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, it 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.
16.07.2024	Is the intraoperative US-guided skin marking to the lesion performed in the operatiing room prior to skin incision included in the independent localizaion method?	If you perform skin marking immediately before start of surgery in the operating room and then use ultrasound to visualize the tumor during surgery, then „Intraoperative ultrasound“ should be chosen as localization technique. Using preoperative skin marking alone without any additional techniques is discouraged becase it is not reliable enough.
17.03.2025	Can patients of the MELODY trial be co-enroled 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. Therefore, 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
08.01.2026	In CRF 8 of the Melody Study, under “in situ component” (see below), does it ask only about DCIS or also about LCIS?	DCIS
30.09.2026	On the CRF 2 form it says that lesions to be removed in one specimen should be documented as one lesion. We sometimes do quite large oncoplastic surgeries that remove multiple lesions as one specimen. How would I document a situation where the specimen contains multiple lesions where some are palpable and some are not? How about if the	In this case document the middle location (e.g. if the tumors are between 1 and 5 hours you can document 3 hours). In case of different histopathologies, please document the most aggressive subtype.

	histopathology of these lesions is different, which histopathology do I document? Same thing applies for reporting the location of the lesion, if the lesions are in vastly different areas of the breast, how do I document this if the lesions are removed as one specimen even though they are far apart?	
07.11.2026	Is pleomorphic LCIS an eligible diagnosis for the MELODY study?	No. Patients with pleomorphic LCIS are not eligible for inclusion in the MELODY study.
07.11.2026	In CRF 6, which answer should be selected for the question on distinguishing markers if one biopsy clip and one Sirius marker were placed in the same breast?	The question refers only to markers suitable for probe-guided detection (e.g. Sirius markers), not to conventional biopsy clips. If one biopsy clip and one probe-detectable marker were placed, 'not applicable' is the correct answer. 'Yes' or 'no' should only be selected if more than one probe-detectable marker was placed in the breast or axilla.

In case of additional questions please contact melody@eubreast.com