



AXSANA

(AXillary Surgery After NeoAdjuvant Treatment)
-EUBREAST 3-
NCT 04373655

A prospective multicenter cohort study to evaluate different surgical methods of axillary staging (sentinel lymph node biopsy, targeted axillary dissection, axillary dissection) in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy

eCRF USER MANUAL

For Remote Monitoring

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1. Responsibility

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2.

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

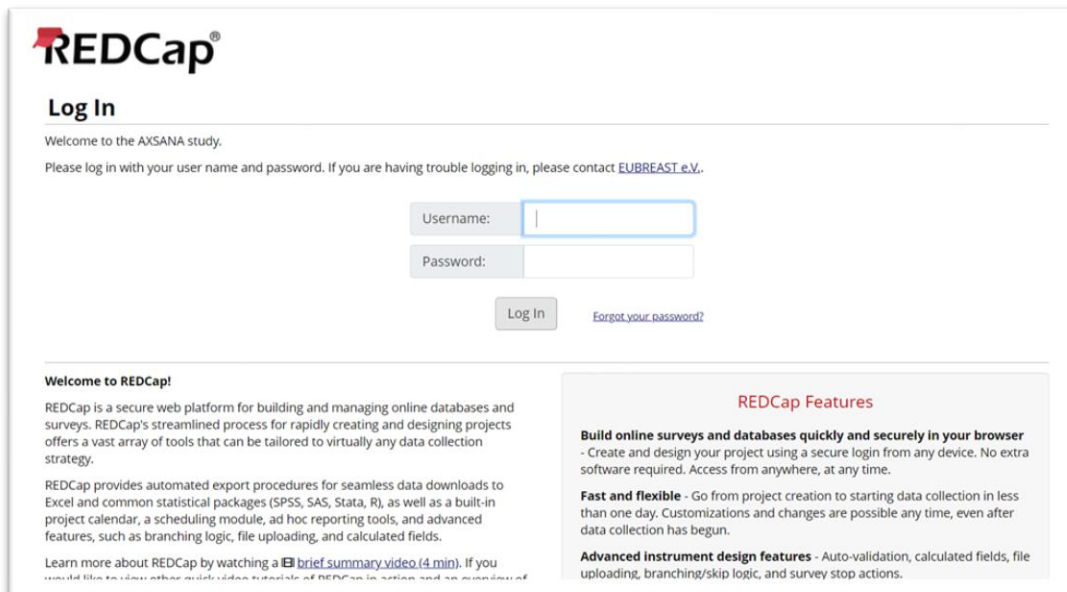
2.1.

Open the eCRF at:

<https://eubreast-axsana.com/>

2.2.

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



The screenshot shows the REDCap login interface. At the top left is the REDCap logo. Below it is the heading "Log In" and a sub-heading "Welcome to the AXSANA study." A message states: "Please log in with your user name and password. If you are having trouble logging in, please contact [EUBREAST e.V.](#)". There are two input fields: "Username:" and "Password:". Below the fields are a "Log In" button and a link for "Forgot your password?".

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to know other available tools of REDCap in online and on-premise of

REDCap Features

Build online surveys and databases quickly and securely in your browser - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

Fast and flexible - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

Advanced instrument design features - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.

2.3.

Click on „My Projects“ and afterwards select „AXSANA“.

Welcome to the AXSANA study.
Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#)

Project Title	PID	Records	Fields	Instruments	Type	Status
AXSANA_demo	14	21	385	13 forms		
AXSANA	17	11	385	12 forms		

2.4.

Choose „Record Status Dashboard“.

EUBREAST e.V.
AXSANA PID 17

Project Home | Project Setup | Other Functionality | Project Revision History | Edit project settings

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 is not used as a template [Add](#)

Current Users (44)	
User	Expires
[Redacted]	

Project Statistics		
Records in project	11	
Most recent activity	09-16-2020 09:06	
Space usage for docs	0.00 MB	

Upcoming Calendar Events (next 7 days)		
Time	Date	Description
		No upcoming events

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 AXSANA for pseudonymization.

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 ● Incomplete (no data saved) ● Complete

Dashboard displayed: Default dashboard Create custom dashboard
 Displaying Data Access Group: ALL
 Displaying record: Page 1 of 1: "1-1" through "15-1" of 11 records ALL (11) records per page

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

Record ID	Study entry		After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	FU 1 year after surgery		FU 3-5 years after surgery				
	CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 2 - to be completed after neoadjuvant therapy	CRF 3a - to be completed after surgery	CRF 3b - to be completed after surgery	CRF 4 - Postoperative histopathology	CRF 5 - Planned adjuvant treatment	CRF 6a - Follow up 1 year after surgery	CRF 6b - Follow up 1 year after surgery	CRF 7a - Follow up 2 years after surgery	CRF 7b - Follow up 3 years after surgery	CRF 7c - Follow up 4 years after surgery	CRF 7d - Follow up 5 years after surgery
5-1 (Patient ID DE-001-001)	●	●	●	●	●	●	●	●	●	●	●	●	●
5-2 (Patient ID DE-001-002)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-1 (Patient ID DE-010-001)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-2 (Patient ID DE-010-002)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-3 (Patient ID DE-010-003)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-4 (Patient ID DE-010-004)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-5 (Patient ID DE-010-005)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-6 (Patient ID DE-010-006)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-7 (Patient ID DE-010-007)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-8 (Patient ID DE-010-008)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-9 (Patient ID DE-010-009)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-10 (Patient ID DE-010-010)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-11 (Patient ID DE-010-011)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-12 (Patient ID DE-010-012)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-13 (Patient ID DE-010-013)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-14 (Patient ID DE-010-014)	●	●	●	●	●	●	●	●	●	●	●	●	●
12-15 (Patient ID DE-010-015)	●	●	●	●	●	●	●	●	●	●	●	●	●

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.

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event, if you wish, you may modify the events below by navigating to the [Default My Events](#) page.

Choose action for record: ▼

Record ID 5-1 (Patient ID DE-001-001)
DE-001

Data Collection Instrument	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	FU 1 year after surgery	FU 3-5 years after surgery
CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	●						
CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	●						
CRF 2 - to be completed after neoadjuvant therapy		●					
CRF 3a - to be completed after surgery			●				
CRF 3b - to be completed after surgery			●				
CRF 4 - Postoperative histopathology				●			
CRF 5 - Planned adjuvant treatment					●		
CRF 6a - Follow up 1 year after surgery						●	
CRF 6b - Follow up 1 year after surgery						●	
CRF 7a - Follow up 2 years after surgery							●
CRF 7b - Follow up 3 years after surgery							●
CRF 7c - Follow up 4 years after surgery							●
CRF 7d - Follow up 5 years after surgery							●

2.7.

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

The screenshot displays the REDCap interface for the 'AXSANA_demo' project. The main content area shows the 'CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)' form. The form is titled 'Editing existing Record ID 1 (Patient ID DE-001-001)' and includes the following fields:

- Event Name:** Study entry
- Record ID:** 1
- Pretherapeutic N stage (before NACT):**
 - Suspicious nodes on palpation: Yes No
 - Suspicious nodes on ultrasound: Yes No
 - Minimally invasive node biopsy: FNA Core biopsy
 - Minimally invasive node biopsy Date: Today (D-M-Y)
 - Number of nodes biopsied: 1 2 >=3
 - of these positive:
 - Max. size of the largest suspicious lymph node [mm]:
 - Marking of the target lymph node (TLN): Yes No
 - Type of marking:
- Form Status:** Incomplete
- Complete?:** Incomplete
- Lock this instrument?:** Lock E-signature

2.8.

If required, you can pose 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“.

The screenshot shows a close-up of two form fields. The first field is 'Breast surgery' with a red asterisk indicating it is required. It has two radio button options: 'Breast-conserving surgery' (selected) and 'Mastectomy'. A red box highlights a speech bubble icon next to the 'Mastectomy' option. The second field is 'Reconstruction' with a red asterisk, having two radio button options: 'Yes' and 'No'. A speech bubble icon is also visible next to the 'No' option.

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: **1**
Event: **Study entry**
Field: **minimally_invasive_node_bi** ("Minimally invasive node biopsy")
Status: **Not Opened**

Date/Time	User	Comments and Details
10-26-2020 08:06	jzeppenfeld	<input checked="" type="radio"/> Verified data value — OR — <input type="radio"/> Open query Assign query to a user (optional): -- select user -- Comment (optional): <input type="text"/>

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.

AXSANA | REDCap

Max. tumor size [mm] * must provide value

Max tumor size based on * must provide value

cT * must provide value

Focality * must provide value

Multicentricity * must provide value

Form Status

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.

Record ID 1 (Patient ID 1111111111)

Data Collection Instrument	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	FU 1 year after surgery	FU 2-5 years after surgery
CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	●						
CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	●						
CRF 2 - to be completed after neoadjuvant therapy		●					
CRF 3a - to be completed after surgery			●				
CRF 3b - to be completed after surgery			●				

Record Status Dashboard

Record ID	Study entry		After neoadj. therapy	After surgery		Postop. histopathology	Planned adj. treatment	FU 1 year after surgery		FU 2-5 years after surgery			
	CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 2 - to be completed after neoadjuvant therapy	CRF 3a - to be completed after surgery	CRF 3b - to be completed after surgery	CRF 4 - Postoperative histopathology	CRF 5 - Planned adjuvant treatment	CRF 6a - Follow up 1 year after surgery	CRF 6b - Follow up 1 year after surgery	CRF 7a - Follow up 2 years after surgery	CRF 7b - Follow up 3 years after surgery	CRF 7c - Follow up 4 years after surgery	CRF 7d - Follow up 5 years after surgery
1 (Patient ID 1111111111)	●	●	●	●	●	●	●	●	●	●	●	●	●
S-1 (Patient ID DE-001-001)	●	●	○	○	○	○	○	○	○	○	○	○	○

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).

My Projects or Control Center

REDCap Messenger

View project as user: -- select a user --

Project Home and Design

Project Home · Project Setup

Designer · Dictionary · Codebook

Project status: Production

Data Collection

Record Status Dashboard

Add / Edit Records

Applications

Alerts & Notifications

Calendar

Data Exports, Reports, and Stats

Data Import Tool

Data Comparison Tool

Logging

File Repository

User Rights and DAGs

Customize & Manage Locking/Esignatures

Data Quality and **Resolve Issues**

API and API Playground

REDCap Mobile App

External Modules

Reports

Search Organize Edit

1) Patient Recruitment

Data Quality

Find Issues Resolve Issues **2** 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 (2)

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
1 comment	1 (Patient ID DE-0 Study entry)	Field: signed_written_informed_co (Signed written informed consent)	-	7.9	"Please check if correct! Signed informed consent is necessary for study participation."	[same as first update]
1 comment	1 (Patient ID DE-0 After neoadj. therapy)	Field: neoadjuvant_systemic_thera (Neoadjuvant systemic therapy administered)	-	7.9	"Please check. No NACT received?"	[same as first update]

2.13.

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

Height [cm] <small>* must provide value</small>	<input type="text" value="176"/>	
Weight [kg] <small>* must provide value</small>	<input type="text" value="80"/>	
Signed written informed consent <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	

[reset](#)


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.

Data Resolution Workflow ✕

[VIDEO: Data Resolution Workflow](#)

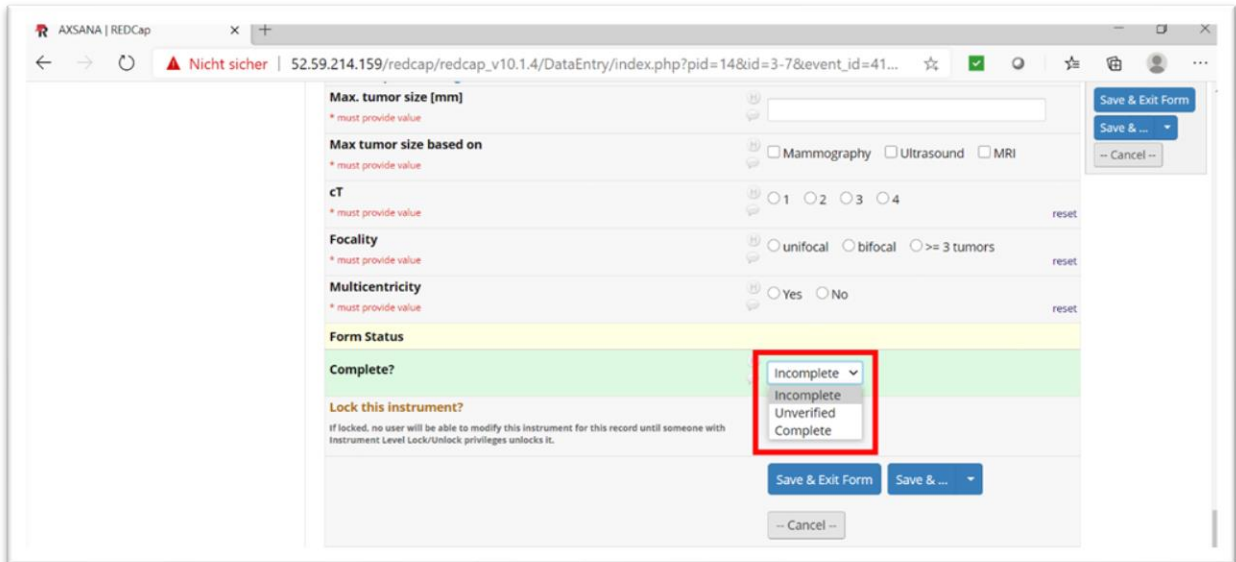
This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users 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: [1](#)
Event: **Study entry**
Field: **signed_written_informed_co** ("Signed written informed consent")
Status:  **Open / Unresolved** (unresponded)

Date/Time	User	Comments and Details
10-18-2020 09:34	banys	Action: Opened query Comment: "Please check if correct! Signed informed consent is necessary for study participation."
10-18-2020 09:34	banys	Data Changes Made: signed_written_informed_co = 'No (0)'
10-26-2020 08:00	jzeppenfeld	<div style="border: 2px solid red; padding: 5px;"><p><input checked="" type="radio"/> Reply with response:</p><p>-- choose response -- ▼</p><p>Upload file (optional):  Upload file</p><p>— OR —</p><p><input type="radio"/> Close the query</p><p>Comment: <input style="width: 100%;" type="text"/></p></div>

2.15.

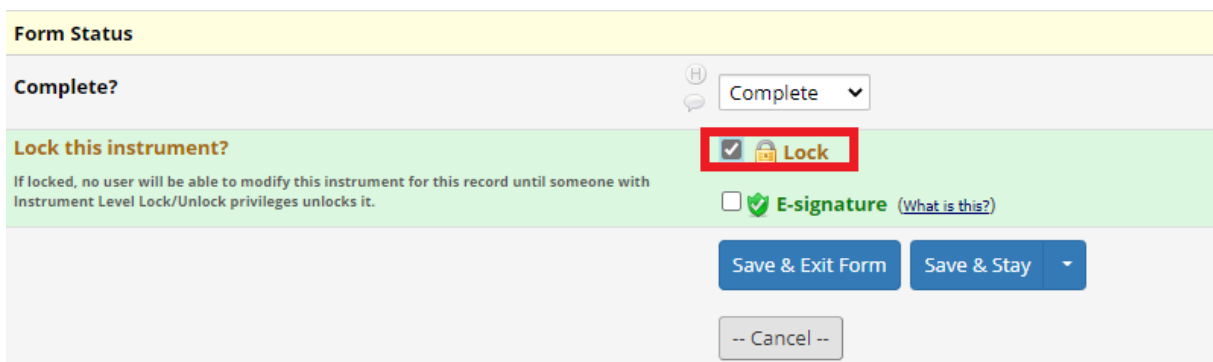
Once all queries have been answered successfully and you regard the CRF form as complete and conclusive, please set the form into "Complete". You find the respective field at the bottom of the page.



The screenshot shows a web browser window with the URL `52.59.214.159/redcap/redcap_v10.1.4/DataEntry/index.php?pid=14&id=3-7&event_id=41...`. The form contains several fields: "Max. tumor size [mm]", "Max tumor size based on" (with checkboxes for Mammography, Ultrasound, MRI), "cT" (radio buttons 1-4), "Focality" (radio buttons unifocal, bifocal, >= 3 tumors), and "Multicentricity" (radio buttons Yes, No). Below these is the "Form Status" section, which includes a "Complete?" dropdown menu. The dropdown is open, showing the following options: "Incomplete", "Incomplete", "Unverified", and "Complete". The "Complete" option is highlighted with a red box. At the bottom of the form, there are buttons for "Save & Exit Form", "Save & ...", and "-- Cancel --".

2.16.

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



The screenshot shows a close-up of the "Form Status" section. The "Complete?" dropdown menu is set to "Complete". Below it is the "Lock this instrument?" section, which includes a checkbox that is checked and a "Lock" button with a padlock icon. This "Lock" button is highlighted with a red box. Below the "Lock" button is an "E-signature" section with a checkbox and a link "(What is this?)". At the bottom of the form, there are buttons for "Save & Exit Form", "Save & Stay", and "-- Cancel --".

2.17.

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

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

Record ID	Study entry		After neoadj. therapy	After surgery		Postop. histopathology	Planned adj. treatment	FU 1 year after surgery		FU 2-5 years after surgery		
	CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	CRF 2 - to be completed after neoadjuvant therapy	CRF 3a - to be completed after surgery	CRF 3b - to be completed after surgery	CRF 4 - Postoperative histopathology	CRF 5 - Planned adjuvant treatment	Follow up 1 year after surgery	Follow up 1 year after surgery	Follow up 2 years after surgery	Follow up 3 years after surgery	Follow up 4 years after surgery
5-1 (Patient ID DE-001-001)	●	●	●	●	●	●	●	●	●	●	●	●
5-2 (Patient ID DE-001-002)	●	●	●	●	●	●	●	●	●	●	●	●
5-3 (Patient ID DE-001-003)	●	●	●	●	●	●	●	●	●	●	●	●
5-4 (Patient ID DE-001-004)	●	●	●	●	●	●	●	●	●	●	●	●
5-5 (Patient ID DE-001-005)	●	●	●	●	●	●	●	●	●	●	●	●
5-6 (Patient ID DE-001-006)	●	●	●	●	●	●	●	●	●	●	●	●
5-7 (Patient ID DE-001-007)	●	●	●	●	●	●	●	●	●	●	●	●
5-8 (Patient ID DE-001-008)	●	●	●	●	●	●	●	●	●	●	●	●
5-9 (Patient ID DE-001-009)	●	●	●	●	●	●	●	●	●	●	●	●
5-10 (Patient ID DE-001-010)	●	●	●	●	●	●	●	●	●	●	●	●
11-1 (Patient ID DE-010-001)	●	●	●	●	●	●	●	●	●	●	●	●
12-1 (Patient ID DE-030-001)	●	●	●	●	●	●	●	●	●	●	●	●
12-2 (Patient ID DE-030-002)	●	●	●	●	●	●	●	●	●	●	●	●
12-3 (Patient ID DE-030-003)	●	●	●	●	●	●	●	●	●	●	●	●
12-4 (Patient ID DE-030-004)	●	●	●	●	●	●	●	●	●	●	●	●

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

Find Issues | Resolve Issues 2 | 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.

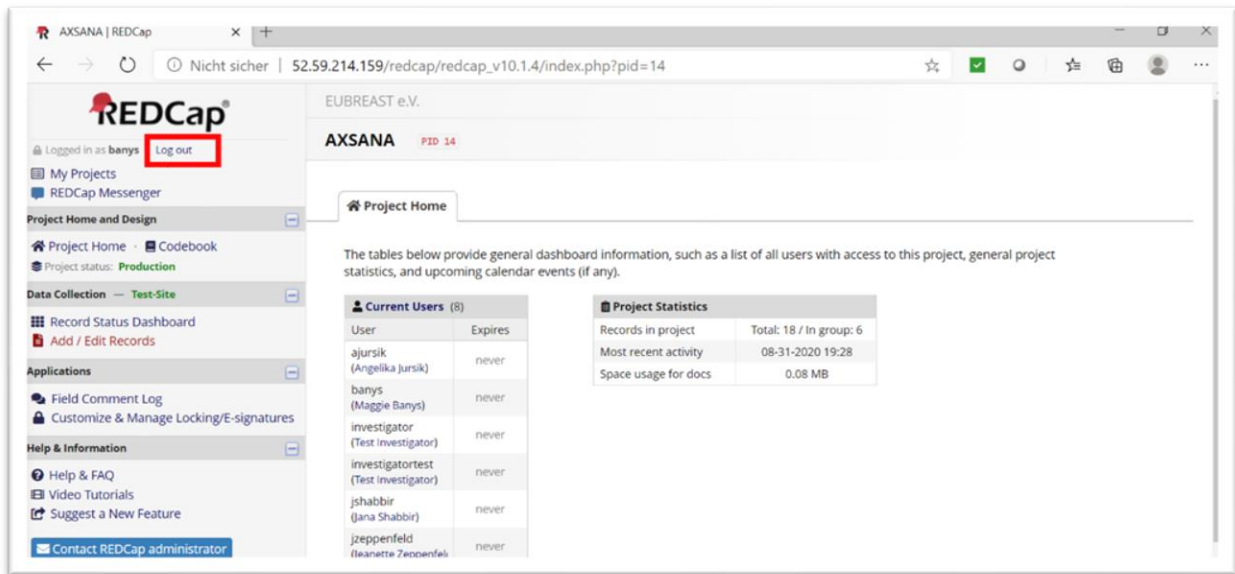
Data Resolution Dashboard

Filters: Open / unresolved issues (2) | 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
1 comment	1 (Patient ID DE-0 Study entry)	Field: signed_written_informed_co (Signed written informed consent)	-	7.9	"Please check if correct! Signed informed consent is necessary for study participation."	[same as first update]
1 comment	1 (Patient ID DE-0 After neoadj. therapy)	Field: neoadjuvant_systemic_thera (Neoadjuvant systemic therapy administered)	-	7.9	"Please check. No NACT received"	[same as first update]

2.19.

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



The screenshot shows the REDCap interface for the project 'AXSANA' (PID 14) under the organization 'EUBREAST e.V.'. The user is logged in as 'banys'. A red box highlights the 'Log out' button in the top left navigation area. The main content area displays 'Project Home' information, including a list of current users and project statistics.

Current Users (8)

User	Expires
ajursik (Angelika Jursik)	never
banys (Maggie Banyys)	never
investigator (Test investigator)	never
investigatortest (Test investigator)	never
jshabbir (Jana Shabbir)	never
jzeppenfeld (Jeanette Zeppenfeld)	never

Project Statistics

Records in project	Total: 18 / In group: 6
Most recent activity	08-31-2020 19:28
Space usage for docs	0.08 MB

3. Remote Monitoring – which fields should be monitored?

Optimally, all fields are completed!

On the other hand, since we would like to keep it simple for the AXSANA study sites, we do not want to generate too many queries. Only in case of important missing data a query should be generated.

CRF 1a

The following fields must be completed:

- Patient ID
- Age
- Sex
- Signed informed consent and date
- ER, PR, HER2
- Max. Tumor size
- cT

Check:

- Inclusion and exclusion criteria

Plausibility check:

- Tumor size and cT stage

CRF 1b

The following fields must be completed if they appear in eCRF (some are shown only in case of specific answers to previous questions):

- Suspicious nodes on palpation
- Suspicious nodes on ultrasound
- Max. number of suspicious nodes
- Marking of the target lymph node
- Minimally invasive node biopsy and results of biopsy if performed
- Final classification
- Type of marking
- **Very important!** Exact clip type in case of clip/coil:
 - Tumark is not enough because there are several types such as Tumark Vision and Tumark Professional etc.
 - Nitinol or Somatex Nitinol is not clip type but only the name of the material the clips are made of

- HydroMARK must be specified (three different shapes available: Barrel, Open Coil, Butterfly)
- O-TWIST is enough, because there is only one type of O-TWIST
- The analysis is easier if the beginning of the clip name is standardized, therefore:
 - Change the beginning of the name to **OTWIST** if you are sure that this clip was used (leave all other information regarding the clip unchanged, e.g., REF number, manufacturer)
 - Change the beginning of the name to **TUMARK VISION** if you are sure that this clip was used
 - Change the beginning of the name to **TUMARK PROFESSIONAL** if you are sure that this clip was used
 - Change the beginning of the name to **Hydromark Opencoil** if you are sure that this clip was used
 - Change the beginning of the name to **Hydromark Barrel** if you are sure that this clip was used
 - Change the beginning of the name to **Hydromark Butterfly** if you are sure that this clip was used
 - Change the beginning of the name to **Hydromark** if you are sure that this clip was used and the exact type is unknown
 - In all other cases leave the answer as it was documented by the site
- If you are unsure if the type is exact enough contact m.banys@outlook.com

Check:

- Type of marking: In case more than one option has been chosen write a query if it is correct (some study sites might think that the question refers to marking of the breast tumor as well)
- If minimally invasive biopsy and Marking of the TLN were on the same day, then usually the pathological report was not available before marking and the answer to “Lymph node metastasis confirmed by...” should be “No” (exception: frozen section of core biopsy performed)

CRF 2

The following fields must be completed:

- Quality of life questionnaires completed...?
- Neoadjuvant systemic therapy administered
- Number of administered chemotherapy cycles
- ycT
- Suspicious nodes on palpation
- Suspicious nodes on ultrasound
- Final classification
- Planned axillary staging – in case of “other” the “please specify” field should be completed

Plausibility check:

- Tumor size and ycT stage
- Suspicious nodes on ultrasound – Yes but Final classification – ycN0 → query
- Suspicious nodes on ultrasound/MRI/PET – No and Suspicious nodes on palpation – No but Final classification – ycN+ → query

CRF 3a

The following fields must be completed if they appear in eCRF (some are shown only in case of specific answers to previous questions):

- Date of surgery
- Total time from incision to skin closure (only if “Reconstruction” and “Surgery of the other breast during the same procedure?” are both answered with “No”)
- Sentinel lymph node tracer injection
- Has the TLN been marked before neoadjuvant therapy?
- Preoperative localization of the target lymph node performed? If yes, all questions referring to this should be answered
- Why has the preoperative localization not been performed?

Plausibility check:

- Check if the data in CRF3a are in agreement with CRF1b, e.g. “Has/have the TLN been marked before neoadjuvant therapy?” (CRF3a) answered with Yes but “Marking of the target lymph node (TLN)” (CRF1b) answered with No

CRF 3b

The following fields must be completed if they appear in eCRF (some are shown only in case of specific answers to previous questions):

- Intraoperative localization of the target lymph node attempted?
- TLN successfully removed?
- ALND performed?
- Have all markers inserted before NACT been removed during SLNB/TAD/TLNB/ALND? -> if no, further questions should be answered

Plausibility checks:

- TLN successfully removed - „No“ but Marking detected in the TLN - „Yes“
- TLN successfully removed - „Yes“ but Marking detected in the TLN - „No“

Frequent problems:

- “Intraoperative localization of the target lymph node attempted” – Yes, specify: Some study sites choose “Gamma probe” because they used it for SLN detection and eventually the SLN contained the marker. This is not correct. Gamma probe should be chosen only if radioactive seeds are used as TLN markers (it is quite popular in some countries but not allowed in others).

CRF 4

The following fields must be completed if they appear in eCRF (some are shown only in case of specific answers to previous questions):

- Tumor stage after NACT
- Resection margin
- The table must be completed

Plausibility checks:

- Check if the data in the table are in agreement with answers in CRF 3a and 3b (e.g. TLN removed according to the table but no pre- or intraoperative localization performed)
- Check if the data in CRF 3a/3b/4 are in agreement with „planned axillary staging“ in CRF2 (e.g. „TAD“ chosen as planned staging but no TLN localization).

CRF 5

The following fields must be completed:

- All fields of “Planned radiation therapy”

Plausibility checks:

- Radiation of the breast – “Yes” but the patient received mastectomy
- Radiation of the thoracic wall – “Yes” but the patient received breast-conserving surgery

In case inclusion / exclusion criteria are not fulfilled or the patient received less than 4 cycles of chemotherapy etc. -> use CRF 8