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

<u>eCRF USER MANUAL</u>
for Study Sites

1.

Each study site staff member receives his/her own login and password. In order to receive login credentials, fill in the Signature & Delegation Log (available at http://melody.eubreast.com and follow the instructions at the bottom of page 1. Each study site staff member will receive an e-mail with login information separately.

2.

Open the eCRF at:

https://eubreast-melody.com

3.

Log In

Welcome to the eCRF-platform of the EUBREAST network.

Please log in with your user name and password. If you are having trouble logging in, please contact EUBREAST Support.

Username:	
Password:	

Log In   Forgot your password?

Log in using your personal username and password.

4.

Now you can see the list of open projects. Choose MELODY.

5.

Choose "Add / Edit Records" to add a new patient or to continue documentation of an existing one.

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6.

To add a new patient, choose "Add new record".

MELODY V1.0 PID 46

📄 **Add / Edit Records**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

Total records: **8** / In group: **1**	
Choose an existing Record ID	-- select record -- ⌄
	+ Add new record

Data Search	
Choose a field to search (excludes multiple choice fields)	All fields ⌄
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	

7.

A new patient has been created.

Please keep in mind that the Record ID (in our example: 1101-2) is a record number created by RedCap and it is not the Patient-ID!

NEW Record ID **1101-2**

Data Collection Instrument	Study entry	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	◉				
CRF 2 Breast Lesion Group		◉			
CRF 3		◉			
CRF 4 Marker placement		◉			
CRF 5 Preoperative wire placement		◉			
CRF 6 Surgery		◉			
CRF 7 Intraoperative localization		◉			
CRF 8 Postoperative histopathology after first surgery		◉			
CRF 9 Postoperative histopathology of all lesions after first surgery			◉		
End of Observation				◉	
PRO German (survey)					◉

8.

Now you can see all CRF forms of your patient.

NEW Record ID **1101-2**

Data Collection Instrument	Study entry	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	○				
CRF 2 Breast Lesion Group		○			
CRF 3		○			
CRF 4 Marker placement		○			
CRF 5 Preoperative wire placement		○			
CRF 6 Surgery		○			
CRF 7 Intraoperative localization		○			
CRF 8 Postoperative histopathology after first surgery		○			
CRF 9 Postoperative histopathology of all lesions after first surgery			○		
End of Observation				○	
PRO German (survey)					○

9.

Choose the form you would like to open.

NEW Record ID **1101-2**

Data Collection Instrument	Study entry	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	○				
CRF 2 Breast Lesion Group		○			
CRF 3		○			
CRF 4 Marker placement		○			
CRF 5 Preoperative wire placement		○			
CRF 6 Surgery		○			
CRF 7 Intraoperative localization		○			
CRF 8 Postoperative histopathology after first surgery		○			
CRF 9 Postoperative histopathology of all lesions after first surgery			○		
End of Observation				○	
PRO German (survey)					○

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Note: The "Add new" button, which allows for the addition of further breast lesions or breast lesion groups, can be activated once at least one CRF form within the first lesion group has been added.

Data Collection Instrument	Study entry	+ Add new Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	🟢				
CRF 2 Breast Lesion Group		🟢			
CRF 3		🟢			
CRF 4 Marker placement		🟢			
CRF 5 Preoperative wire placement		🟢			
CRF 6 Surgery		🟢			
CRF 7 Intraoperative localization		🟢			
CRF 8 Postoperative histopathology after first surgery		🟢			
CRF 9 Postoperative histopathology of all lesions after first surgery			🟢		
End of Observation				⚪	
PRO German (survey)					⚪

10.

Fill in the CRF form. Fields marked as "must provide value" are mandatory.

📄 **CRF 1 Study entry**

⊕ Adding new Record ID **1101-2**.	
Event: **Study entry**	
Record ID	1101-2
CRF 1 Study entry	

Patient ID
* must provide value

（_ _-_ _ _-_ _ _) country-site-patient

Signed written informed consent
* must provide value

○ yes
○ no
reset

Sex
* must provide value

○ female
○ male
reset

Age at time of first surgery
* must provide value

(in years)

Height
* must provide value

(in cm)

Weight
* must provide value

(in kg)

Pregnancy at time of surgery
* must provide value

○ yes
○ no
reset

11.

Do not forget to enter Patient-ID that you created according to the instructions in the Subject & Identification Log (Country code – Site ID – consecutive patient number).

12.

If some information required in this CRF form are missing at the time, choose "Incomplete" at the bottom of the page.

Form Status

Complete? Incomplete ▼

Incomplete
Unverified
Complete

– Cancel –

Now the CRF page is red ("Incomplete"):

Data Collection Instrument	Study entry
CRF 1 Study entry	●
CRF 2 Breast Lesion Group	
CRF 3	
CRF 4 Marker placement	
CRF 5 Preoperative wire placement	
CRF 6 Surgery	
CRF 7 Intraoperative localization	
CRF 8 Postoperative histopathology after first surgery	
CRF 9 Postoperative histopathology of all lesions after first surgery	
End of Observation	
PRO German (survey)	

13.

Once you have finished, choose "Complete".

Form Status	
Complete?	Ⓗ 💬 Complete ▾

Incomplete
Unverified
Complete

[rm] [Save & ... ▾]

– Cancel –

Now the CRF page is green:

		+ Add new
Data Collection Instrument	**Study entry**	**Breast lesion (group)**
CRF 1 Study entry	🟢	
CRF 2 Breast Lesion Group		🟢
CRF 3		🟢
CRF 4 Marker placement		🟢
CRF 5 Preoperative wire placement		🟢
CRF 6 Surgery		🟢
CRF 7 Intraoperative localization		🟢
CRF 8 Postoperative histopathology after first surgery		🟢
CRF 9 Postoperative histopathology of all lesions after first surgery		
End of Observation		
PRO German (survey)		

14.

Patient Reported Outcomes are part of the MELODY study. The patient can either complete the questionnaire online or use printed forms.

Patient Questionnaire OPTION 1 (less time-consuming for Study Sites):

Choose Patient Reported Outcomes (PRO) in your local language:

Data Collection Instrument	Study entry	**+ Add new** Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	●				
CRF 2 Breast Lesion Group		●			
CRF 3		●			
CRF 4 Marker placement		●			
CRF 5 Preoperative wire placement		●			
CRF 6 Surgery		●			
CRF 7 Intraoperative localization		●			
CRF 8 Postoperative histopathology after first surgery		●			
CRF 9 Postoperative histopathology of all lesions after first surgery			●		
End of Observation				◉	
PRO German (survey)					◉

Choose "Survey options":

PRO German

Invitation status: ✉ [📄 Survey options ▽]

🖉 Editing existing Record ID **1101-1**. (Patient ID **DE-064-002**)

Event: **Patient Questionnaire**

Record ID	1101-1

Liebe Patientin, lieber Patient,
Im Rahmen Ihrer Teilnahme an der MELODY-Studie bitten wir Sie, eine Reihe von Fragen zu Ihrem Befinden und möglichen Beschwerden in Bezug auf Ihre Brustoperation zu beantworten.

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Choose "Survey Access Code & QR Code:
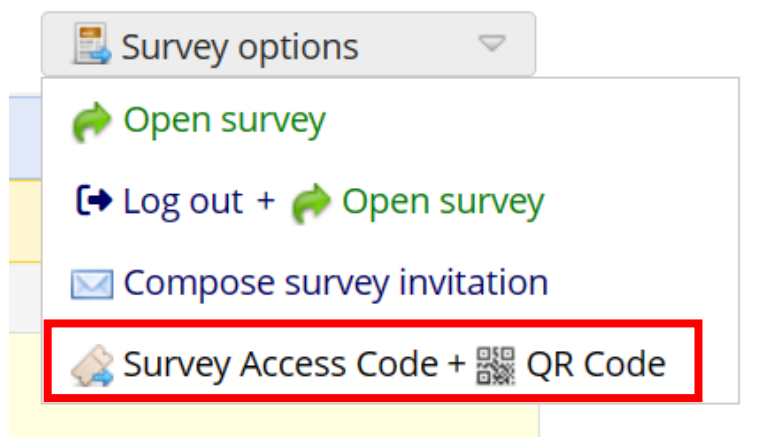
The personal link and QR Code appear. Please choose "Print for Respondent":

Now give the printed page to the patient and ask her to complete the questionnaire after the surgery. All answers will appear directly in the eCRF.

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Patient Questionnaire OPTION 2 (more time-consuming for Study Sites):

Print the Patient Questionnaire in your local language (available at
http://melody.eubreast.com) and give it to the patient. Please inform the patient that the
questionnaire should be completed after the surgery. Once the questionnaire has been
completed, transfer all answers to the eCRF:

First, choose Patient Reported Outcomes (PRO) in your local language:

Data Collection Instrument	Study entry	+ Add new Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	●				
CRF 2 Breast Lesion Group		●			
CRF 3		●			
CRF 4 Marker placement		●			
CRF 5 Preoperative wire placement		●			
CRF 6 Surgery		●			
CRF 7 Intraoperative localization		●			
CRF 8 Postoperative histopathology after first surgery		●			
CRF 9 Postoperative histopathology of all lesions after first surgery			●		
End of Observation				○	
PRO German (survey)					○

Now, transfer all answers to the eCRF:

Actions: 📄 Download PDF of instrument(s) ▽   🎞 Video: Basic data entry

Save & ... ▾
– Cancel –

📋 **PRO German**

Invitation status: ✉   🗒 Survey options ▽

🖊 Editing existing Record ID **1101-1**. (Patient ID **DE-064-002**)	
Event: **Patient Questionnaire**	
Record ID	1101-1

Liebe Patientin, lieber Patient,
Im Rahmen Ihrer Teilnahme an der MELODY-Studie bitten wir Sie, eine Reihe von Fragen
zu Ihrem Befinden und möglichen Beschwerden in Bezug auf Ihre Brustoperation zu
beantworten.

Bitte versuchen Sie nicht, "richtige" oder "falsche" Antworten zu finden, sondern geben Sie
die Antwort an, die am besten zu Ihnen passt. Bitte beantworten Sie die Fragen, ohne sie mit
anderen zu besprechen und versuchen Sie keine Fragen unbeantwortet zu lassen, da sie
alle gleich wichtig sind. Ihre Antworten werden stets vertraulich gehandelt.
Bitte geben Sie diesen Fragebogen Ihrer Ärztin / Ihrem Arzt oder einem Studienkoordinator
nach der Operation zurück.

Vielen Dank für Ihre Teilnahme!

Datum der Operation
* must provide value

Ⓗ 💬   [＿＿＿＿] 📅 [Today] D-M-Y

Wurde ein Draht, Marker oder Farbstoff in Ihre Brust gelegt, um den Tumor für die
Operation zu lokalisieren?

JA → denken Sie an die Zeit nach dieser Prozedur, wenn Sie die Fragen 1-10
beantworten

15.

Now you can see the status of all forms. Locked forms have already been checked by monitors. If you wish to edit them again send an e-mail to: melody@eubreast.com

Data Collection Instrument	Study entry	+ Add new Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	🟢🔒				
CRF 2 Breast Lesion Group		🟢			
CRF 3		🟢			
CRF 4 Marker placement		🟢			
CRF 5 Preoperative wire placement		🟢			
CRF 6 Surgery		🟢			
CRF 7 Intraoperative localization		🟢			
CRF 8 Postoperative histopathology after first surgery		🟢			
CRF 9 Postoperative histopathology of all lesions after first surgery			🟢		
End of Observation				⚪	
PRO German (survey)					⚪

16.

You can see all patients recruited at your Study Site by choosing "Record Status Dashboard".
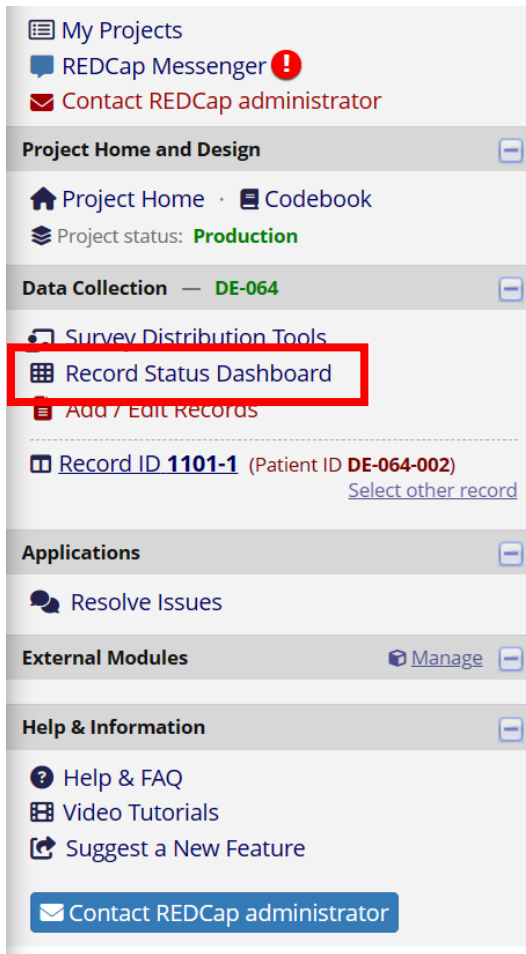
17.

In case of inconclusive or missing data, you might receive a query from one of the Monitors. Forms with open queries are shown as yellow.

18.

The fields in the CRF form for which a query has been generated have a small speech bubble sign with an exlamation mark next to them.You can click on the sign to see the query.

19.

Once you clicked on the speech bubble, the query will appear:

20.

Now you can reply and comment the query. Afterwards, click on "Respond to query".

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21.

Once you have responded to the query, the status of the speech bubble changes.

Location or quadrant	
Location:	10 o'clock
or quadrant:	◉ upper outer ○ upper inner ○ lower outer ○ lower inner ○ central reset

IMPORTANT: Do not change the status of the CRF form. It should remain "Unverified" until the monitor has closed the query. Once the query has been closed by the monitor, the status of the CRF form will be changed to "Complete" (green) and the form will be locked.

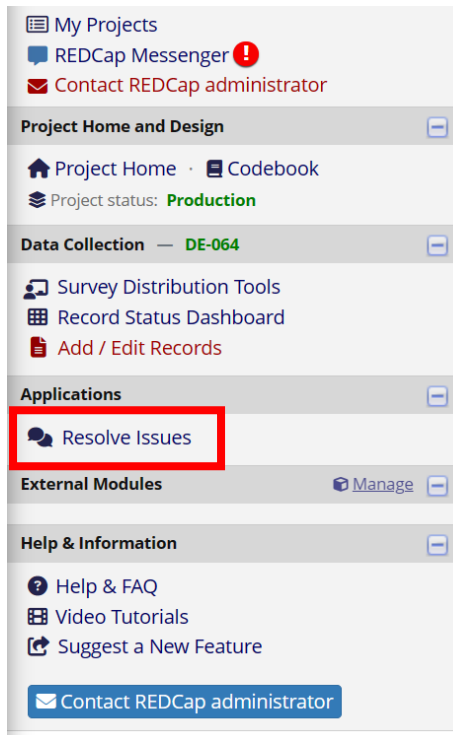| Form Status	
Complete?	Unverified ▾
	Incomplete
	Unverified
	Complete
	Save & ...
	– Cancel –

22.

Next to questions with resolved queries you will see a speech bubble with a green "tick" mark.

Location or quadrant	
Location:	9 o'clock
or quadrant:	◉ upper outer ○ upper inner ○ lower outer ○ lower inner ○ central

23.

To see all queries/comments, click on "Resolve Issues".

Now click on the query/comment you would like to see (No. 1). To see the CRF form the query refers to click on the Record Number (No. 2).

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24.

Once you are finished, you can log out.

**In case of questions concerning the use of eCRF, you can contact
melody@eubreast.com.**