



**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

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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.



#### 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?](#)

---

## 2.3.

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

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](#)

**My Projects** [Organize](#) [Collapse All](#)

Project Title	Records	Fields	Instruments	Type	Status
AXSANA	4943	492	16 forms		✓
MELODY V1.0	103	660	20 forms 1 survey		✓
MELODY V1.0	321	643	10 forms 8 surveys		✓

☐ Show Completed Projects

## 2.4.

Choose „Record Status Dashboard“.

**REDcap** EUBREAST

MELODY V1.0 PID 46

[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	322
Most recent activity	11-22-2023 09:09
Usage for docs	0.25 MB

**Record Status Dashboard**

[The REDCap Consortium](#) | [Citing REDCap](#)

REDcap 13.4.10 - © 2023 Vanderbilt University

## 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.

The screenshot shows the REDCap Record Status Dashboard. On the left is a sidebar with navigation options. The main area displays a table of records. The table has columns for Record ID, Patient ID, and various CRF forms. The CRF forms are grouped under 'Breast lesion (group)' and include 'All lesions', 'End of Observation', and 'Patient Questionnaire'. The table shows records for Patient ID DE-064-001 through DE-064-009. The 'Study entry' column shows a red dot for the first record, indicating it is still working on.

Record ID	Study entry	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire
1 (Patient ID DE-064-001)	●				
1101-1 (Patient ID DE-064-002)	●				
1101-2 (Patient ID DE-064-003)	●				
1101-3 (Patient ID DE-064-004)	●				
1101-4 (Patient ID DE-064-005)	●				
1101-5 (Patient ID DE-064-006)	●				
1101-6 (Patient ID DE-064-007)	●				
1101-7 (Patient ID DE-064-008)	●				
1101-8 (Patient ID DE-064-009)	●				


## 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.

The screenshot shows the REDCap Record Detail page for Record ID 1142-1 (Patient ID PK-001-001). The page displays a list of CRF forms and their status. The 'Study entry' column shows a green dot for the first record, indicating it is ready for monitoring. The 'Breast lesion (group)' column shows a green dot for the first record, indicating it is ready for monitoring. The 'All lesions' column shows a green dot for the first record, indicating it is ready for monitoring. The 'End of Observation' column shows a green dot for the first record, indicating it is ready for monitoring. The 'Patient Questionnaire' column shows a green dot for the first record, indicating it is ready for monitoring.

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)					●
PRO Polish (survey)					●
PRO Turkish (survey)					●
PRO Spanish (survey)					●

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



Logged in as **hartmannmonitor**  
 Log out

My Projects

REDCap Messenger 1

Contact REDCap administrator

**Project Home and Design**

Project Home · Codebook

Project status: Production

**Data Collection**

Survey Distribution Tools

Record Status Dashboard

Add / Edit Records

**Record ID 1101-21** (Patient ID DE-064-021)  
[Select other record](#)

Event: Study entry

Data Collection Instruments:

CRF 1 Study entry

Lock entire record

**Applications**

Data Exports, Reports, and Stats

Customize & Manage Locking/E-signatures

Resolve Issues

**External Modules** Manage

EUBReaST

**MELODY V1.0**
PID 46

Actions: Download PDF of instrument(s)
Video: [Basic data entry](#)

Save & Exit Form  
Save & ...  
Cancel

CRF 1 Study entry

Data Access Group: DE-064

Editing existing Record ID 1101-21. (Patient ID DE-064-021)

Event: Study entry

Record ID	1101-21
<b>CRF 1 Study entry</b>	
<b>Patient ID</b> <span style="color: red;">* must provide value</span>	<div style="border: 1px solid #ccc; padding: 2px;">DE-064-021</div> <div style="color: red; font-size: small;">(-----) country-site-patient</div>
<b>Signed written informed consent</b> <span style="color: red;">* must provide value</span>	<div style="display: flex; align-items: center;"> <input type="radio"/> yes  <input type="radio"/> no         </div> <div style="text-align: right; color: gray; font-size: small;">reset</div>
<b>Sex</b> <span style="color: red;">* must provide value</span>	<div style="display: flex; align-items: center;"> <input type="radio"/> female  <input type="radio"/> male         </div> <div style="text-align: right; color: gray; font-size: small;">reset</div>
<b>Age at time of first surgery</b> <span style="color: red;">* must provide value</span>	<div style="border: 1px solid #ccc; padding: 2px;"></div> <div style="color: gray; font-size: small;">(in years)</div>
<b>Height</b> <span style="color: red;">* must provide value</span>	<div style="border: 1px solid #ccc; padding: 2px;"></div> <div style="color: gray; font-size: small;">(in cm)</div>
<b>Weight</b> <span style="color: red;">* must provide value</span>	<div style="border: 1px solid #ccc; padding: 2px;"></div> <div style="color: gray; font-size: small;">(in kg)</div>

## 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“.

<b>Stage at time of diagnosis</b>	
<b>Left breast</b>	
<b>Stage</b> * must provide value	<input type="radio"/> invasive BC <input type="radio"/> DCIS <input type="radio"/> none
<b>History of ipsilateral BC</b> * must provide value	
<input type="radio"/> invasive <input type="radio"/> in situ <input type="radio"/> no	

## 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.

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: **1101-21**  
Event: **Study entry**  
Field: **crf1\_hist\_of\_ipsilat\_bc\_I** ("History of ipsilateral BC")  
Status: **Not Opened**

Date/Time	User	Comments and Details
11-22-2023 09:41	hartmannmonitor	<div><div><div><div><input checked="" type="radio"/> Verified data value</div><div><input type="radio"/> Open query</div></div><div><div>Assign query to a user (optional):</div><div>-- select user --</div></div></div><div><div>Notify this user of their assignment using:</div><div><input type="checkbox"/> Email</div><div><input type="checkbox"/> REDCap Messenger</div></div><div><div>Comment (optional):</div><div></div></div></div>

Verified data value

Cancel

## 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.

Additional lesions (e.g., benign) to be removed:

☐ yes, details

☐ no

reset

Stage at time of diagnosis

Right breast

Stage

☐ invasive BC

☐ DCIS

☐ none

reset

History of ipsilateral BC

☐ invasive

☐ in situ

☐ no

reset

History of ipsilateral breast irradiation

☐ yes

☐ no

reset

Additional lesions (e.g., benign) to be removed:

☐ yes, details

☐ no

reset

Form Status

Complete?

Unverified

Incomplete

Unverified

Complete

Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

Save & Exit Form

Save & ...

- Cancel -



## 2.11.

The required CRF form is now highlighted 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					

## Record Status Dashboard

Record ID	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	PRO Polish	PRO Turkish
1103-1 (Patient ID ES-001-001)													
1106-1 (Patient ID TR-014-001)													
1106-2 (Patient ID TR-014-002)													
1106-3 (Patient ID TR-014-005)													
1106-4 (Patient ID TR-014-004)													

## 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).

**Data Quality**

**Resolve Issues** 59 **Resolution Metrics**

[VIDEO: Data Resolution Workflow](#) or [Read introduction to Data Resolution Workflow](#)

This page displays all data queries that are currently unresolved or have already been resolved using the Data Resolution Workflow. Some issues may have been initiated by users on data collection instruments, and others may have been initiated after executing Data Quality rules on the Find Issues tab. The table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the query status type (e.g., open, closed), by certain fields or Data Quality rules, and also by users assigned to it. Each data query may be viewed by clicking the button to its left.

**Data Resolution Dashboard** Filters: Open / unresolved issues (59)   
 All fields and rules   
 All events   
 All data access groups   
 User assigned (all users) or not assigned

Click button to view data query

Record (Sorted by DAG)	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
1101-1 (#1) (Patient ID D) (Broad lesson (group) (DE-064))	Field: crf5_how_easy_question (How easy was the localization procedure, on a scale from 0...)	-	106.7	"Bitte hier eine Angabe machen. Danke"	[same as first update]
1101-1 (#1) (Patient ID D) (Broad lesson (group) (DE-064))	Field: crf5_how_satisfied_quest (How satisfied are you with the localization method used in...)	-	106.7	"Bitte hier eine Angabe machen. Danke"	[same as first update]

## 2.13.

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

How easy was the localization procedure, on a scale from 0 to 10? 0 = unable to mark

\* must provide value

1

How satisfied are you with the localization method used in this patient, on a scale from 0 to 10? 0 = very dissatisfied

\* must provide value

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.

Field: **crf2\_type\_of\_marker** ("Type of marker: ")  
 Status: 🚩 **Open / Unresolved** (unresponded)

Date/Time	User	Comments and Details
09-05-2023 22:56		crf2_type_of_marker = crf2_type_of_marker(4) = checked crf2_type_of_marker(8) = checked'
09-14-2023 15:36		Action: <b>Opened query</b> Comment: "Bitte prüfen: wurde der Tumor tatsächlich doppelt (mit Clip und Saviscout) markiert?" <a href="#">Assign query to a user</a>
10-25-2023 22:18		Response: <b>Verified - Confirmed correct (no error)</b> Comment: "Tumor in Breast with Clip Tumor from Lymph node with Saviscout" <a href="#">Assign query to a user</a>
10-30-2023 18:00		Action: <b>Sent back for further attention</b> Comment: "Dann bitte hier nur den Brusttumor (Clip) und nicht den LK (Saviscout) angeben." <a href="#">Assign query to a user</a>
11-21-2023 19:32		Data Changes Made: crf2_type_of_marker = 'crf2_type_of_marker(1) = checked crf2_type_of_marker(4) = unchecked crf2_type_of_marker(8) = unchecked'
11-22-2023 10:26		<input checked="" type="radio"/> <b>Reply with response:</b> -- choose response -- Upload file (optional): <a href="#">Upload file</a> — OR — <input type="radio"/> <b>Close the query</b> Comment: <div></div>

## 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.

**Timepoint of wire placement:**

☒ day of surgery  
☐ day before surgery  
☐ other

**Control mammogram after wire placement performed:**

☒ yes  
☐ no

**Control MRI after wire placement performed:**

☐ yes  
☒ no

**Wire located in the lesion:**

☒ yes  
☐ no, closest wire-to-lesion distance: mm

**Have any complications related to wire placement occurred?**

☐ yes, specify:  
☒ no

**Form Status**

**Complete?**

☒ Complete  
☐ Incomplete  
☐ Unverified  
☐ Complete

**Lock this instrument?**

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

## 2.16.

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

Form Status

Complete?

Complete

▼

Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

☒

Lock

Save & Exit Form

Save & ... ▼

- Cancel -

## 2.17.

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

Resolve Issues

External Modules Manage

Help & Information

Help & FAQ

Video Tutorials

Suggest a New Feature

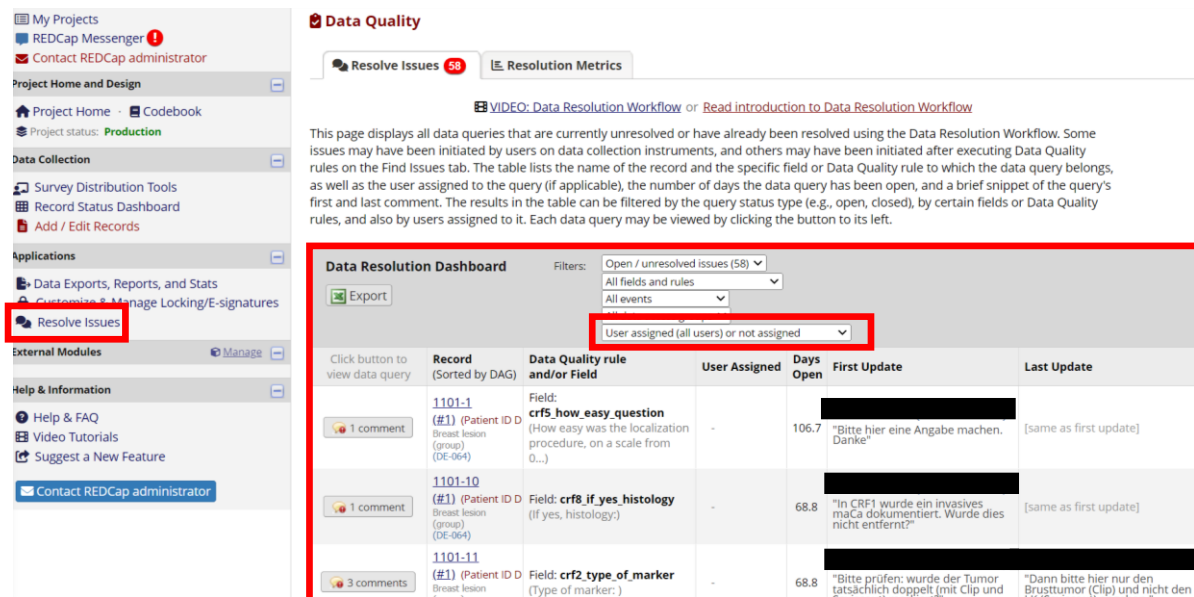
Contact REDCap administrator

Displaying: Instrument status only | Lock status only All status types Table not displaying properly ?

Record ID	Study entry	Breast lesion (group)							All lesions	End of Observation	Patient Question		
	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	PRO Polish	PRO Turkish
1 (Patient ID DE-064-001)													
<a href="#">1101-1</a> (Patient ID DE-064-002)													
<a href="#">1101-2</a> (Patient ID DE-064-003)													
<a href="#">1101-3</a> (Patient ID DE-064-004)													
<a href="#">1101-4</a> (Patient ID DE-064-005)													
<a href="#">1101-5</a> (Patient ID DE-064-006)													
<a href="#">1101-6</a> (Patient ID DE-064-007)													
<a href="#">1101-7</a> (Patient ID DE-064-008)													
<a href="#">1101-8</a> (Patient ID DE-064-009)													
<a href="#">1101-9</a> (Patient ID DE-064-0001)													
<a href="#">1101-10</a> (Patient ID DE-064-010)													
<a href="#">1101-11</a> (Patient ID DE-064-011)													
<a href="#">1101-12</a> (Patient ID DE-064-012)													
<a href="#">1101-13</a> (Patient ID DE-064-013)													
<a href="#">1101-14</a> (Patient ID DE-064-014)													

## 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.



**Data Quality**

Resolve Issues (58) Resolution Metrics

[VIDEO: Data Resolution Workflow](#) or [Read introduction to Data Resolution Workflow](#)

This page displays all data queries that are currently unresolved or have already been resolved using the Data Resolution Workflow. Some issues may have been initiated by users on data collection instruments, and others may have been initiated after executing Data Quality rules on the Find Issues tab. The table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to the query (if applicable), the number of days the data query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by the query status type (e.g., open, closed), by certain fields or Data Quality rules, and also by users assigned to it. Each data query may be viewed by clicking the button to its left.

**Data Resolution Dashboard**

Filters: Open / unresolved issues (58)

Export

All fields and rules

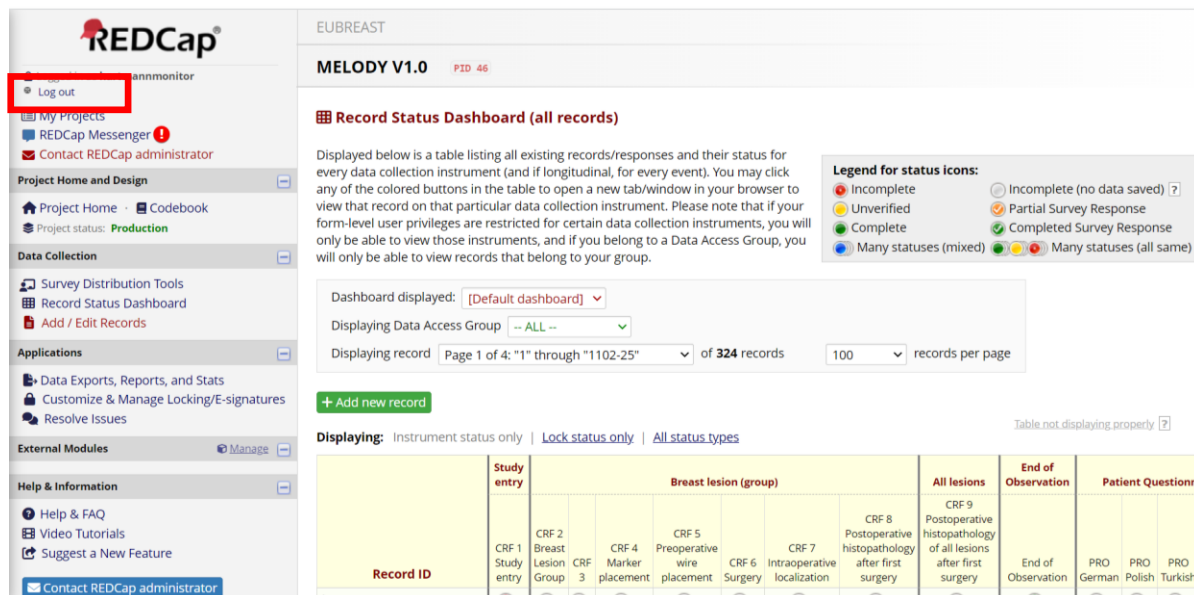
All events

User assigned (all users) or not assigned

Click button to view data query	Record (Sorted by DAG)	Data Quality rule and/or Field	User Assigned	Days Open	First Update	Last Update
1 comment	1101-1 (#1) (Patient ID D Breast lesion (group) (DE-064))	Field: crf5_how_easy_question (How easy was the localization procedure, on a scale from 0...)	-	106.7	"Bitte hier eine Angabe machen. Danke"	[same as first update]
1 comment	1101-10 (#1) (Patient ID D Breast lesion (group) (DE-064))	Field: crf8_if_yes_histology (If yes, histology:)	-	68.8	"In CRF1 wurde ein invasives maCa dokumentiert. Wurde dies nicht entfernt?"	[same as first update]
3 comments	1101-11 (#1) (Patient ID D Breast lesion)	Field: crf2_type_of_marker (Type of marker:)	-	68.8	"Bitte prüfen, wurde der Tumor tatsächlich doppelt (mit Clip und	"Dann bitte hier nur den Brusttumor (Clip) und nicht den

## 2.19.

Once you are finished, you can log out from the system.



**REDCap**

Log out

annmonitor

My Projects

REDCap Messenger

Contact REDCap administrator

**Project Home and Design**

Project Home

Codebook

Project status: Production

**Data Collection**

Survey Distribution Tools

Record Status Dashboard

Add / Edit Records

**Applications**

Data Exports, Reports, and Stats

Customize & Manage Locking/E-signatures

Resolve Issues

**External Modules**

Manage

**Help & Information**

Help & FAQ

Video Tutorials

Suggest a New Feature

Contact REDCap administrator

**EUBREAST**

**MELODY V1.0** PID 46

**Record Status Dashboard (all records)**

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

**Legend for status icons:**

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved) ?
- Partial Survey Response
- Completed Survey Response
- Many statuses (all same)

Dashboard displayed: [Default dashboard]

Displaying Data Access Group: -- ALL --

Displaying record: Page 1 of 4: "1" through "1102-25" of 324 records 100 records per page

**+ Add new record**

Displaying: Instrument status only | Lock status only | All status types

Record ID	Study entry	Breast lesion (group)	All lesions	End of Observation	Patient Questionnaire							
1 (Patient ID: DE-064/001)	CRF 1 Study entry	CRF 2 Breast Lesion Group	CRF 3 Marker placement	CRF 4 Preoperative wire placement	CRF 5 Surgery	CRF 6 Intraoperative localization	CRF 7 Postoperative histopathology after first surgery	CRF 8 Postoperative histopathology of all lesions after first surgery	CRF 9 End of Observation	PRO German	PRO Polish	PRO Turkish

### 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.

**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

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.

**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

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.