



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 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.

Welcome to the eCRF-platform of the EUBREAST network.
Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#)

Project Title	Records	Fields	Instruments	Type	Status
AXSANA			16 forms		✓
MELODY V1.0			10 forms 4 surveys		✓

5.

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

Project Home

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Project Statistics	
Records in project	Total: 8 / In group: 1
Most recent activity	08-04-2023 20:16
Space usage for docs	0.00 MB



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	<input type="radio"/>				
CRF 2 Breast Lesion Group		<input type="radio"/>			
CRF 3		<input type="radio"/>			
CRF 4 Marker placement		<input type="radio"/>			
CRF 5 Preoperative wire placement		<input type="radio"/>			
CRF 6 Surgery		<input type="radio"/>			
CRF 7 Intraoperative localization		<input type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input type="radio"/>		
End of Observation				<input type="radio"/>	
PRO German <small>(survey)</small>					<input type="radio"/>

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	<input type="radio"/>				
CRF 2 Breast Lesion Group		<input type="radio"/>			
CRF 3		<input type="radio"/>			
CRF 4 Marker placement		<input type="radio"/>			
CRF 5 Preoperative wire placement		<input type="radio"/>			
CRF 6 Surgery		<input type="radio"/>			
CRF 7 Intraoperative localization		<input type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input type="radio"/>		
End of Observation				<input type="radio"/>	
PRO German (survey)					<input type="radio"/>

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	<input checked="" type="radio"/>				
CRF 2 Breast Lesion Group		<input type="radio"/>			
CRF 3		<input type="radio"/>			
CRF 4 Marker placement		<input type="radio"/>			
CRF 5 Preoperative wire placement		<input type="radio"/>			
CRF 6 Surgery		<input type="radio"/>			
CRF 7 Intraoperative localization		<input type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input type="radio"/>		
End of Observation				<input type="radio"/>	
PRO German (survey)					<input type="radio"/>


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	<input checked="" type="radio"/>				
CRF 2 Breast Lesion Group		<input checked="" type="radio"/>			
CRF 3		<input checked="" type="radio"/>			
CRF 4 Marker placement		<input checked="" type="radio"/>			
CRF 5 Preoperative wire placement		<input checked="" type="radio"/>			
CRF 6 Surgery		<input checked="" type="radio"/>			
CRF 7 Intraoperative localization		<input checked="" type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input checked="" type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input checked="" type="radio"/>		
End of Observation				<input type="radio"/>	
PRO German (survey)					<input type="radio"/>

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).

CRF 1 Study entry


+ Adding new Record ID 1101-2.	
Event: Study entry	
Record ID	1101-2
CRF 1 Study entry	
Patient ID <small>* must provide value</small>	<input type="text"/> <small>(_ - _ - _ - _) country-site-patient</small>
Signed written informed consent <small>* must provide value</small>	<input type="radio"/> yes <input type="radio"/> no <small>reset</small>
Sex <small>* must provide value</small>	<input type="radio"/> female <input type="radio"/> male <small>reset</small>
Age at time of first surgery <small>* must provide value</small>	<input type="text"/> <small>(in years)</small>
Height <small>* must provide value</small>	<input type="text"/> <small>(in cm)</small>
Weight <small>* must provide value</small>	<input type="text"/> <small>(in kg)</small>
Pregnancy at time of surgery <small>* must provide value</small>	<input type="radio"/> yes <input type="radio"/> no <small>reset</small>

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?	<div> <div>Incomplete ▾</div> <div> Incomplete Unverified Complete </div> </div> <div> <div>- Cancel -</div> <div>Save & ... ▾</div> </div>

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:

Data Collection Instrument	Study entry	Breast lesion (group)
CRF 1 Study entry	<input checked="" type="radio"/>	
CRF 2 Breast Lesion Group		<input checked="" type="radio"/>
CRF 3		<input checked="" type="radio"/>
CRF 4 Marker placement		<input checked="" type="radio"/>
CRF 5 Preoperative wire placement		<input checked="" type="radio"/>
CRF 6 Surgery		<input checked="" type="radio"/>
CRF 7 Intraoperative localization		<input checked="" type="radio"/>
CRF 8 Postoperative histopathology after first surgery		<input checked="" type="radio"/>
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	<input checked="" type="radio"/>				
CRF 2 Breast Lesion Group		<input checked="" type="radio"/>			
CRF 3		<input checked="" type="radio"/>			
CRF 4 Marker placement		<input checked="" type="radio"/>			
CRF 5 Preoperative wire placement		<input checked="" type="radio"/>			
CRF 6 Surgery		<input checked="" type="radio"/>			
CRF 7 Intraoperative localization		<input checked="" type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input checked="" type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input checked="" type="radio"/>		
End of Observation				<input checked="" type="radio"/>	
PRO German (survey)					<input checked="" type="radio"/>

Choose "Survey options":

 **PRO German**

Invitation status: 

 Survey options 

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

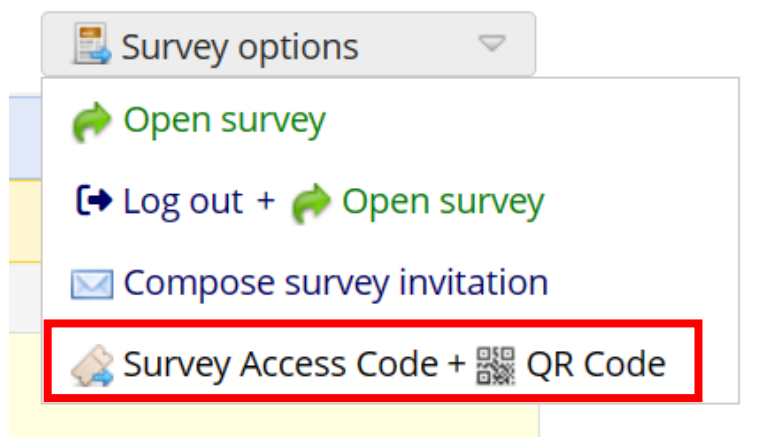
Event: **Patient Questionnaire**

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.

Choose "Survey Access Code & QR Code":




The personal link and QR Code appear. Please choose "Print for Respondent":


Survey Access Code or  QR Code
✕

Survey title: **"PRO German"**

A Survey Access Code and a QR Code both allow respondents to begin a survey on another computer or device without someone having to email them an invitation. This is especially useful if the respondent is currently nearby or if you will be sending the survey invitation to a physical mailing address (i.e. 'snail mail'). You may click the Print button at the bottom if you wish to print out the instructions for the respondent.


Enter the Survey Access Code

To allow a respondent to begin this survey, have them navigate to the URL below and enter the survey access code. The code is permanent and will never change. (Note: The web address is the same for all projects and surveys, so you may bookmark the address on a computer or device to quickly return to it multiple times.)


1.) Go to this web address:

https://eubreast-axsana.com/redcap/surveys/


2.) Then enter this code:

K9R3FMH3M


OR


Generate Short Code

Alternatively, you may generate a shorter, temporary code that will expire after


Scan the QR Code

The survey link has been converted into a QR code, which can now be scanned by a device that has an app capable of reading QR codes. Once the QR code below is scanned, it should take the respondent directly to the survey in a web browser.



Print for Respondent
Close

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.



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	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
CRF 1 Study entry	<input checked="" type="radio"/>				
CRF 2 Breast Lesion Group		<input checked="" type="radio"/>			
CRF 3		<input checked="" type="radio"/>			
CRF 4 Marker placement		<input checked="" type="radio"/>			
CRF 5 Preoperative wire placement		<input checked="" type="radio"/>			
CRF 6 Surgery		<input checked="" type="radio"/>			
CRF 7 Intraoperative localization		<input checked="" type="radio"/>			
CRF 8 Postoperative histopathology after first surgery		<input checked="" type="radio"/>			
CRF 9 Postoperative histopathology of all lesions after first surgery			<input checked="" type="radio"/>		
End of Observation				<input checked="" type="radio"/>	
PRO German (survey)					<input checked="" type="radio"/>



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
<p>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.</p> <p>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.</p> <p>Vielen Dank für Ihre Teilnahme!</p>	
<p>Datum der Operation <input type="text"/> Today D-M-Y</p> <p><small>* must provide value</small></p>	
<p>Wurde ein Draht, Marker oder Farbstoff in Ihre Brust gelegt, um den Tumor für die Operation zu lokalisieren?</p> <p>JA → denken Sie an die Zeit nach dieser Prozedur, wenn Sie die Fragen 1-10 beantworten</p>	

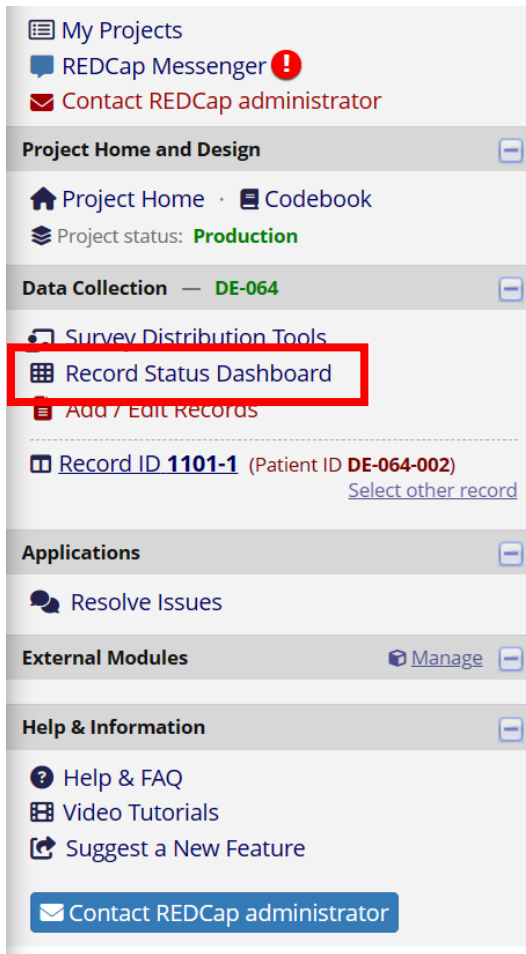
15.

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	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.

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)					

18.

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

Side:

☐ left
☒ right

* must provide value

reset

Location or quadrant

Location:

o'clock

or quadrant:

☐ upper outer
☒ upper inner
☐ lower outer
☐ lower inner
☐ central

19.

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

Data Resolution Workflow
✕

[VIDEO: Data Resolution Workflow](#)

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Record ID: **1101-1**
 Event: **Breast lesion (group)**
 Field: **crf2_quadrant** ("or quadrant:")
 Status: 🗨️ **Open / Unresolved** (unresponded)

Date/Time	User	Comments and Details
07-26-2023 08:40		Data Changes Made: crf2_quadrant = 'upper outer (1)'
08-04-2023 19:54	banys	Action: Opened query Comment: "10 o'clock but upper inner quadrant of the right breast? Please check the localization."
08-04-2023 19:54	banys	Data Changes Made: crf2_quadrant = 'upper inner (2)'
08-04-2023 19:56		Reply with response: -- choose response -- Upload file (optional): ➕ Upload file Comment: <div style="border: 1px solid #add8e6; height: 30px; width: 100%;"></div>

Respond to query
Cancel

20.

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



Reply with response: -- choose response --
 Upload file (optional): -- choose response --
 Comment:

-- choose response --
 Corrected - Data missing
 Corrected - Typographical error
 Corrected - Wrong source used
 Verified - Confirmed correct (no error)
 Other


Respond to query
Cancel

21.

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



Location or quadrant	
Location:	<input type="text" value="10"/>  o'clock
or quadrant:	<div> <input checked="" type="radio"/> upper outer <input type="radio"/> upper inner <input type="radio"/> lower outer <input type="radio"/> lower inner <input type="radio"/> central </div> 
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?	<div>  <div> Unverified <div> Incomplete Unverified Complete </div> </div> </div>
<div> <div>rm</div> <div>Save & ...</div> <div>- Cancel -</div> </div>	

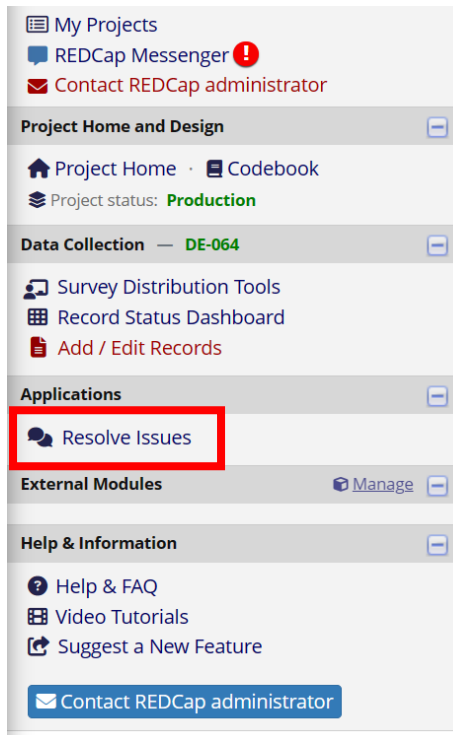
22.

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

Location or quadrant	
Location:	<input type="text" value="9"/>  o'clock
or quadrant:	<div> <input checked="" type="radio"/> upper outer <input type="radio"/> upper inner <input type="radio"/> lower outer <input type="radio"/> lower inner <input type="radio"/> central </div> 

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).

Data Resolution Dashboard						
<div> <div>Export</div> <div> <div>1</div> <div>Click button to view data query</div> </div> </div>		<div>Filters:</div> <div> <div>All status types (1)</div> <div>All fields and rules</div> <div>All events</div> <div>User assigned (all users) or not assigned</div> </div>				
	Record	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
<div> <div>2</div> <div>3 comments</div> </div>	<div>1101-1</div> <div>(#1) (Patient ID D Breast lesion (group))</div>	Field: crf2_quadrant (or quadrant:)	-	0	<div>banys (08-04-2023 19:54):</div> <div>"10 o'clock but upper inner quadrant of the right breast? Please check the localization."</div>	<div>banys (08-04-2023 20:15):</div> <div>"ok"</div>

24.

Once you are finished, you can log out.



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