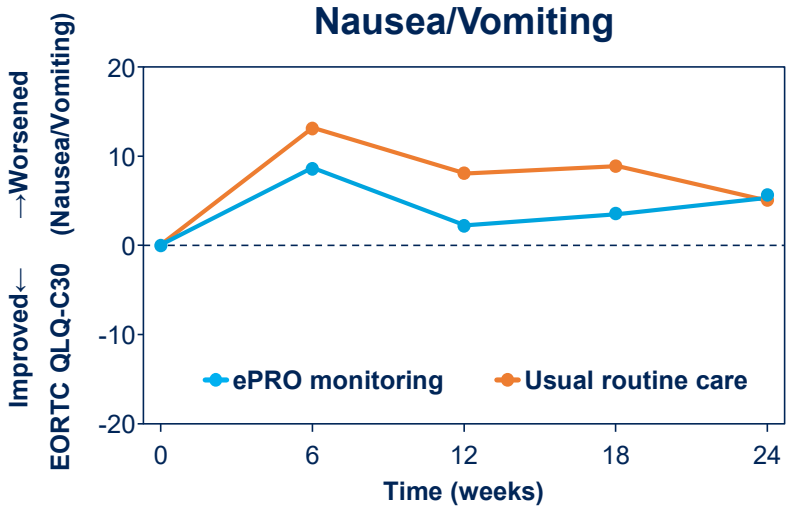

ePRO monitoring	Estimated value*	4.2	0.1	-1.2	-0.9
Usual routine care	Estimated value*	8.3	8	6.1	7.5
Difference between groups (ePRO monitoring − usual routine care)	Estimated value*	-4.1	-7.9	-7.2	-8.4
	95% CI	-12.2, 4.0	-15.3, -0.4	-14.5, 0.1	-16.1, -0.6

ePRO monitoring	Estimated value*	8.7	2.2	3.5	5.4
Usual routine care	Estimated value*	13.2	8.1	8.9	4.9
Difference between groups (ePRO monitoring − usual routine care)	Estimated value*	-4.5	-5.8	-5.4	0.5
	95% CI	-12.1, 3.2	-11.5, -0.2	-10.4, -0.3	-6.2, 7.1

*Change from baseline
CI, confidence interval; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; QLQ-C30, Quality of Life Core 30 questionnaire.

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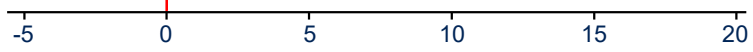
Secondary Endpoints: Functioning Scale (QLQ-C30)

Role, cognitive, and social functioning were better in the ePRO monitoring group, with mean differences of 10.0 (95% CI 1.1, 18.9), 6.3 (95% CI 1.1, 11.5), and 10.9 (95% CI 3.9, 18.0), respectively

		LS means		Difference between groups
		ePRO monitoring	Usual routine care	LS mean (95% CI)
Physical functioning	6 weeks	0.7	−4.1	4.8 (−0.6, 10.2)
	12 weeks	1.2	−3.7	4.9 (−0.7, 10.4)
	18 weeks	2.2	−1.1	3.3 (−1.8, 8.4)
	24 weeks	0.8	−2	2.8 (−3.4, 8.9)
Role functioning	6 weeks	−3.8	−11.6	7.7 (0.2, 15.3)
	12 weeks	−0.2	−8.3	8.1 (0.4, 15.8)
	18 weeks	3.0	−6.1	9.1 (1.2, 17.0)
	24 weeks	0.3	−9.7	10.0 (1.1, 18.9)
Cognitive functioning	6 weeks	3.7	−0.8	4.5 (−0.2, 9.3)
	12 weeks	5.0	−0.8	5.8 (0.8, 10.7)
	18 weeks	5.3	−1.1	6.4 (1.2, 11.6)
	24 weeks	3.0	−3.3	6.3 (1.1, 11.5)
Emotional Functioning	6 weeks	4.0	1.1	2.9 (−2.0, 7.8)
	12 weeks	6.3	1.2	5.1 (0.6, 9.6)
	18 weeks	7.2	1.5	5.7 (0.4, 10.9)
	24 weeks	5.0	0.8	4.2 (−0.8, 9.2)
Social functioning	6 weeks	−2.3	−7.7	5.4 (−1.8, 12.7)
	12 weeks	0.9	−5.2	6.1 (−1.0, 13.2)
	18 weeks	6.5	−2.5	8.9 (2.0, 15.9)
	24 weeks	3.2	−7.8	10.9 (3.9, 18.0)



Favors usual routine care group ← → **Favors ePRO monitoring group**

CI, confidence interval; ePRO, electronic patient-reported outcome; LS, least squares; QLQ-C30, Quality of Life Core 30 questionnaire.

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		LS means		Difference between groups
		ePRO monitoring	Usual routine care	LS mean (95% CI)
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	12 weeks	1.2	−3.7	4.9 (−0.7, 10.4)
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	12 weeks	−0.2	−8.3	8.1 (0.4, 15.8)
	18 weeks	3.0	−6.1	9.1 (1.2, 17.0)
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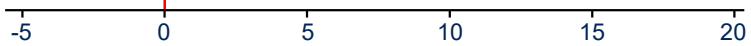
Cognitive functioning	6 weeks	3.7	−0.8	4.5 (−0.2, 9.3)
	12 weeks	5.0	−0.8	5.8 (0.8, 10.7)
	18 weeks	5.3	−1.1	6.4 (1.2, 11.6)
	24 weeks	3.0	−3.3	6.3 (1.1, 11.5)
Emotional Functioning	6 weeks	4.0	1.1	2.9 (−2.0, 7.8)
	12 weeks	6.3	1.2	5.1 (0.6, 9.6)
	18 weeks	7.2	1.5	5.7 (0.4, 10.9)
	24 weeks	5.0	0.8	4.2 (−0.8, 9.2)
Social functioning	6 weeks	−2.3	−7.7	5.4 (−1.8, 12.7)
	12 weeks	0.9	−5.2	6.1 (−1.0, 13.2)
	18 weeks	6.5	−2.5	8.9 (2.0, 15.9)
	24 weeks	3.2	−7.8	10.9 (3.9, 18.0)



Favors usual routine care group ← → **Favors ePRO monitoring group**

CI, confidence interval; ePRO, electronic patient-reported outcome; LS, least squares; QLQ-C30, Quality of Life Core 30 questionnaire.

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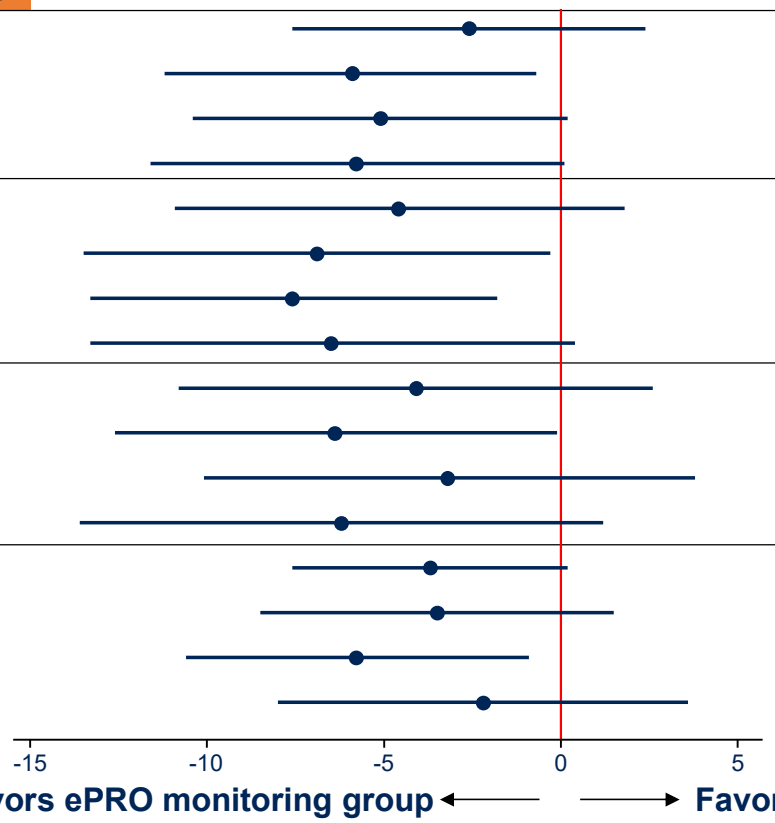
Secondary Endpoints: Cancer-Related Fatigue (FA12)

		LS means		Difference between groups
		ePRO monitoring	Usual routine care	LS mean (95% CI)
Total score	6 weeks	1.8	4.4	−2.6 (−7.6, 2.4)
	12 weeks	−1.4	4.6	−5.9 (−11.2, −0.7)
	18 weeks	−2.5	2.6	−5.1 (−10.4, 0.2)
	24 weeks	−0.7	5.0	−5.8 (−11.6, 0.1)
Physical score	6 weeks	2.8	7.3	−4.6 (−10.9, 1.8)
	12 weeks	−1.3	5.6	−6.9 (−13.5, −0.3)
	18 weeks	−3.3	4.3	−7.6 (−13.3, −1.8)
	24 weeks	−1.4	5.0	−6.5 (−13.3, 0.4)
Emotional score	6 weeks	−1.1	2.9	−4.1 (−10.8, 2.6)
	12 weeks	−3.2	3.1	−6.4 (−12.6, −0.1)
	18 weeks	−2.0	1.2	−3.2 (−10.1, 3.8)
	24 weeks	−0.8	5.3	−6.2 (−13.6, 1.2)
Cognitive score	6 weeks	−3.0	0.7	−3.7 (−7.6, 0.2)
	12 weeks	−1.7	1.8	−3.5 (−8.5, 1.5)
	18 weeks	−4.2	1.6	−5.8 (−10.6, −0.9)
	24 weeks	0.2	2.4	−2.2 (−8.0, 3.6)



CI, confidence interval; ePRO, electronic patient-reported outcome; LS, least squares.

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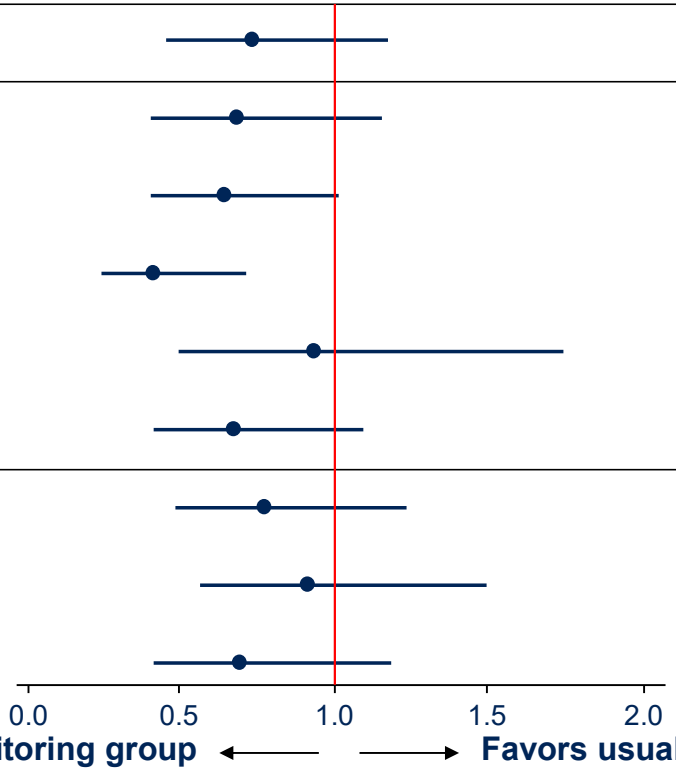
Secondary Endpoints: Time to First Deterioration (QLQ-C30)

	Estimated time to first deterioration, months		HR (95% CI)
	ePRO monitoring	Usual routine care	
GHS/QoL	3.9	3.0	0.73 (0.45, 1.17)
Physical functioning	13.9	9.4	0.68 (0.40, 1.15)
Role functioning	6.7	3.2	0.64 (0.40, 1.01)
Cognitive functioning	16.3	5.3	0.41 (0.24, 0.71)
Emotional functioning	NE	NE	0.93 (0.49, 1.74)
Social functioning	12.2	3.0	0.67 (0.41, 1.09)
Fatigue	6.7	2.6	0.77 (0.48, 1.23)
Nausea/Vomiting	3.9	2.5	0.91 (0.56, 1.49)
Pain	13.6	6.8	0.69 (0.41, 1.18)



Clinically meaningful deterioration is defined as a change of ≥ 10 points from baseline[1].

CI, confidence interval; ePRO, electronic patient-reported outcome; GHS, global health status; HR, hazard ratio; NE, not estimable; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life.

1.Kim Cocks et al. J Clin Oncol.2011 29(1):89–96.

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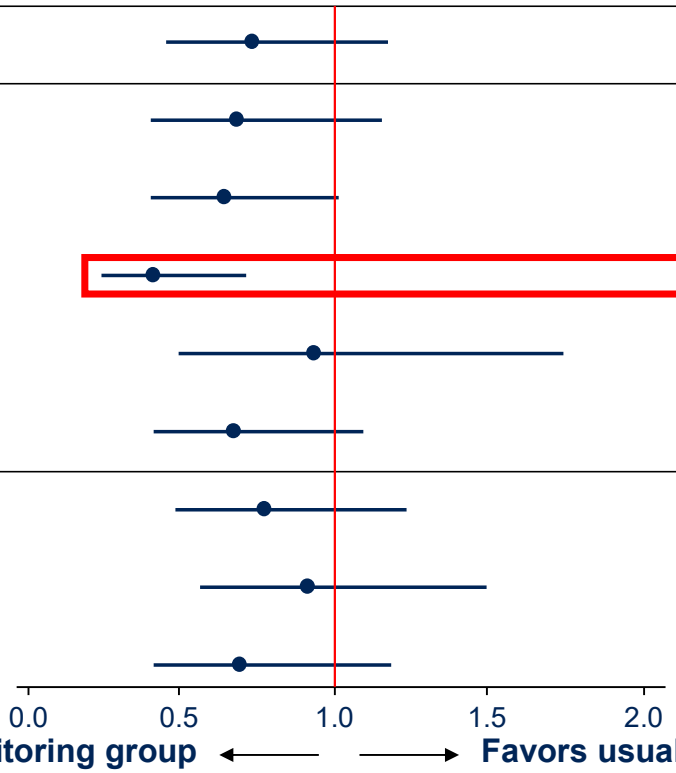

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Limitations

- The alpha error was set at 10% due to the exploratory nature of the study
- Alert notification thresholds were determined by expert consensus without pilot testing
- The long-term effectiveness and generalizability of ePRO monitoring to other countries and regions remain uncertain

ePRO, electronic patient-reported outcome.

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Conclusions

- The mean change from baseline in global QoL (primary endpoint) measured using EORTC QLQ-C30 at week 24 was significantly better in the ePRO monitoring group vs usual routine care group (mean difference; 8.0 [90% CI 0.2, 15.8]; p = 0.091)
  - Mean changes from baseline in functioning scale (role, cognitive, and social functioning) and symptom scale (fatigue) were better in the ePRO monitoring group vs usual routine care group
  - Time to first deterioration was extended in the ePRO monitoring group vs usual routine care group for cognitive functioning (16.3 vs 5.3)

The results of this study suggest that ePRO monitoring may be associated with maintenance/improvement of QoL in T-DXd-treated patients with HER2-positive metastatic breast cancer

CI, confidence interval; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; HER2, human epidermal growth factor receptor 2; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life; T-DXd, trastuzumab deruxtecan.

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&

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Baseline EORTC QLQ-C30 Scores

Scores were similar between the two groups

EORTC QLQ-C30	QoL analysis population (n = 108)			
	ePRO monitoring (n = 54)		Usual routine care (n = 52)	
	Responses, n	Mean (SD)	Responses, n	Mean (SD)
GHS/QoL	52	67.2 (21.6)	51	67.5 (23.5)
Physical functioning	53	83.3 (11.9)	51	80.0 (17.5)
Role functioning	54	80.3 (18.6)	50	80.7 (24.8)
Emotional functioning	54	84.3 (16.9)	51	80.6 (18.4)
Cognitive functioning	54	84.0 (18.0)	52	82.7 (17.8)
Social functioning	54	83.6 (22.3)	50	86.0 (22.4)
Fatigue	52	30.1 (18.4)	50	30.0 (20.5)
Nausea and vomiting	52	4.8 (11.1)	50	2.0 (5.5)
Pain	54	24.4 (20.1)	51	17.0 (21.0)
Dyspnea	52	19.2 (21.2)	51	15.7 (20.4)
Insomnia	54	19.8 (21.0)	50	20.0 (21.3)
Appetite loss	54	16.7 (19.2)	51	13.1 (21.2)
Constipation	54	17.3 (23.1)	52	16.7 (23.3)
Diarrhea	53	6.3 (16.1)	52	7.7 (15.6)
Financial difficulties	54	13.0 (23.7)	51	17.0 (24.4)

EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; GHS, global health status; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life; SD, standard deviation.

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Baseline EORTC FA12 Scores

Scores were similar between the two groups

EORTC FA12	QoL analysis population (n = 108)			
	ePRO monitoring (n = 54)		Usual routine care (n = 52)	
	Responses	Mean (SD)	Responses	Mean (SD)
Total score	50	17.4 (16.1)	52	18.1 (13.7)
Physical score	52	24.2 (20.2)	52	22.8 (16.2)
Emotional score	52	11.8 (14.0)	52	17.1 (17.4)
Cognitive score	54	7.4 (14.7)	52	9.3 (13.8)

EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; QoL, quality of life; SD, standard deviation.

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