



# How are clinical trials for breast cancer treatments currently being designed? A clinical trial database analysis

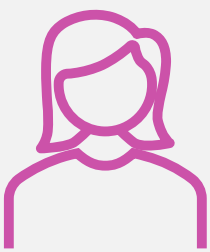
Charlotte Verbeke<sup>1,\*</sup>, Justine De Tavernier<sup>1</sup>, Annette Eeraerts<sup>1</sup>, Lara Torfs<sup>1</sup>, Patrick Neven<sup>2</sup>, Isabelle Huys<sup>1</sup>

<sup>1</sup>Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Belgium

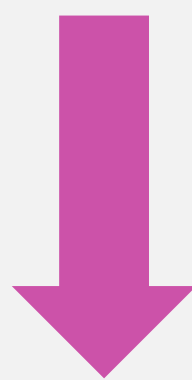
<sup>2</sup>Department of Obstetrics and Gynaecology, Division of Gynaecological Oncology, University Hospitals Leuven, Belgium

\*Contact: charlotte.verbeke@kuleuven.be

## BACKGROUND & OBJECTIVE



- Breast cancer is highly prevalent among women, with an impact on patients’ quality of life
- New treatments developed and tested in clinical trials



- Provide a comprehensive overview of breast cancer clinical trials
  - How are the clinical trials designed?
  - What are the endpoints in the clinical trials?
  - Whether patients are involved in clinical trials
  - If and how patients’ needs and QoL are assessed

## METHODS - Database analysis

- Database: ClinicalTrials.gov
- Search conducted November 2024

Applied filters in ClinicalTrials.gov
(i) female
(ii) adult participants (18-64 years old)
(iii) completed trials
(iv) trials with results
(v) phase III and phase IV
(vi) interventional studies

\*Important note: All filters represent minimum inclusion requirements; broader study characteristics (e.g., wider age ranges or both sexes) were allowed.

- Systematically screening of the trials after applying the filters
- Data extraction in a predefined excel table
- Patient involvement was assessed by evaluating secondary endpoints in the clinical trials

## RESULTS - preliminary findings

- 280 trials were identified and analysed
- Included trials started between 1997-2021

Clinical trials (N=280)	
Clinical phase	
Phase III	244 (87%)
Phase IV	36 (13%)
Primary purpose of clinical trial	
Treatment	216 (77%)
Supportive care	32 (11%)
Prevention	14 (5%)
Diagnostic	11 (4%)
Other/Not specified	7 (3%)
Most mentioned treatment categories in the clinical trials (also in combinations)	
Chemotherapy	114
Targeted therapy	117
Hormonal therapy	64

- Number of participants in the trial
  - Median: 433,5
  - 9 (min) – 9779 (max)

➤ Follow up time
  - Median: 39 months
  - 6 hours (min) – 190 months (max)

➤ Breast cancer subtype included in trial – not specified in 151 trials

### (co-)primary endpoints most identified

- 1

Progression free survival (64 trials)
- 3

Overall survival (23 trials)
- 2

Disease free survival (41 trials)
- 4

Pathologic complete response (16 trials)

### Patient involvement

- Assessment of patients’ needs and QoL via questionnaires (103 trials)
- Non-breast cancer specific questionnaires
  - Cancer specific: EORTC QLQ-C30
  - Non-disease specific: EQ-5D
  - Non-disease specific: VAS

➤ Breast cancer specific questionnaires
  - FACT-B
  - EORTC-QLQ-BR23

## CONCLUSIONS - preliminary findings

- Unclear elements in trial design (i.e., subtypes of breast cancer patients included)
- Strongly focussed on survival-based endpoints
- Limited information whether patients are involved and whether needs are evaluated

### LIST OF ABBREVIATIONS

EORTC QLQ: European Organization for Research and Treatment for Cancer Quality of Life Questionnaire; EQ-5D: EuroQol 5D; FACT-B: Functional Assessment of Cancer Therapy – Breast; QoL: Quality of Life; VAS: Visual Analogue Scale

### ACKNOWLEDGMENTS

This work is supported by KU Leuven and partly supported by the internal KU Leuven funding C3/22/052