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

eCRF USER MANUAL

For Remote Monitoring
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## 1. Responsibility

<table>
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2. Remote Monitoring – Technical aspects

This User Manual describes how to generate queries, check the eCRF and lock the eCRF after ensuring it is complete.

2.1.
Open the eCRF at:

https://eubreast-melody.com

2.2.
Log in with your own username and password provided to you via e-mail.
2.3.

Click on „My Projects“ and afterwards select „MELODY V1.0“.

2.4.

Choose „Record Status Dashboard“.
2.5.

This will open the list of all patients. On the left side you can see the Record IDs, next to them the Patient IDs and on the right side the CRF forms. Keep in mind that the Record ID is generated by the RedCap. The Patient ID is the ID used in MELODY for pseudonymization.

2.6.

Select one patient by clicking on the Record ID. Now you can see all CRF forms of this patient. Please select the form you would like to review by clicking on the highlighted button in the screenshot below. Keep in mind that only CRF forms highlighted in green are ready for monitoring. The red color means the study site is still working on the CRF form.
2.7.

The information contained in the form you choose is now displayed.

2.8.

If required, you can create queries to each individual field in the eCRF. To do so, please click on the bubble which is displayed next to each field to open the so-called „Data Resolution Workflow“.
2.9.

After opening the “Data Resolution Workflow” you will see the field the comment is connected to. Please add the query text in the field “Comment”. Please click on “open query”. Select yourself as user so that you can filter your queries more easily.

2.10.

Please set the CRF form into “Unverified”, so that the site can see that an answer to the query is required. You find the respective field at the bottom of the page.
2.11.
The required CRF form is now highlighted as yellow.

Record Status Dashboard
2.12.

You can see all queries added in the field “Resolve Issues”. This does also apply if the site has answered your query. To see all queries, comments, and answers, please click on “Resolve Issues” (No. 1 highlighted in the screenshot below) and then choose the comment you would like to see (No. 2).

2.13.

Open unanswered queries are highlighted in red (1) next to the speech bubble. All answered and verified queries are green (2).

2.14.

If necessary, you can answer to the comment. Upon clicking on the speech bubble, all comments will be displayed in chronological order. If you would like to comment on the answer to your query, please add it in the field “Comment”. You can give a response if you want to. Please close the query if everything is clear.
2.15.

Once all queries have been answered successfully and you regard the CRF form as complete and conclusive, please set the form into “Complete”. You find the respective field at the bottom of the page.
2.16.

Now lock the page. The respective field is located at the bottom of the page.

2.17.

To see all CRF forms with “Locks” and without “Locks”, choose “All status types”.

![Image of CRF forms with Lock status selection]

Displaying: Instrument status only | Lock status only

All status types
2.18.

If you would like to see only the queries you generated, choose your login in the field “User assigned (all users) or not assigned”. You can also filter the queries so that you see open queries (“unresolved issues”) only.

2.19.

Once you are finished, you can log out from the system.
3. Remote Monitoring – Aspects of content

Fields marked as “must provide value” are mandatory. In case of missing data in one of those fields a query should be generated.

Please also check the correct formatting of the patient ID (Country code – Site ID – consecutive patient number). If this is not correct, a query should be generated.

In case inclusion / exclusion criteria are not fulfilled (CRF1) use CRF End of Observation.

Plausibility checks should be performed for all mandatory data also across the individual CRF pages.