

Follow-up in Early and Locally Advanced Breast Cancer Patients: An EORTC QLQ-BCG-ROG Protocol

V. Bjelic-Radiscic, F. Cardoso, D. Cameron, K. Pogoda, G. Vellkova, C. Martinez-Mena, F. Duhoux, P. Neven, A. Roelstraete, E. Rivin del Campo, G. Noel, F. van Duijnhoven, E. Fernández Lizarbe, S. Hartup, E. Senkus-Konefka, I. Meattini, M. E. Cazzaniga, V. Lewitzki, A. Palacios Eito, P. Schmid, G. Jerusalem, R. Olofsson Bagge, J. Arraras, D. Taylor, J. Kazmierska, M. Pinto, E. Cretella, S. Serpentine, K. Kuljanic, A. Costantini, T. Kuhnt, B. Sousa, H. Abdel-Razek, N. Afonso, A. Henni, R. Popescu, I. Rubio, H. Westenber, A. Bottomley, M. Beauvois, T. Verbiest, C. Coens

STUDY RATIONALE

Breast cancer is the most frequent type of cancer in women, and incidence increases. Many different treatment regimens are available today, with survival rates increasing to about 78% for 10 years or more. An increasing number of BC patients will live with **long-term side effects of disease/therapy**. This can have a significant impact on the quality of life of these patients, including long-term functional impairment, physical menopausal symptoms and emotional distress.

The existing routine follow-up is still lacking evidence-based follow-up strategies to

- Identify high-risk patients for recurrence/toxicity
- Address the patients' health care needs, and
- Evaluate their quality of life (physical and psychosocial problems)

→ **Need to develop follow-up models for long-term conditions**

OBJECTIVES

Main objectives:

- To assess the physical, sexual and emotional needs of early breast cancer (EBC) and locally advanced breast cancer (LABC) patients across Europe following treatment with curative intent
- To describe current follow-up patterns of EBC and LABC in different countries (length and frequency of follow-up).
- To describe using patients self-reports: what support patients are currently getting, from who, and what would be their preferred model of support

Secondary objectives:

- To identify patients at high-risk of emotional or physical problems
- To compare different follow-up models regarding patients outcomes
- To investigate correlations between physical, sexual and emotional needs with factors specific to the patients and specific to disease and its treatment.

DESIGN

- Observational, non-interventional study of EBC and LABC patients after primary therapy, to assess the physical, sexual and emotional needs of BC patients across Europe.
- Prospective collection of limited clinical and demographic data, and patient-reported outcome measures data.
- Cross-sectional = 1 assessment per patient of current status; no follow-up over time.
- 830 patients to be included
- Study duration: Recruitment = 1,5 year

Inclusion Criteria

- EBC and LABC patients who have completed their primary treatment (except hormonal therapy); between 12 and 36 months after the diagnosis
- Disease-free without any evidence of relapse

Exclusion Criteria

- Metastatic breast cancer
- Other cancer diagnosis in the past 5 years
- Male breast cancer
- Ductales Carcinoma in situ (DCIS)

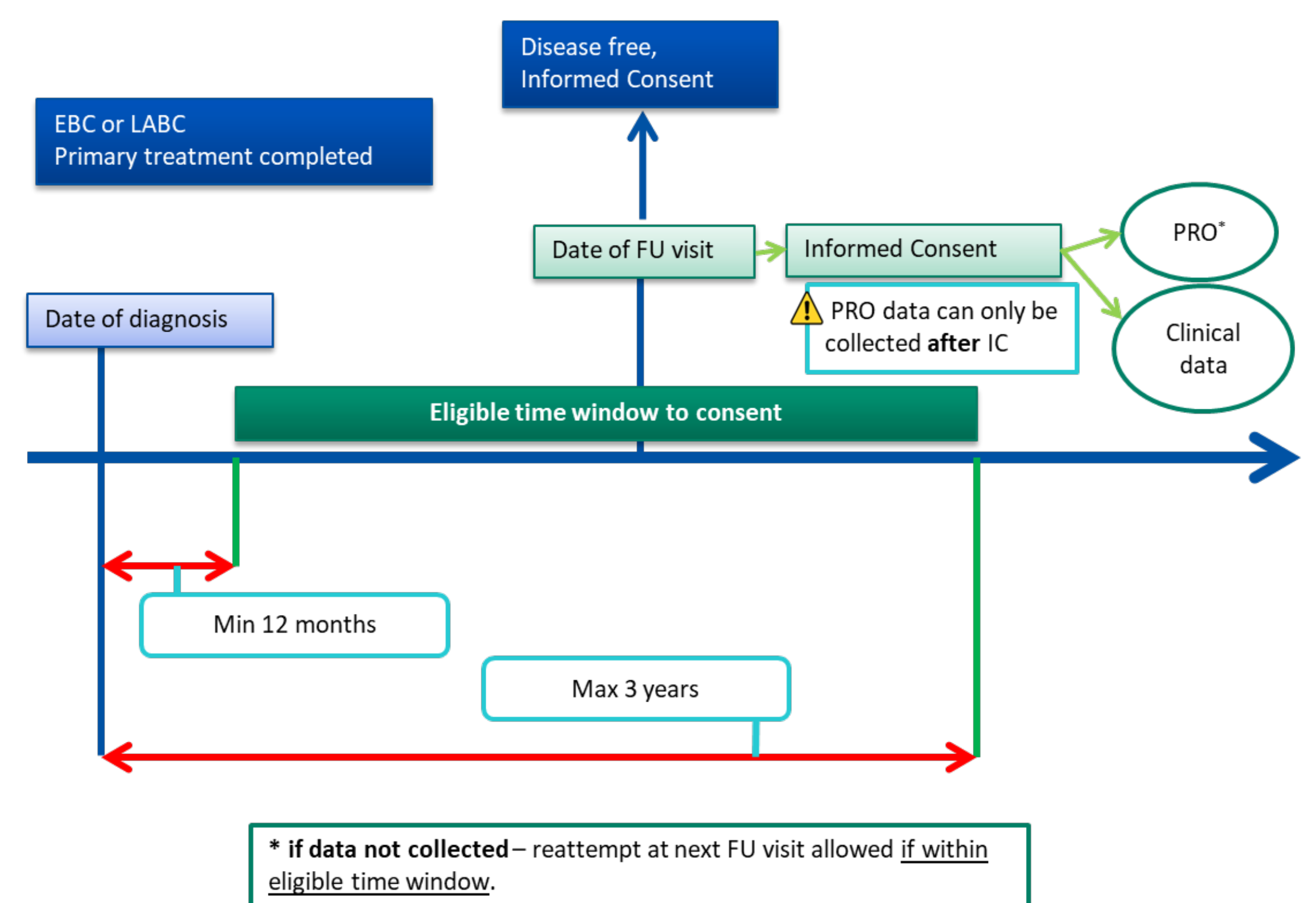


Figure 1. Study design

DATA COLLECTION

Clinical / demographic data

- Tumor characteristics: Disease stage (TNM), Histological type, receptor status, date of diagnosis, NPI risk score
- Treatment history: type and duration
- Patient characteristics: Age, Performance status, comorbidity (current)
- Follow-up characteristics: Date of last follow-up & of next planned follow-up
- Demographic data: country, marital status, employment, education

Patient-reported Outcome Measures

- EORTC QLQ-C30
- EORTC QLQ-BR45
- EORTC QLQ-SHQ 22
- 8 questions from IN-PATSAT32
- Distress Thermometer
- 2 additional questions on anxiety
- G8 (if ≥ 70 years)

CURRENT STATUS

- Site status: 36 sites in total (13 countries)
→ 7 sites activated (date: 06.01.2021)
- Recruitment status: 70 patients (3 countries; date: 06.01.2021)

PI: Vesna Bjelic-Radiscic
Co-PI: Fatima Cardoso

Contact:
vesna.bjelic-radiscic@helios-gesundheit.de
fatimacardoso@fundacaochampalimaud.pt