



## MELODY: Methods for Localization of Different Types of Breast Lesions

### A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/iBRA-NET)

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#### Why do we need the MELODY study?

In the last decades, the proportion of breast cancer patients receiving breast-conserving surgery has increased, reaching 70-80% in some countries. In case of non-palpable lesions, surgical excision requires some form of breast localization. While wire-guided localization has long been considered gold standard, it carries several limitations, including logistical difficulties, the potential for displacement and patient discomfort, and re-excision rates reaching 21%. Other techniques have been developed with the aim of overcoming these disadvantages (Fig. 1). However, comparative data on the rates of successful lesion removal, negative margins and re-operations are limited. In most studies, patient's perspective with regard to discomfort and pain level has not been evaluated. The aim of MELODY is to compare different localization methods with regard to oncological safety, patient-reported outcomes, and surgeon and radiologist satisfaction.

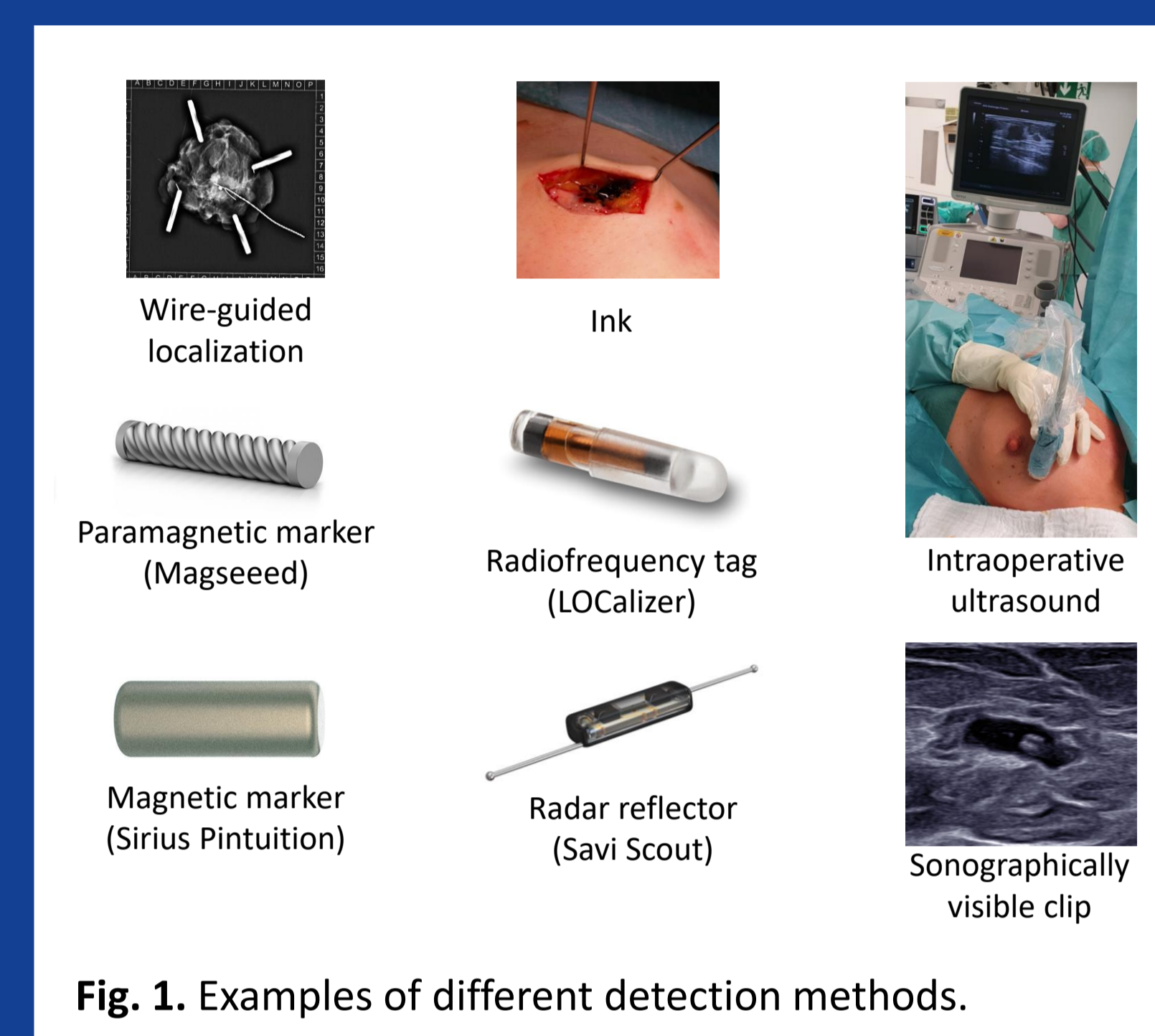


Fig. 1. Examples of different detection methods.

#### Study Lead

EUBREAST / iBRA-NET (Intergroup Study)

#### Study design

Prospective non-interventional multicenter cohort study (IIT)

Target accrual: 7,416 patients

Current enrollment (May 5, 2024): 1,011 patients

Enrollment begin: January 2023

#### Financial support

Endomag, Merit Medical, Sirius Pintuition, Hologic

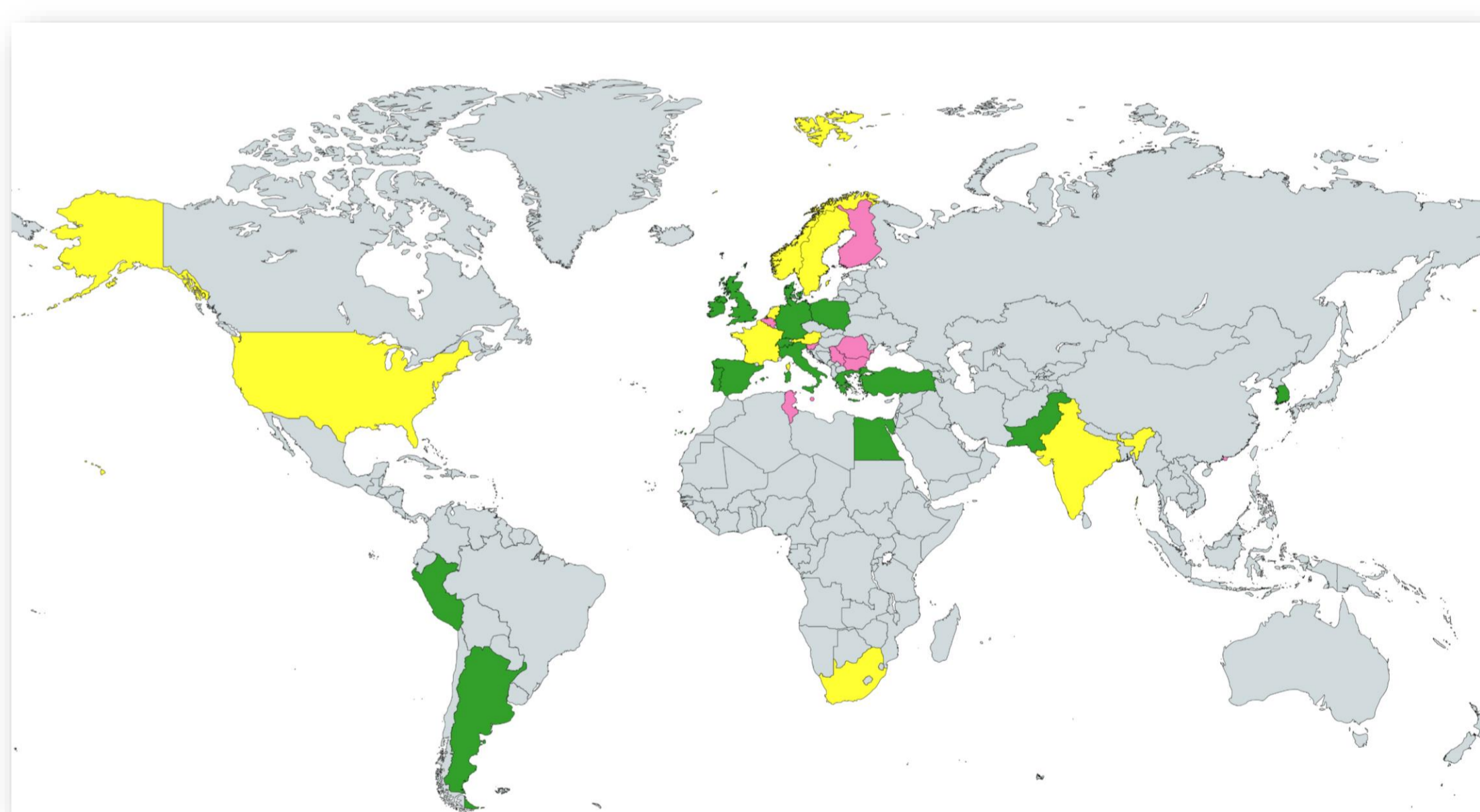


Fig. 2. Current state of international participation.

- Recruiting
- Applying for ethical approval
- Planning to join

#### Inclusion criteria

- Malignant breast lesion requiring breast-conserving surgery and imaging-guided localization (DCIS or invasive; multiple or bilateral lesions and the use of neoadjuvant chemotherapy are allowed)
- Planned surgical removal of the lesion using imaging-guided localization

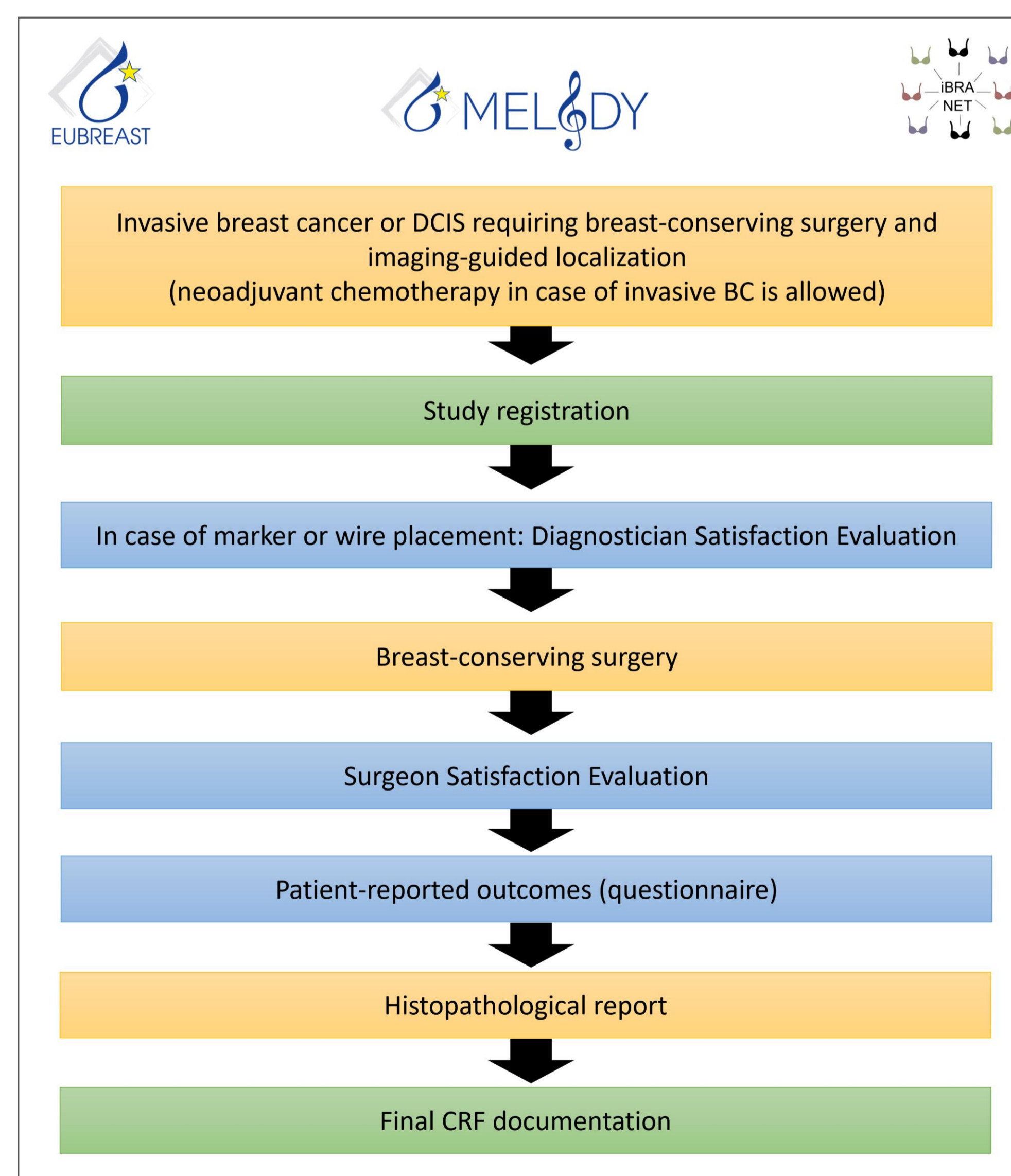


Fig. 3. MELODY Flow chart.

#### Primary outcomes

- Intended target lesion and/or marker removal
- Negative resection margin rates (defined as lesion removal with no invasive or non-invasive carcinoma on ink) at first surgery

#### Secondary outcomes

- Second surgery
- Secondary mastectomy
- Resection Ratio
- Duration of surgery
- Marker dislocation
- Marker placement failure
- Localization failure
- Patient-reported outcomes (e.g., patient's discomfort, pain level, and impairment of breathing)
- Diagnostician/radiologist's satisfaction
- Surgeon's satisfaction
- "Lost markers"
- Volume and weight of resected tissue
- Learning curve
- Impact of self-reported ethnicity
- Economic resources
- MRI artifacts
- Complication rates

For more information:

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