



## **MEthods for Localization of Different types of breast lesions**

-EUBREAST 4-  
NCT 05559411

A prospective non-interventional multicenter cohort study to evaluate different imaging– guided methods for localization of malignant breast lesions

### **Frequently Asked Questions (FAQ)**

	Question	Answer
07.03.2024	Does the question of whether the axilla was operated on refer only to the first surgery or in general? (CRF 6)	All questions in CRF 6 relate to the first surgery
28.03.2024	If a patient has a finding on the left side (for example, an invasive cancer) but no finding on the right, is it necessary to fill out other questions about the right breast other than the stage (history of previous BC, irradiation and additional lesions)?	No. If "none" is entered for "Right side", all subsequent questions on the right side in CRF1 can be left blank. We want to limit the effort for the participating sites.
08.04.2024	Which date should be entered for "Age at time of first surgery" if the operation in neoadjuvant is in the future and cannot yet be answered? (CRF 1)	Please enter the age at time of study enrollment.
08.04.2024	Which ethnicity classification should be used, if the study site is in the European Union (UK or US)?	You can use either one. An official classification does not exist in the EU. The information on the ethnicity is optional.
17.03.2025	Can patients of the MELODY trial be co-enrolled for the LOLIPOP trial.	Yes, participation in both trials is possible.  If you are planning co-enrolment for any other study please get in touch with the MELODY team.
07.04.2025	When must the CRF "8 End of Observation" be completed?	CRF 8 is only completed in case of premature exclusion from the study. (e.g. withdrawal of informed consent, drop-out, death).

07.04.2025	Is it necessary to create two records for a patient with two lesions?	No, you can add additional CRF pages (CRF2-CRF8) in RedCap. Therefor, you can first click on the Record ID, afterwards you chose "+Add new" above the Breast lesion (group).
07.04.2025	Is it necessary to create two records for a patient with bilateral breast cancer?	No, you can fill enter both sites in one Record and add additional CRFs for the breast lesions groups.
14.07.2025	Patient with radioactive seed guided removal of primary breast cancer in ectopic breast tissue in the axilla. I am not sure this patient can be included due to not having a "classic BCS"?	No, the lesion should be in the breast
14.07.2025	Patient having a local recurrence removed by radioactive seed guided BCS. The patient had IORT at first surgery and were accordingly still eligible for BCS. Is only primary breast cancer included?	Recurrences are also allowed

In case of further questions please contact [melody@eubreast.com](mailto:melody@eubreast.com)