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Supplementary Data

Electronic Patient-Reported Outcomes With Vital Signs Monitoring Versus Usual Care During Trastuzumab Deruxtecan Treatment for Metastatic Breast Cancer: Updated Results From the PRO-DUCE Study

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Key Takeaways

Long-term findings from the PRO-DUCE study suggest that integrating ePRO with vital signs monitoring, an approach inherently promoting active patient involvement in their care, is significantly effective in clinical practice for maximizing QoL for patients receiving T-DXd.

A comparison between the monitoring group and the usual care group revealed the following trends:

1. In the monitoring group, global QoL change from baseline was significantly better at week 24, and this difference was maintained over time
2. ePROs with vital signs monitoring were favored over usual care across all cancer-related fatigue questionnaires at week 24; this difference remained consistent beyond week 24
3. Survival outcomes showed no significant difference between the monitoring group and the usual care group

ePRO, electronic patient-reported outcome; QoL, quality of life; T-DXd, trastuzumab deruxtecan.

Statistical Analysis

Primary Endpoint:

- A mixed-effects model for repeated measures (MMRM) was used for CFB in GHS/QoL at week 24
- Considering the exploratory nature of the study, a two-sided alpha error < 0.10 was considered statistically significant (power 87%)
- The required sample size was 55 in each group

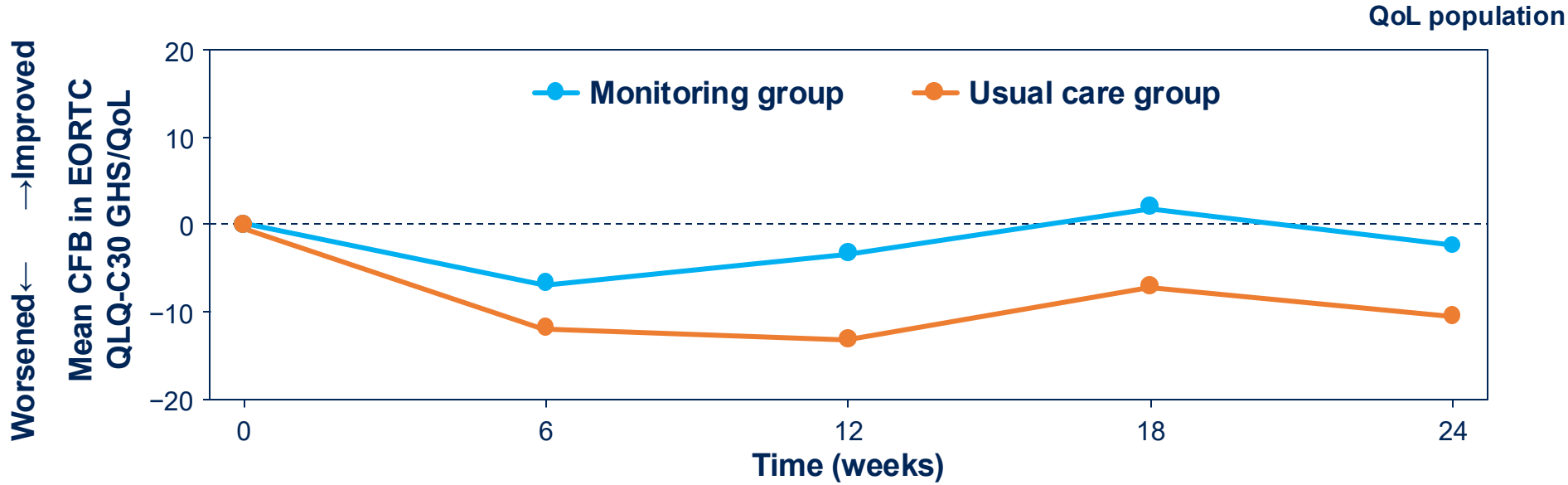
Secondary Endpoint:

- OS, PFS, and TTF were calculated using the Kaplan-Meier method
- Adherence with ePRO was quantified by calculating the proportion of completed questionnaires

CFB, change from baseline; EORTC, European Organisation for Research and Treatment of Cancer; ePRO, electronic patient-reported outcome; FA12, cancer-related fatigue; MMRM, mixed-effects model for repeated measures; OS, overall survival; PFS, progression-free survival; QLQ-C30, Quality of Life Core 30 questionnaire; TTF, time to treatment failure.

Primary Endpoint: Change from baseline in EORTC QLQ-C30 GHS/QoL

Primary results presented at ASCO 2024 showed that at week 24, the CFB in GHS/QoL scores was significantly better ($p < 0.10$) in the monitoring group compared with that in the usual care group, based on MMRM analysis



Monitoring group	Estimated CFB	−6.7	−3.3	1.6	−2.4
Usual care group	Estimated CFB	−11.8	−13.1	−7.0	−10.4
Difference between groups (monitoring group − usual care group)	Estimated CFB	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

CFB, 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.

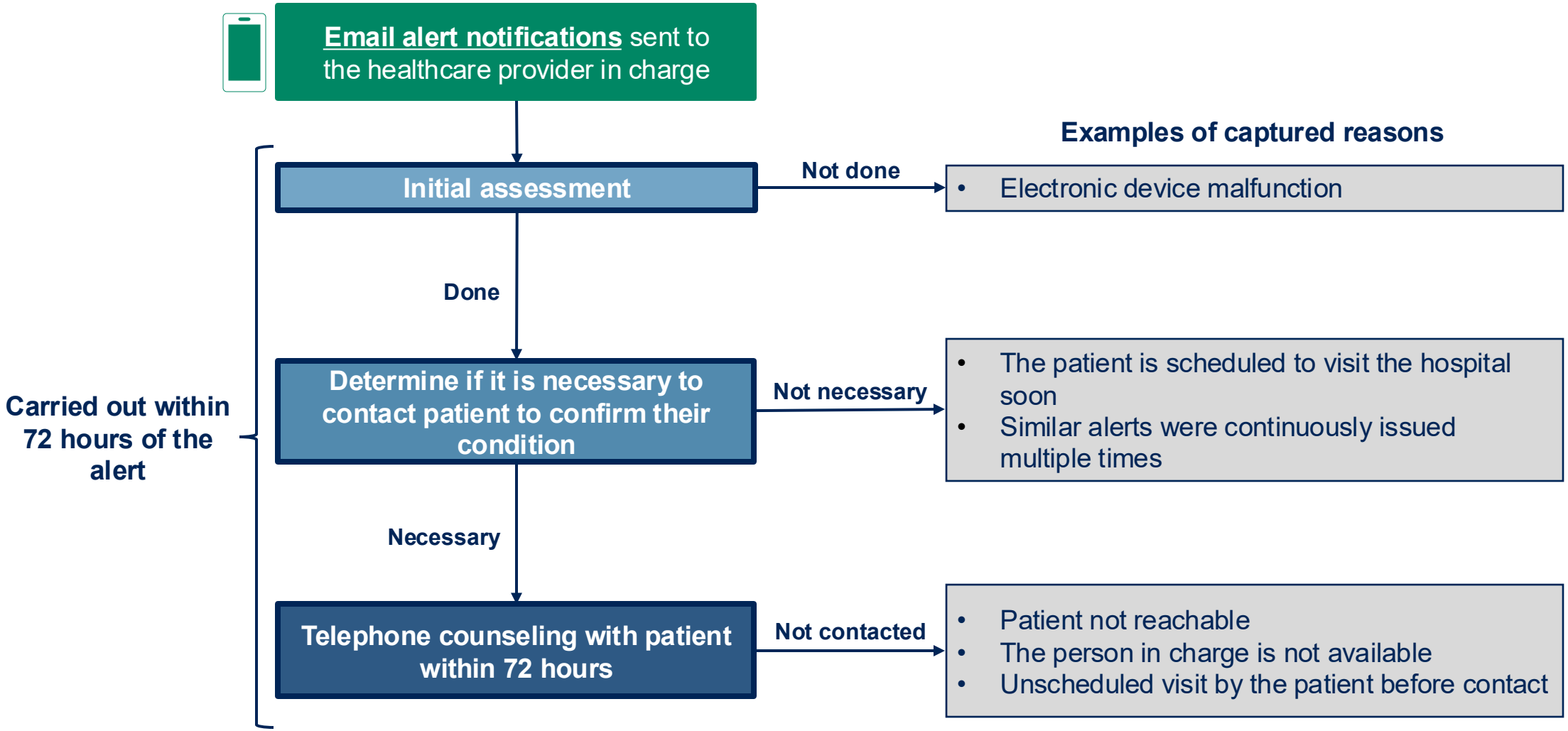
ePRO Monitoring Procedures

- Participants used the “Hibilog app” on personal devices for daily logging of body temperature and SpO_2 (a pulse oximeter was provided for home SpO_2 monitoring) and weekly reporting of selected PRO-CTCAE symptoms
- Investigators and healthcare providers had real-time access to PRO data via the app
- Alert notifications were 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

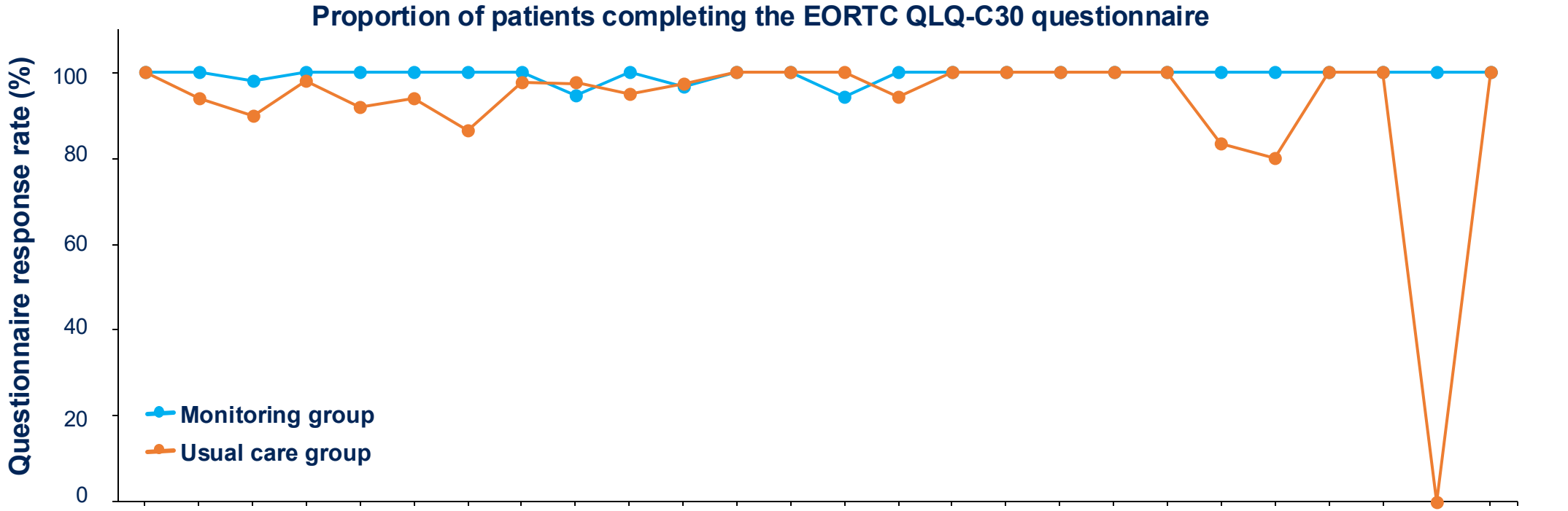
PRO-CTCAE, version 1.0 (Japanese version) http://www.jcog.jp/doctor/tool/PRO_CTCAE.html
ePRO, electronic patient-reported outcome; PRO, patient-reported outcome; PRO-CTCAE, PRO version of the Common Terminology Criteria for Adverse Events; SpO_2, oxygen saturation.

Flowchart of Actions Taken in Response to Alert Notifications



EORTC QLQ-C30 Questionnaire Adherence Throughout the Entire Observation Period

QoL population

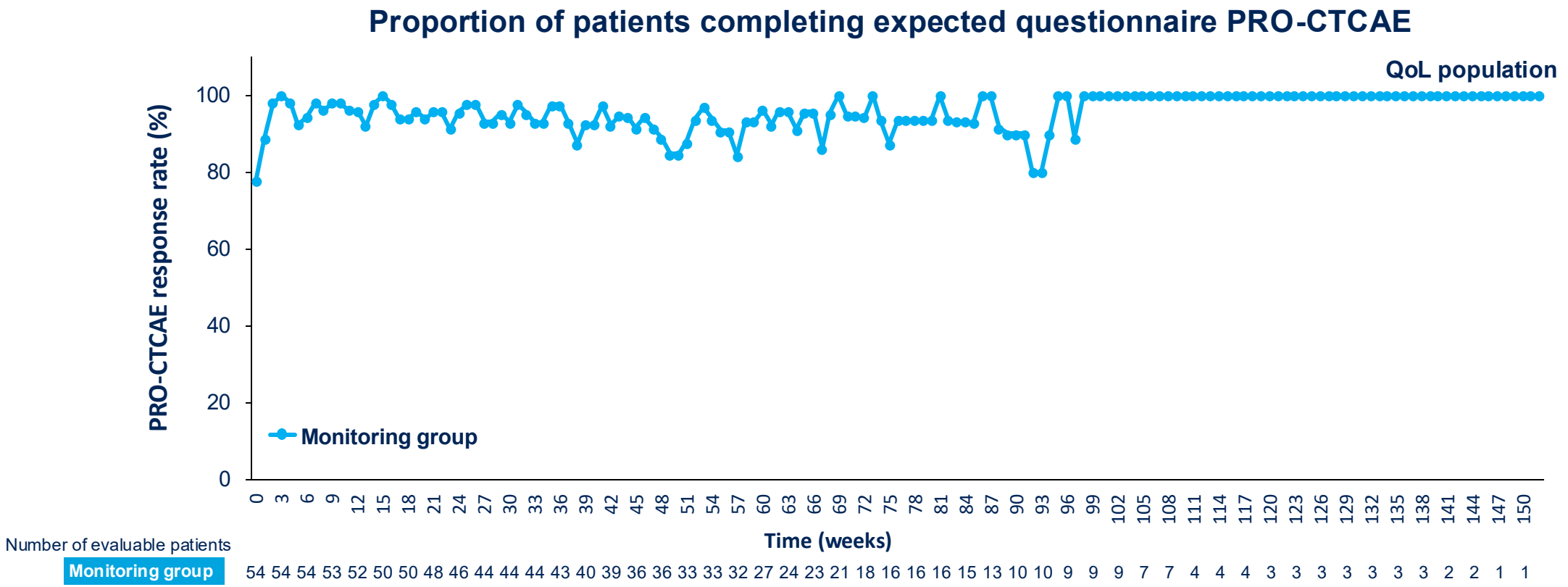


Number of evaluable patients	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90	96	102	108	114	120	126	132	138	144	150
Monitoring group	54	54	53	50	47	44	42	40	37	34	31	25	21	18	17	12	11	11	8	4	3	3	3	3	2	1
Usual care group	52	51	50	50	49	49	45	42	41	40	36	28	25	23	18	15	14	11	10	7	6	5	3	2	1	1

Questionnaire response rates remained high throughout the observation period

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

PRO-CTCAE Questionnaire Adherence Throughout the Entire Observation Period



Questionnaire response rates remained high throughout the observation period

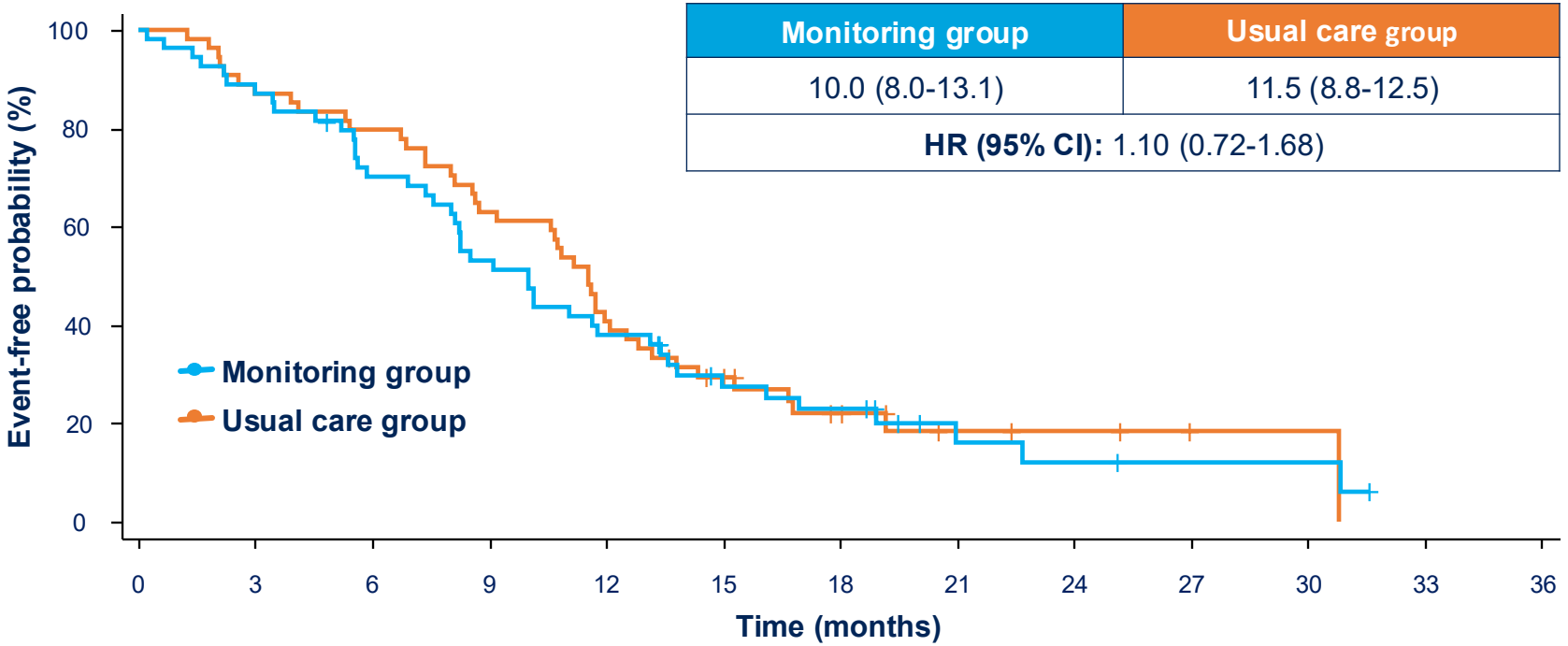
EORTC, European Organisation for Research and Treatment of Cancer; PRO-CTCAE, patient-related outcome version of the Common Terminology Criteria for Adverse Events; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life.

Endpoint: TTF

M-ITT population

Median TTF (95% CI), months

Monitoring group	Usual care group
10.0 (8.0-13.1)	11.5 (8.8-12.5)
HR (95% CI): 1.10 (0.72-1.68)	



Monitoring group	54	47	37	28	20	12	10	4	3	2	2	0	-
Usual care group	54	47	43	34	22	14	8	4	3	1	1	0	-

Reason for treatment failure	Monitoring group n = 54	Usual care group n = 54
Discontinuation	44 (81.5%)	43 (79.6%)
Disease progression	29	28
Adverse event	11	10
Other (patient preference)		2
Other (transfer to another hospital)	1	2
Other (financial issues)		1
Other (due to clinical trials)	1	
Other (discussion with the patient)	1	
Other (surgery)	1	

CI, confidence interval; ePRO, electronic patient-reported outcomes; HR, hazard ratio; M-ITT, modified intention to treat; TTF, time to treatment failure.

Study Limitations

- The sample size was small, and the alpha error was set at 10% due to the exploratory nature of this unblinded study
- There might be selection bias because patients who were not familiar with digital devices were not enrolled in this study
- Alert notification thresholds were determined by expert consensus without pilot testing

Participating Study Sites

Sapporo Medical University Hospital, Teine Keijinkai Hospital, Hokkaido Cancer Center, Asahikawa Medical University Hospital, Hokkaido University Hospital, Aomori Prefectural Central Hospital, Akita University Hospital, Tohoku University Hospital, Advanced Cancer Translational Research Institute, Showa University, Tokyo Medical University Hospital, National Center for Global Health and Medicine, Tokyo Saiseikai Central Hospital, Toranomon Hospital, Chiba University Hospital, International University of Health and Welfare Narita Hospital, JCHO Saitama Medical Center, Kitasato University Hospital, Tokai University Hospital, Yokohama City University Hospital, Saiseikai Yokohamashi Nanbu Hospital, Yokohama City University Medical Center, Jichi Medical University Hospital, Niigata City General Hospital, National Hospital Organization Shibukawa Medical Center, NHO Nagoya Medical Center, Nagoya City University Hospital, Hamamatsu University Hospital, Mie University Hospital, National Hospital Organization Osaka National Hospital, Osaka Police Hospital, Osaka International Cancer Institute, Kansai Medical University Hospital, Kindai University Hospital, Yao Municipal Hospital, Kobe University Hospital, Kobe City Nishi-Kobe Medical Hospital, Hyogo Cancer Center, Okayama University Hospital, Fukuyama City Hospital, National Hospital Organization Shikoku Cancer Center, Kochi Health Sciences Center, Sagara Hospital, Kurume General Hospital, Kurume University Hospital, Nagasaki University Hospital, National Hospital Organization Kyusyu Cancer Center