

Dear Study Sites, dear Friends and Supporters of the MELODY Study,

We are proud to present to you the first international MELODY newsletter. With this newsletter, we will inform you regularly about the current state of the study.

You can also find important information and files for download at our website: <http://melody.eubreast.com>

On behalf of the International Steering Board and the Organizing Committee,

PD Dr. Maggie Banys-Paluchowski
Prof. Dr. Thorsten Kühn
Prof. Dr. Jana de Boniface
Rajiv Dave
Dr. Oreste Davide Gentilini

Prof. Bahadır M. Güllüoğlu
Prof. Dr. med. Markus Hahn
James Harvey
Prof. Dr. G. Karadeniz Çakmak
Dr. Andreas Karakatsanis

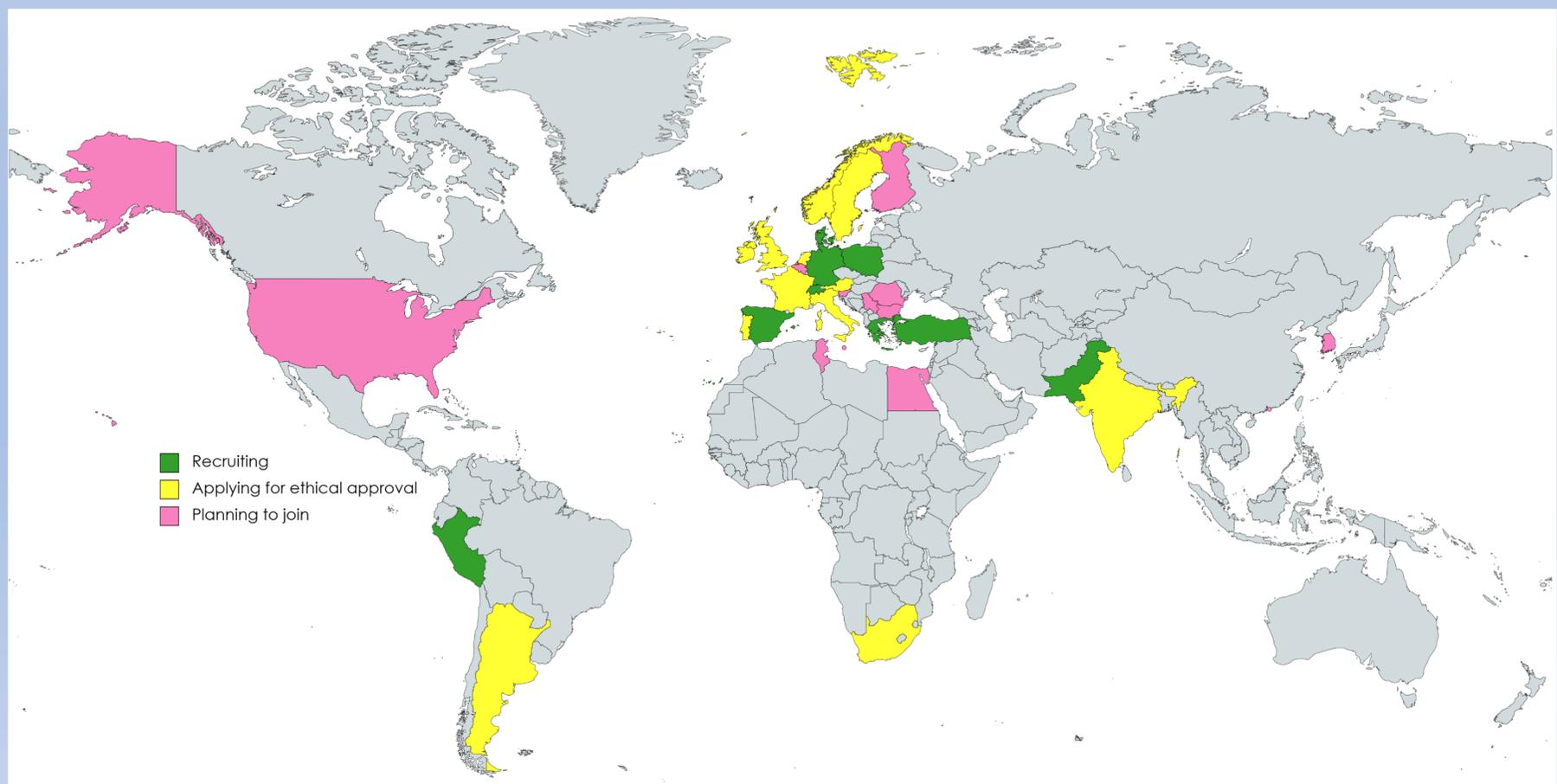
Dr. Ash Kothari
Prof. Dr. med. Michael Lux
Shelley Potter
Dr. Isabel Rubio
Prof. Marjolein Smidt

Prof. Dr. Walter Weber
Dr. Yazan Masannat
Prof. Dr. Nina Ditsch
PD Dr. Steffi Hartmann
PD Dr. Natalia Krawczyk

Enrollment status

Currently, 22 study sites are open in nine countries. We congratulate the National Steering Committees of the following countries, which enrolled at least one patient:

- **Turkey** (Prof. Neslihan Cabioglu & Prof. Zafer Canturk)
- **Poland** (Prof. Dawid Murawa, Dr. Justyna Jelinska)
- **Greece** (Prof. Michalis Kontos)
- **Germany** (Prof. Dr. Nina Ditsch, PD Dr. Steffi Hartmann, PD Dr. Natalia Krawczyk)
- **Pakistan** (Prof. Mah Muneer Khan, Dr. Irum Sabir Ali)
- **Spain** (Dr. Antonio Esgueva, Dr. Isabel Rubio)
- **Switzerland** (Dr. Maria Luisa Gasparri, Prof. Walter Weber)



MELODY Initiation presentation

The study sites are kindly asked to participate in an initiation presentation. The next international initiation presentation in English will take place on **30th November (Thursday) 2023 at 7 p.m. CET (Time Zone Berlin, Paris, Madrid, Rome) = 6 p.m. London** (please check your local time!)

Zoom link:

<https://us02web.zoom.us/j/85252105650?pwd=Zk5TSIZCdHkyQ2ZhaGVWVGxSGlCdz09>

You can also visit our website to see the recorded initiation videoconference (link: [EUBREAST Network – MELODY](#))

ASCO Annual Meeting 2023

The concept of the MELODY study has been presented at several national conferences and recently in the „Ongoing Trials“ session at the ASCO in June 2023. The video abstract can be watched at: [EUBREAST Network – MELODY](#)

Abstract #TPS626; ASCO Annual Meeting, June 2-6, 2023

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)

Study Lead: EUBREAST / IBRA-NET (Intergroup Study)

Study design: Prospective non-interventional multicenter cohort study (IIT)

Target accrual: 7,416 patients

Enrollment begin: January 2023

Financial support: Endomag, Merit Medical, Sirius Pintout and Hologic

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 developed 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. 2). 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.

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 on other outcome measures – Economic resources – MRI artifacts – Complication rates

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 one or more of the following imaging-guided localization techniques:
 - Wire-guided localization
 - Intraoperative ultrasound
 - Magnetic localization
 - Radioactive seed localization
 - Radio-guided Occult Lesion Localization (ROLL)
 - Radar localization
 - Radiofrequency identification (RFID) tag localization
 - IRK/Carbon localization

Fig. 2. Examples of different detection methods for breast lesions.

Fig. 3. Current state of international participation.

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Enrollment status

	Enrolled patients	Number of open study sites
Total	324	22
Denmark	0	1
Germany	59	2
Greece	7	1
Pakistan	1	1
Peru	0	1
Poland	50	1
Spain	1	1
Switzerland	1	3
Turkey	205	11

International MELODY Teams

Country	Heads (underlined) & Members of the National Steering Committee
Argentina	<u>Dra. Verónica Yamila Fabiano</u> , Laura Cosaka
Austria	<u>Prof. Florentia Peintinger</u> , Angelika Rief
Denmark	<u>Dr. Tove Filtenborg Tvedskov</u> , Dr. Lina Pankratjevaite, Dr. Panagiotis Pappas
France	<u>Dr Séverine Alran</u> , Dr Noémie Lotersztajn, Dr Marion Cortet, Dr Parwana Zarka, Dr Marie Rose El Bejjani, Dr Sophie Beranger
Germany	<u>Prof. Dr. Nina Ditsch</u> , PD Dr. Steffi Hartmann, PD Dr. Natalia Krawczyk
Greece	<u>Prof. Michalis Kontos</u>
India	<u>Prof. S.V.S. Deo</u>
Ireland	<u>Prof. Aoife Lowery</u>
Italy	<u>Dr. Rosa di Micco</u>
Pakistan	<u>Prof. Mah Muneer Khan</u> , Dr. Irum Sabir Ali
Peru	<u>Lía Pamela Rebaza, M.D.</u>
Poland	<u>Prof. Dawid Murawa</u> , Dr. Justyna Jelinska
Portugal	<u>Maria Antónia Vasconcelos, MD</u> , Dr. David Pinto
South Africa	<u>Dr Sarah Nietz & Dr Françoise Malherbe</u>
Spain	<u>Dr. Antonio Esgueva</u> , Dr. Isabel Rubio
Sweden	<u>Dr. Andreas Karakatsanis</u> , Prof. Dr. Jana de Boniface
Switzerland	<u>Dr. Maria Luisa Gasparri</u>
Turkey	<u>Prof. Neslihan Cabioglu & Prof. Nuh Zafer Canturk</u>
United Kingdom	<u>Dr Yazan Masannat</u>

IMPRESSUM

EUBREAST & IBRA-NET

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Financial support:
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