EUROPEAN BREAST CANCER RESEARCH ASSOCIATION OF SURGICAL TRIALISTS

International Prospective REgistry on PRe-PectorAl Breast Reconstruction

I-PREPARE EUBREAST-11R Newsletter n.1- March, 2025

Dear **I-PREPARE EUBREAST-11R** Collaborators,

It is a pleasure to send you our first monthly ***NEWSLETTER*** with the latest information about **the I-PREPARE EUBREAST-11R** study.

The first patient was recruited in Italy in *October 2023*. Since that time, 21 sites from 9 different countries have started recruiting, with a total of 271 patients currently enrolled in the study. We continue to activate and finalize contracts with new sites from around the world.

Please remember that you can start recruiting patients only after you have obtained written approval from your Ethics Committee/IRB and Authorization from your hospital. Once you have received these documents, please contact us directly so we can help you begin recruiting as rapidly as possible.

We would like to thank all centers who are recruiting as well as those who have expressed interest in participating!

Prof. Oreste Gentilini (Chairman) - Italy

Dr. Rosa Di Micco (Vice-Chairwoman) - Italy

Prof. Maria Luisa Gasparri (Treasurer) - Switzerland

You can find out more information about this study on the **EUBREAST website** by clicking on **THIS LINK**.

PRIMARY ENDPOINT

The **aim** of this observational trial is to evaluate the surgical and aesthetic results of breast reconstruction with pre-pectoral implants using different techniques in breast cancer patients (undergoing or not undergoing post-mastectomy radiation therapy). The **primary endpoint** is implant loss at three months after surgery, i.e. removal or loss of the prosthesis as a result of infection or other complications at three months after surgery.

Screening Phase

- Patients who are candidates for implant-based reconstruction should be informed about the possibility of participating in this clinical study. The inclusion and exclusion criteria will then be verified by the investigator and an informed consent should be obtained from the patient.

Surgery

- Data on surgery and neo-adiuvant treatments are collected.

Follow-up

- At 3, 6, 12, and 24 months, data on complications, flap thickness and recurrence are collected.

SECONDARY ENDPOINTS

Additional secondary endpoints are infection, re-admission and re-operation rates, subgroup analysis according to technique and device used, late-onset complication at 3-6-12-24 months, further surgery at 24 months, time to postoperative anti-cancer therapy and Quality of Life through BREAST-Q Breast Reconstruction Module questionnaires before and after breast reconstruction at 6,12, and 24 months;

Information on patients' **Quality of Life** will be collected before and after breast reconstruction at 6,12, and 24 months through a phone or tablet **APP** developed by **BRIGHTFISH/LOGEX Patient Engagement.**

Selected questionnaires: **BREAST-Q Vers. 2.0 Reconstruction Module** and **EQ-5D-5L**

(this part of the study is optional, so each center can choose whether to participate or not)

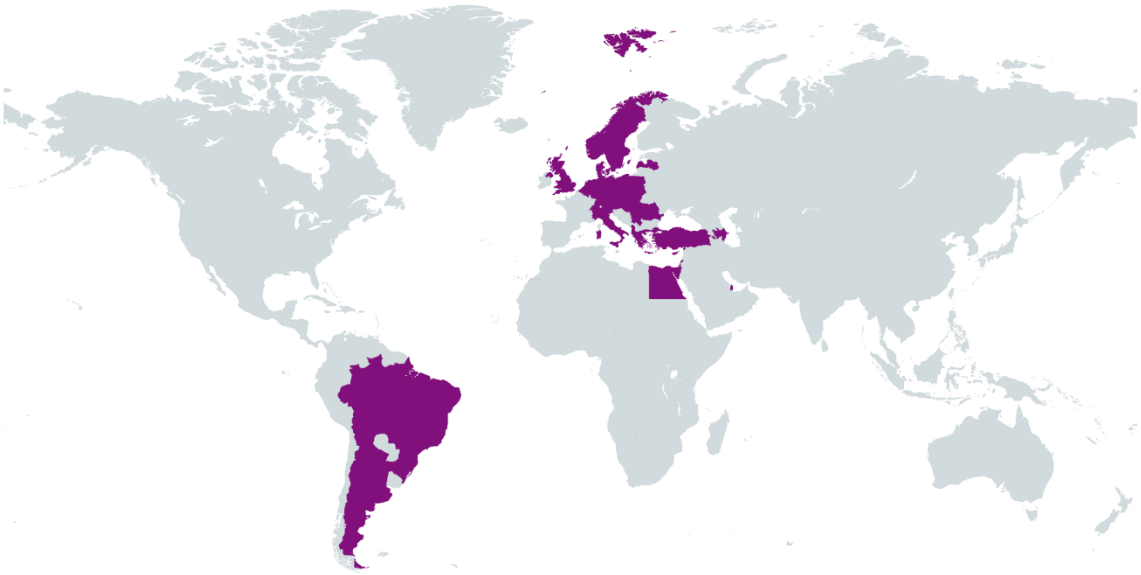
App registration process: the physician clicks on **THIS LINK** to fill out the form with the patient's ID, center name, and estimated date of surgery

➔ a **QR code** will be displayed. To log in the App, the patient needs to scan her QR code directly from the log in page of the App. The QR code serves as a **unique passcode** for the patient. The questionnaires will then directly appear in the App and the patient can fill them out.

RECRUITMENT STATUS

Currently, **271** patients have been enrolled out of a total sample size of **1236**.

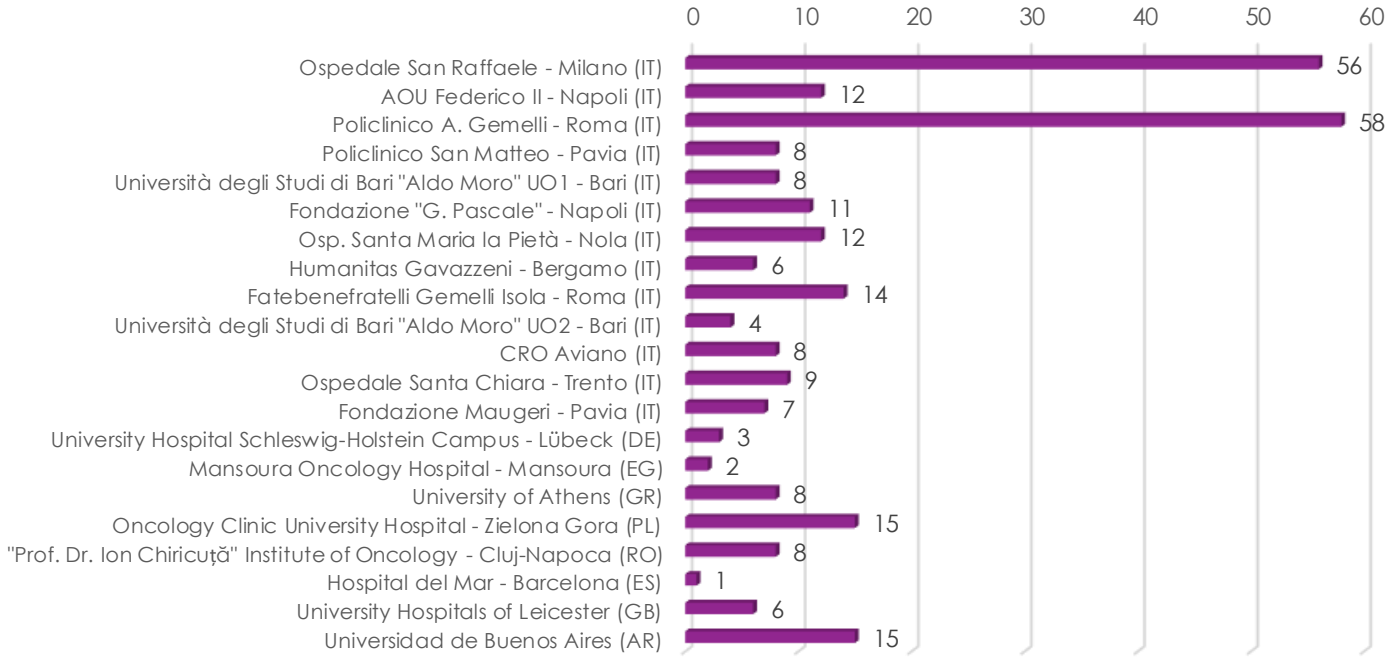
114 centers filled in the feasibility questionnaire to join the study



TOP RECRUITING CENTERS:

1. **Fondazione Policlinico Universitario Agostino Gemelli, Rome (Italy) –** 58 patients
2. **IRCCS Ospedale San Raffaele, Milan (Italy) –** 56 patients
3. **Universidad de Buenos Aires (Argentina) –** 15 patients
4. **Oncology Clinic University Hospital, Zielona Gora (Poland) –** 15 patients
5. **Fatebenefratelli - Gemelli Isola, Rome (Italy) –** 14 patients
6. **AOU Federico II, Naples (Italy) –** 12 patients
7. **Ospedale Santa Maria della Pietà, Nola (Italy) –** 12 patients

ACTIVE RECRUITING CENTERS



CONTACTS

For any clinical questions related to the Protocol:
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If you wish to represent your country and it is not listed, email: Sarah Jennie Goldman, goldman@eubreast.com

For any questions related to the CRF and documents about the study:
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