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Characterization of Patient-Reported Outcome Utilization and Results Reported in Breast Cancer Trials Registered on ClinicalTrials.gov (2020-2024)

Kyungwan Hong, PharmD, PhD, Ankit Gandhi, PharmD

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Introduction

Patient-reported outcomes (PROs) provide valuable information on treatment benefits and harms reported directly by patients and support informed decision-making, particularly in breast cancer.

Previous studies of PRO use in breast cancer trials focused on pivotal or industry-sponsored trials and PRO reporting in drug labels.

This analysis provides a review of PRO use in breast cancer trials registered on ClinicalTrials.gov, a database of >575,000 clinical trials including non-pivotal and non-industry-sponsored trials, and PRO reporting in corresponding publications.

Aim

- To characterize PRO use in breast cancer trials registered on ClinicalTrials.gov over the past five years.
- To compare PRO measures reported on ClinicalTrials.gov and matching publications.

Methods

- Searched ClinicalTrials.gov for:
  - Trials of drug and biological products for breast cancer treatment or prevention
  - Study Completion Dates: From 1/1/2020 to 12/31/2024
  - With study results posted
- Outcome measure fields (as of 11/19/2025) were reviewed to identify PRO use.
  - Verified using eProvide, a clinical outcomes assessment database.
- Publications linked to ClinicalTrials.gov records were reviewed to determine whether PROs reported on ClinicalTrials.gov were also reported in corresponding publications.
  - Excluded duplicates and publications that do not report trial results (e.g., study protocols, letters to the editor, plain language summaries, etc.)
- Both authors extracted data and resolved discrepancies through discussions.

Results

Among 312 breast cancer trials reviewed, 56 (17.9%) reported PROs as trial outcomes on ClinicalTrials.gov (Figure 1).

Characteristics of these trials include:
- Median size: 313.5 participants (IQR, 126-622)
- Primarily industry-sponsored: 43 (76.8%)
- Randomized: 47 (83.9%)
- Phase 2: 24 (42.9%); Phase 3: 29 (51.8%)

PRO Use:
- In the 56 trials, PROs were used as:
  - Secondary endpoints: 47 (83.9%)
  - Primary & secondary endpoints: 6 (10.7%)
  - Primary endpoints: 1 (1.8%)
  - Other pre-specified endpoints: 2 (3.6%)
- Approximately half (25; 44.6%) used ≥2 PRO measures simultaneously.

PRO Measures:
- Across the trials, 41 unique PRO measures were reported (Table 1).
  - EORTC QLQ-C30 was the most frequently used measure to assess global health/quality of life (26; 46.4%)
  - Other frequently used PRO measures include:
    - EORTC QLQ-BR23: 9 (16.1%)
    - EQ-5D-3L: 6 (10.7%); FACT-B: 6 (10.7%); BPI: 6 (10.7%)

Reporting of PROs in Journal Publications:
- As of 11/19/2025, in ClinicalTrials.gov:
  - 46 trials linked a total of 197 publications
  - 10 trials had no linked publications.
- After excluding duplicates and publications without trial results, 143 publications were reviewed.
- Through publications, 32 of the 56 total trials (57.1%) reported results for 20 of the 41 PRO measures (48.8%).

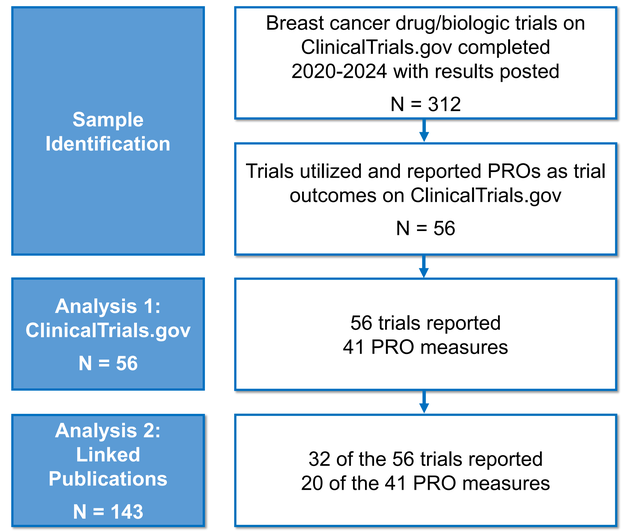

Figure 1. Overview of Study Flow and Analysis

Table 1. Trial-level Reporting of PRO Measures in ClinicalTrials.gov and Linked Publications (N = 56)[a,b,c]

PRO Measures	No. reported in ClinicalTrials.gov (%)	No. reported in linked publications (%)
EORTC QLQ-C30	26 (46.4%)	19 (33.9%)
EORTC QLQ-BR23	9 (16.1%)	5 (8.9%)
EQ-5D-3L	6 (10.7%)	3 (5.4%)
FACT-B	6 (10.7%)	4 (7.1%)
BPI (including short form)	6 (10.7%)	2 (3.6%)
EQ-5D-5L	3 (5.4%)	1 (1.8%)
BCPT Eight Symptom Scale, PROMIS Cognitive Function, or PROMIS Fatigue	2 (3.6%)	1 (1.8%)
BSFS, FACIT-D, FACT-Cog, FACT-G, FACT-O, GLQ-8, MenQOL, PPQ, PROMIS Depression, PROMIS Emotional Distress-Anxiety, or TASQ	1 (1.8%)	1 (1.8%)
BFI, Cancer-Related Cachexia Symptom Assessment, CES-D, EORTC QLQ-BM22, EORTC QLQ-BN20, EORTC QLQ-C15-PAL, EORTC QLQ-CIPN20, Epworth Sleep Scale, FACIT-F, Geriatric Depression Scale, HADS, MDASI-BT, MFI, OSDQ, Minnesota Living with Heart Failure Questionnaire, MOS-SSS, Pain Visual Analog Scale, Quality of Recovery Score, SF-36, STAI, or Veterans RAND12	1 (1.8%)	0 (0%)

[a] Explanation of selected abbreviations: *EORTC QLQ-C30* European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Core Questionnaire, *EORTC QLQ-BR23* European Organization for Research and Treatment of Cancer, Breast Cancer-Specific Quality of Life Questionnaire, *EQ-5D-3L* The 3-level EuroQol 5 Dimensions, *FACT-B* Functional Assessment of Cancer Therapy – Breast, *BPI* Brief Pain Inventory, *BCPT* Breast Cancer Prevention Trial, *PROMIS* Patient-Reported Outcomes Measurement Information System
[b] Using the publications linked to eProvide and/or information provided in the official PRO measure websites, we categorized older PRO measure names to align with current terminology (e.g., EQ-5D to EQ-5D-3L).
[c] Categories are not mutually exclusive as some trials used multiple PRO measures simultaneously.

Conclusion

- About 20% of examined breast cancer trials collected and reported PROs on ClinicalTrials.gov, mainly assessing global health or quality of life.
- Nearly half of these trials reported PROs only on ClinicalTrials.gov and not in journal publications.
  - This is likely attributable to most PROs being designated as secondary outcomes.
- This analysis suggests that ClinicalTrials.gov can complement journal publications in the reporting of valuable patient-centered trial information.
- Limitations include the exclusion of supplementary appendices and study protocols that may provide additional details on PROs collected during trials.
- Future research is warranted to determine if similar incomplete PRO reporting extends to trials of other diseases and therapeutic areas.

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