



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 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 and follow the instructions at the bottom of page 1 and 2. Each study site staff member will receive an e-mail with login information separately.

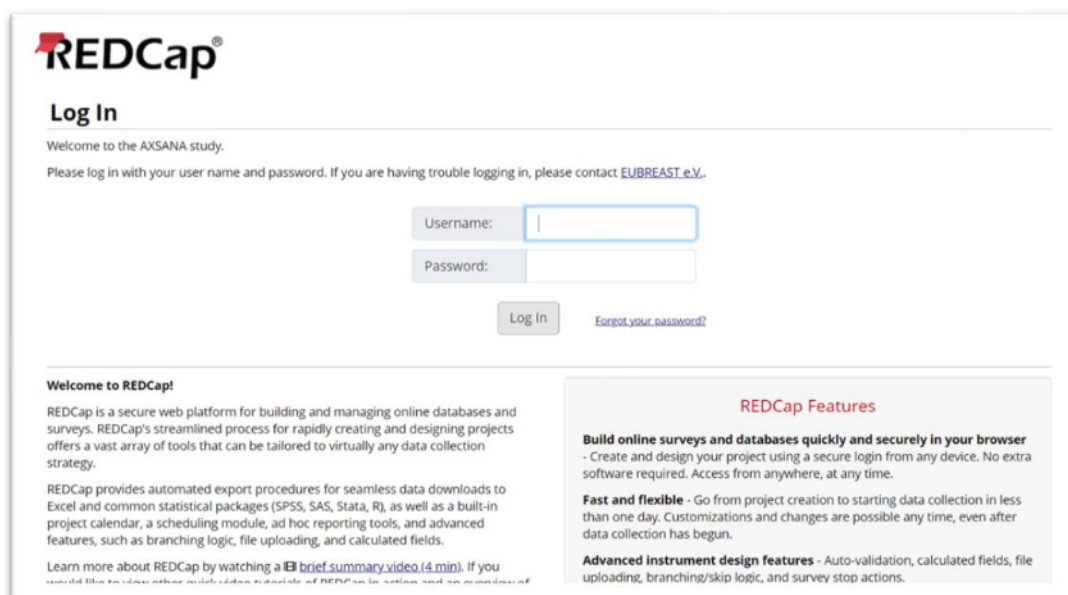
Updated version of user manual includes: "End of observation". Please document all patients in this section that leave the study, due to withdrawal, death, drop out, or lost to follow up.

2.

Open the eCRF at:

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

3.



Log in using your personal username and password.

4.

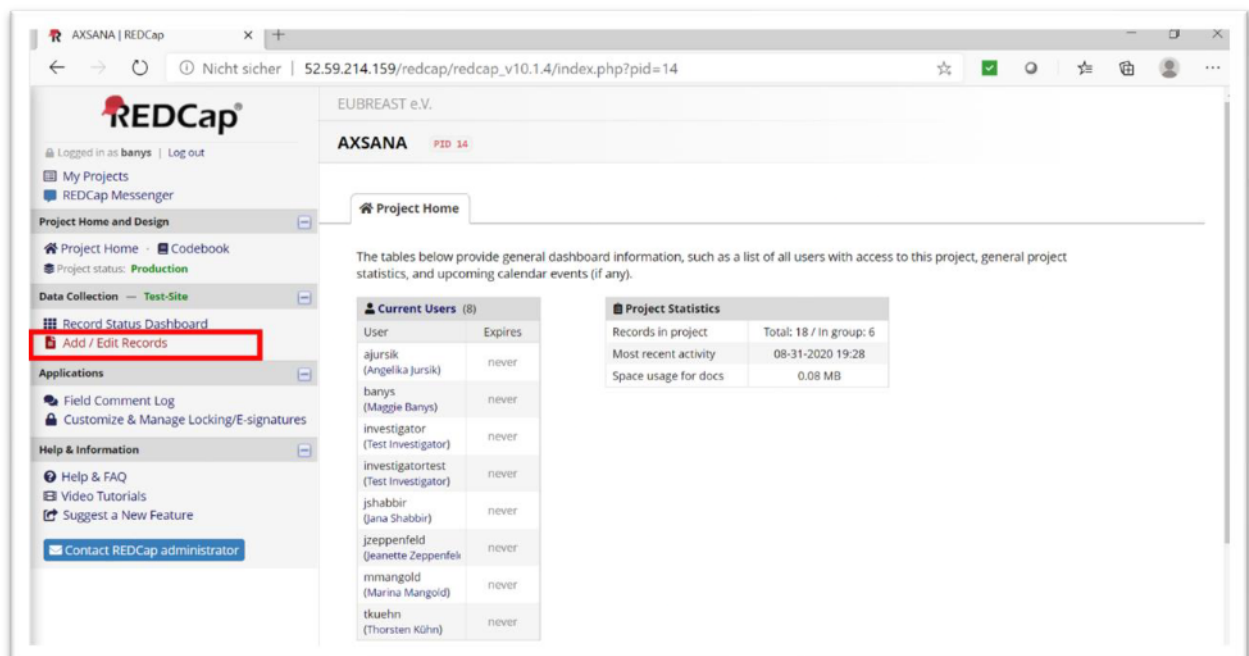
Now you can see the list of open projects. Choose AXSANA.

Do not click on “New Project”.



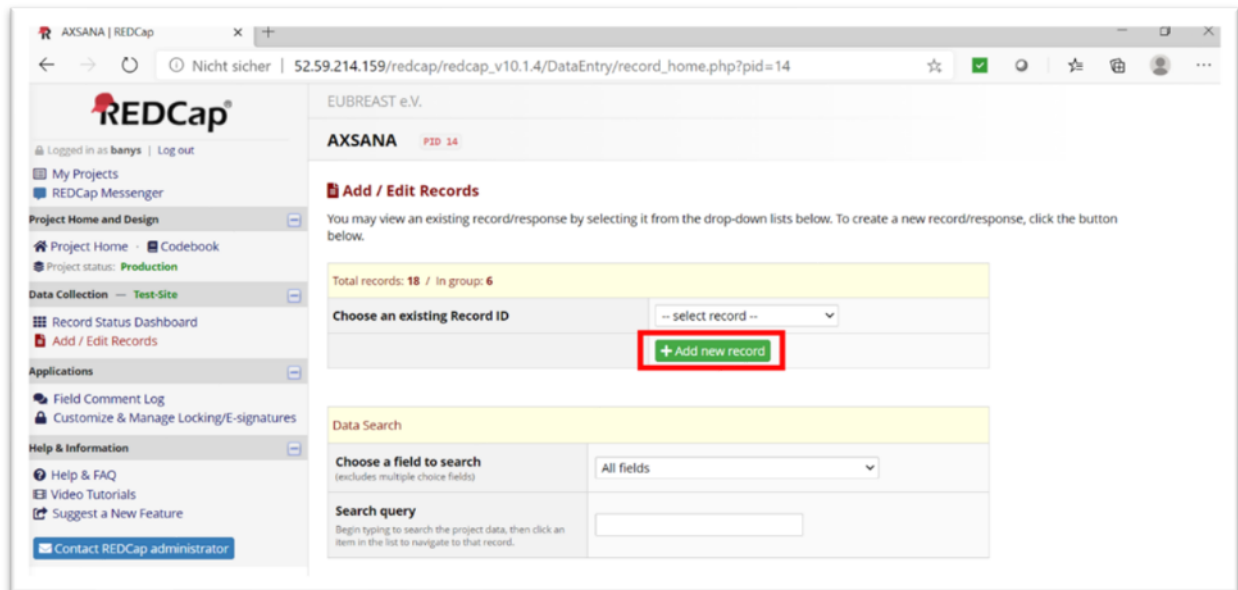
5.

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



6.

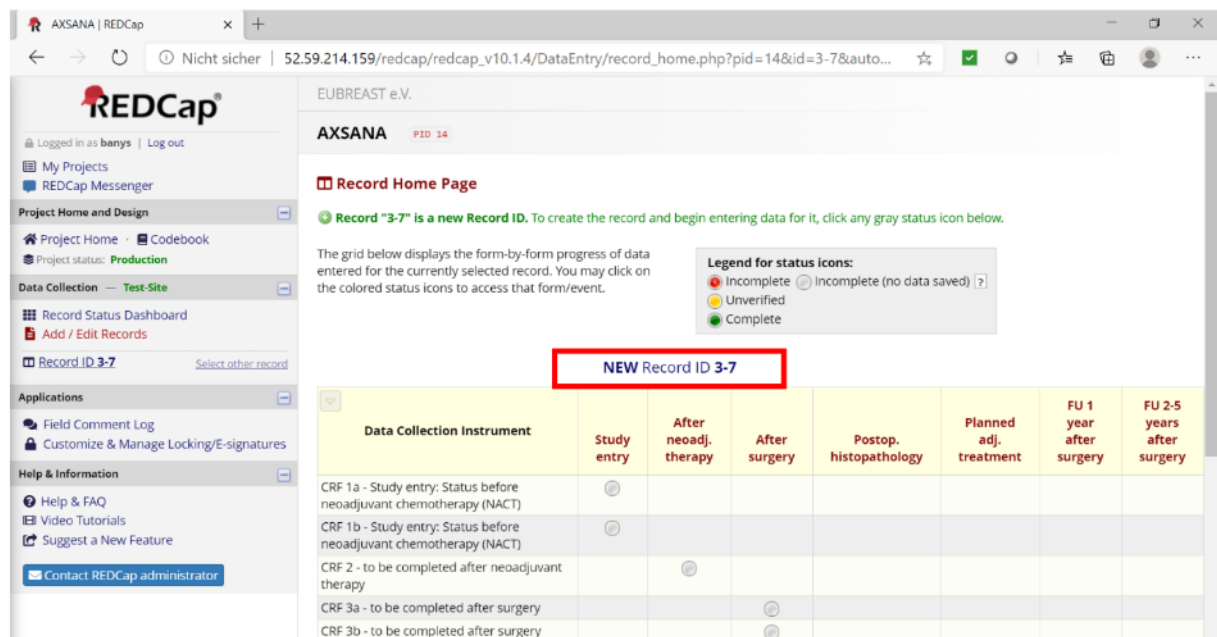
To add a new patient, choose “Add new record”.



7.

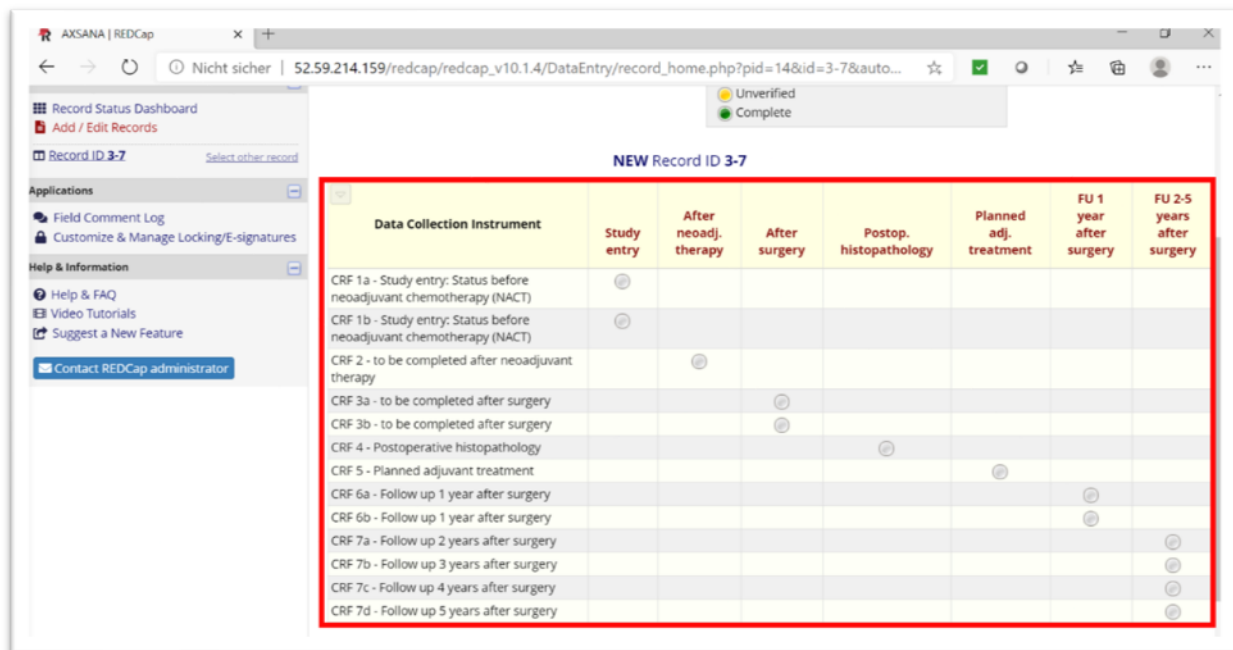
A new patient has been created.

Please keep in mind that the Record ID (3-7) is a record number created by RedCap and it is not the Patient-ID!



8.

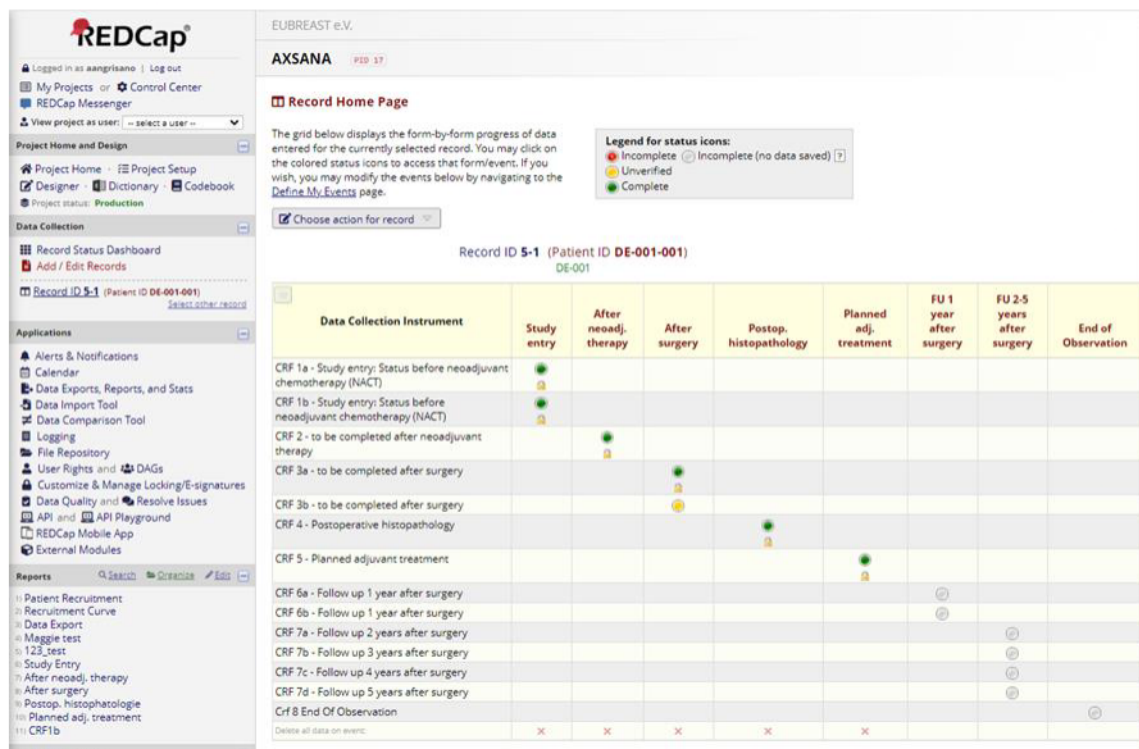
Now you can see all CRF forms of your patient.



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)	Complete						
CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	Complete						
CRF 2 - to be completed after neoadjuvant therapy		Complete					
CRF 3a - to be completed after surgery			Complete				
CRF 3b - to be completed after surgery			Complete				
CRF 4 - Postoperative histopathology				Complete			
CRF 5 - Planned adjuvant treatment					Complete		
CRF 6a - Follow up 1 year after surgery						Complete	
CRF 6b - Follow up 1 year after surgery						Complete	
CRF 7a - Follow up 2 years after surgery							Complete
CRF 7b - Follow up 3 years after surgery							Complete
CRF 7c - Follow up 4 years after surgery							Complete
CRF 7d - Follow up 5 years after surgery							Complete

9.

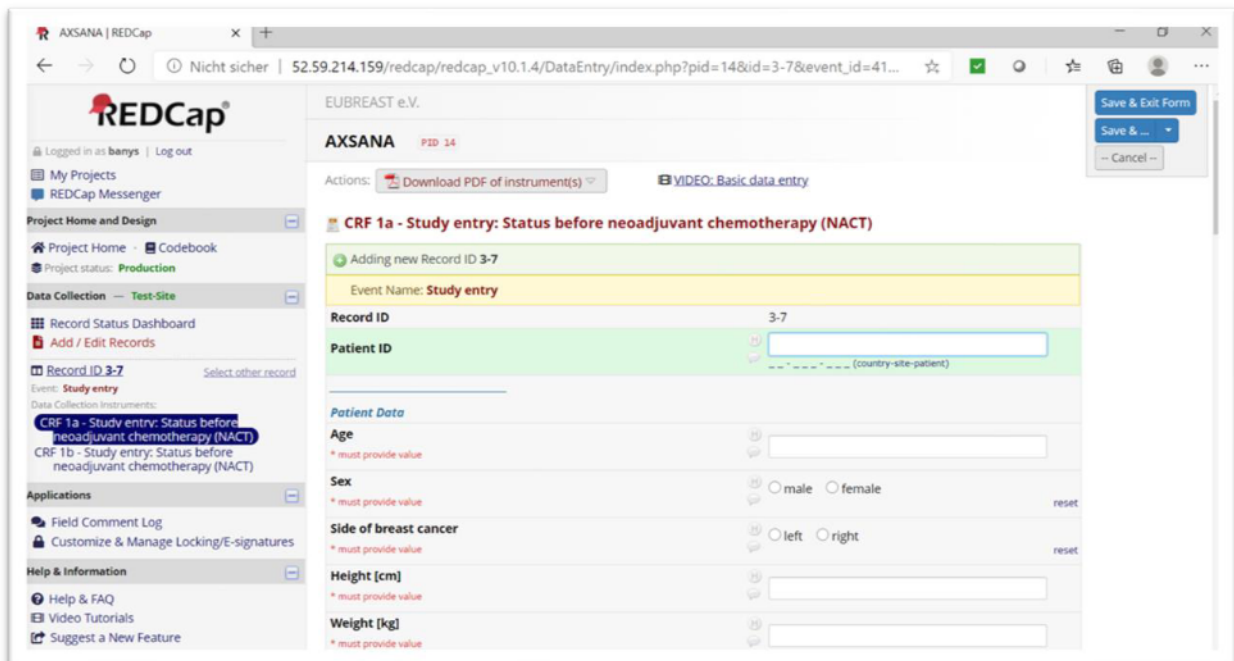
Choose the form you would like to open.



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	End of Observation
CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)	Complete							
CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)	Complete							
CRF 2 - to be completed after neoadjuvant therapy		Complete						
CRF 3a - to be completed after surgery			Complete					
CRF 3b - to be completed after surgery			Complete					
CRF 4 - Postoperative histopathology				Complete				
CRF 5 - Planned adjuvant treatment					Complete			
CRF 6a - Follow up 1 year after surgery						Complete		
CRF 6b - Follow up 1 year after surgery						Complete		
CRF 7a - Follow up 2 years after surgery							Complete	
CRF 7b - Follow up 3 years after surgery							Complete	
CRF 7c - Follow up 4 years after surgery							Complete	
CRF 7d - Follow up 5 years after surgery							Complete	
CRF 8 End Of Observation								Complete

10.

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



AXSANA | REDCap

52.59.214.159/redcap/redcap_v10.1.4/DataEntry/index.php?pid=14&id=3-7&event_id=41...

REDCap®

Logged in as banyys | Log out

My Projects

REDCap Messenger

Project Home and Design

Project Home | Codebook

Project status: Production

Data Collection — Test-Site

Record Status Dashboard

Add / Edit Records

Record ID 3-7

Select other record

Data Collection Instruments:

CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)

CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)

Applications

Field Comment Log

Customize & Manage Locking/E-signatures

Help & Information

Help & FAQ

Video Tutorials

Suggest a New Feature

EUBREAST e.V.

AXSANA PID 14

Actions: Download PDF of instrument(s) VIDEO: Basic data entry

Save & Exit Form

Save & ...

Cancel

CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)

Adding new Record ID 3-7

Event Name: Study entry

Record ID 3-7

Patient ID

Age

Sex

Side of breast cancer

Height [cm]

Weight [kg]

Age

Sex

Side of breast cancer

Height [cm]

Weight [kg]

Age

Sex

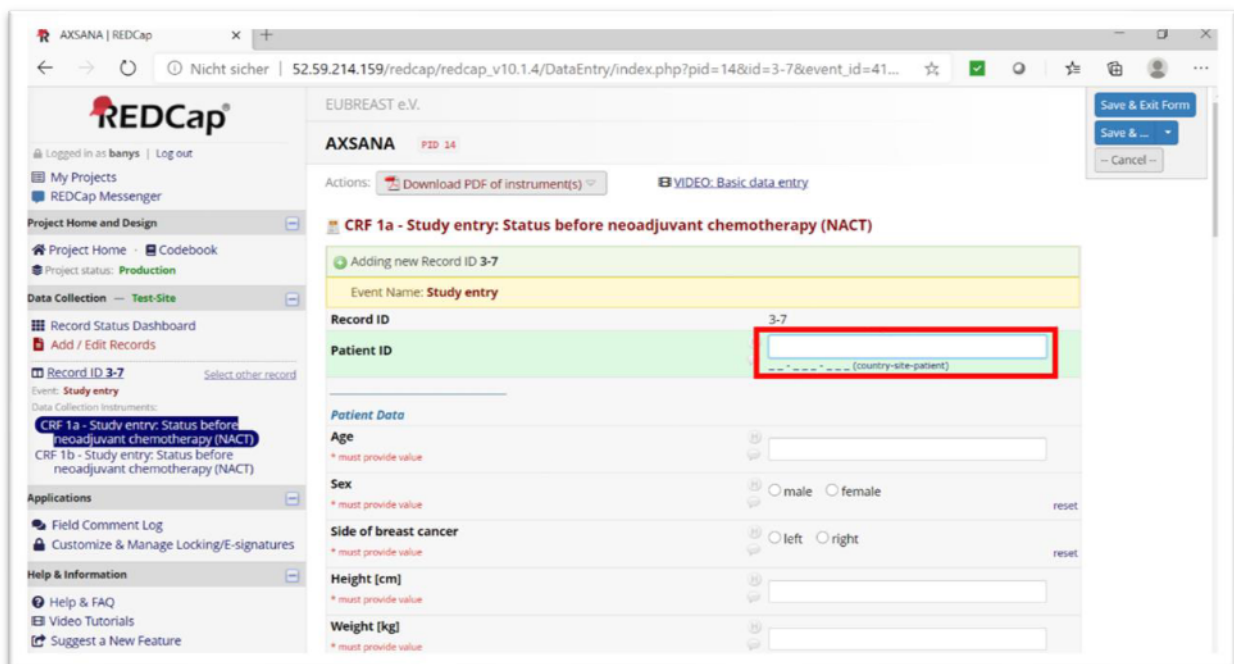
Side of breast cancer

Height [cm]

Weight [kg]

11.

Do not forget to enter Patient-ID that you created according to the instructions in the Subject & Identification Log.



AXSANA | REDCap

52.59.214.159/redcap/redcap_v10.1.4/DataEntry/index.php?pid=14&id=3-7&event_id=41...

REDCap®

Logged in as banyys | Log out

My Projects

REDCap Messenger

Project Home and Design

Project Home | Codebook

Project status: Production

Data Collection — Test-Site

Record Status Dashboard

Add / Edit Records

Record ID 3-7

Select other record

Data Collection Instruments:

CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)

CRF 1b - Study entry: Status before neoadjuvant chemotherapy (NACT)

Applications

Field Comment Log

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Help & FAQ

Video Tutorials

Suggest a New Feature

EUBREAST e.V.

AXSANA PID 14

Actions: Download PDF of instrument(s) VIDEO: Basic data entry

Save & Exit Form

Save & ...

Cancel

CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)

Adding new Record ID 3-7

Event Name: Study entry

Record ID 3-7

Patient ID

Age

Sex

Side of breast cancer

Height [cm]

Weight [kg]

Age

Sex

Side of breast cancer

Height [cm]

Weight [kg]

Age

Sex

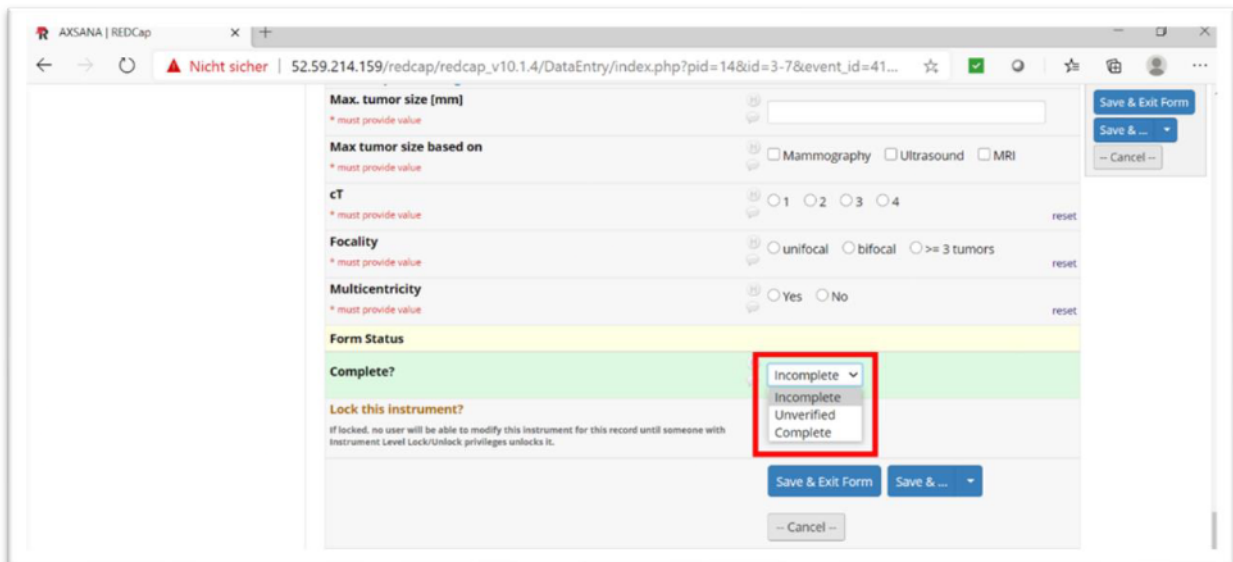
Side of breast cancer

Height [cm]

Weight [kg]

12.

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



AXSANA | REDCap

52.59.214.159/redcap/redcap_v10.1.4/DataEntry/index.php?pid=14&id=3-7&event_id=41...

Max. tumor size [mm]
* must provide value

Max tumor size based on
* must provide value

☐ Mammography ☐ Ultrasound ☐ MRI

cT
* must provide value

☐ 1 ☐ 2 ☐ 3 ☐ 4

Focality
* must provide value

☐ unifocal ☐ bifocal ☐ >= 3 tumors

Multicentricity
* must provide value

☐ Yes ☐ No

Form Status

Complete?

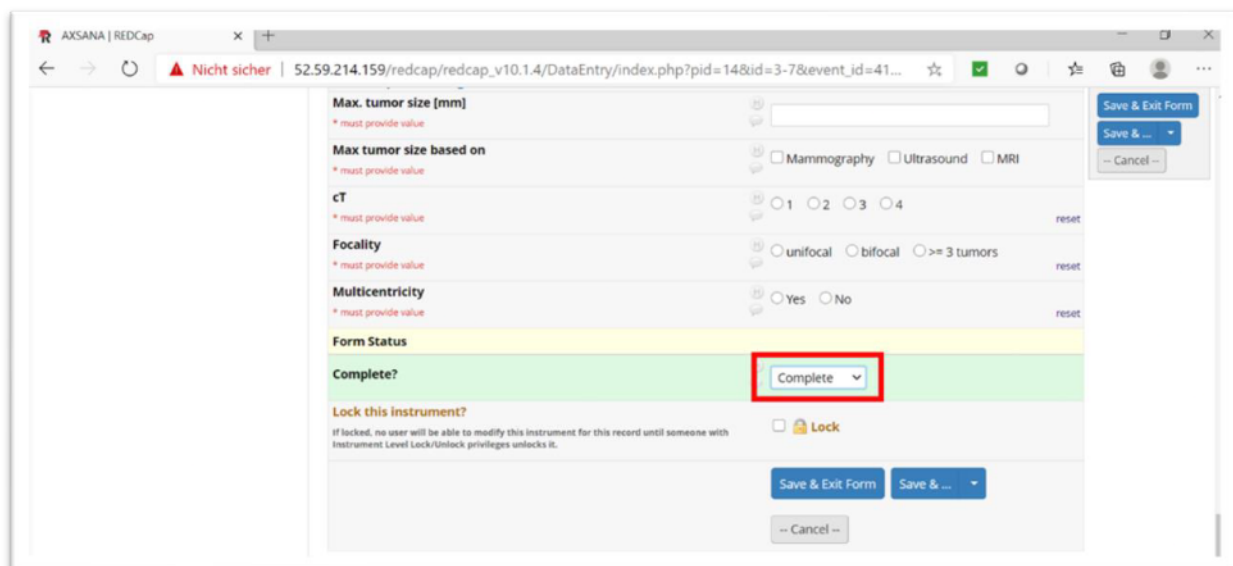
Incomplete
Incomplete
Unverified
Complete

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

13.

Once you have finished, choose “Complete”. Do not Lock the form – this will be done by the monitors as soon as they performed the plausibility checks.



AXSANA | REDCap

52.59.214.159/redcap/redcap_v10.1.4/DataEntry/index.php?pid=14&id=3-7&event_id=41...

Max. tumor size [mm]
* must provide value

Max tumor size based on
* must provide value

☐ Mammography ☐ Ultrasound ☐ MRI

cT
* must provide value

☐ 1 ☐ 2 ☐ 3 ☐ 4

Focality
* must provide value

☐ unifocal ☐ bifocal ☐ >= 3 tumors

Multicentricity
* must provide value

☐ Yes ☐ No

Form Status

Complete?

Complete
Complete
Unverified
Complete

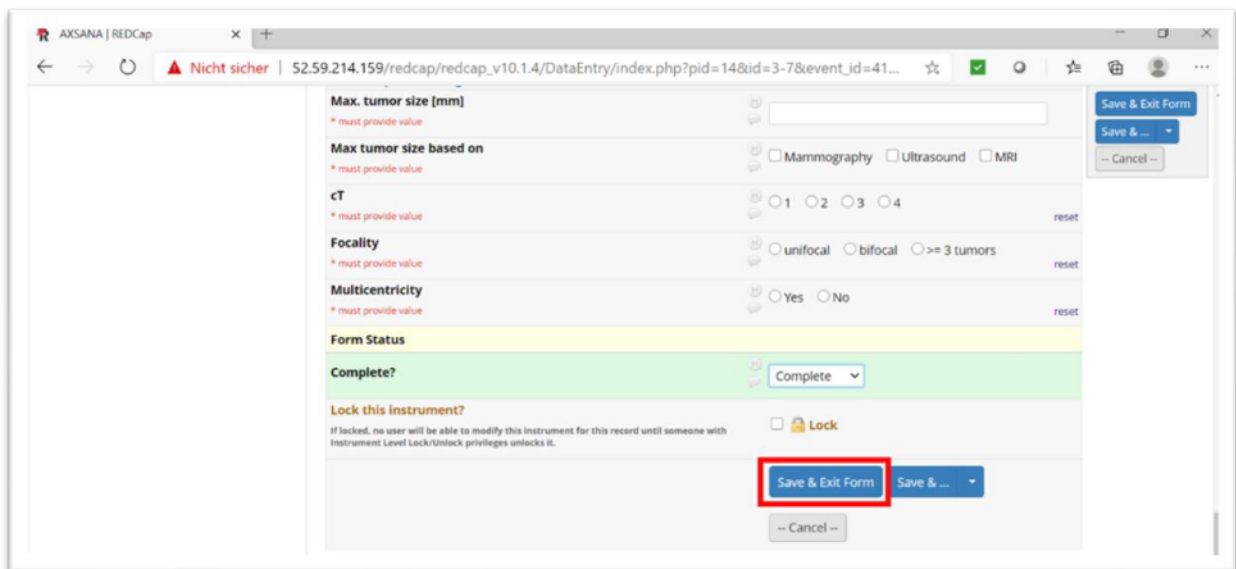
Lock this instrument?
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

☐ Lock

Save & Exit Form
Save & ...
Cancel














14.

Do not forget to save the form before leaving.







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: jursik@eubreast.com and shabbir@eubreast.com

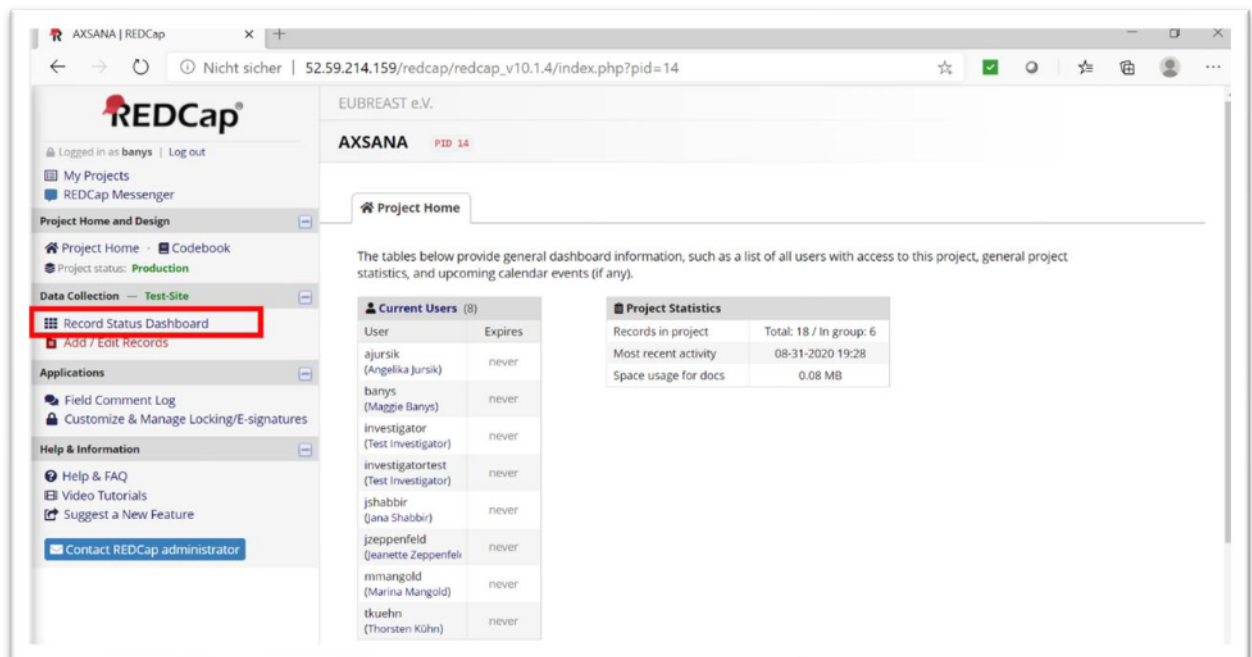
Data Collection Instrument	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	FU 1 year after surgery	FU 2-5 years after surgery
CRF 1a - Study entry: Status before neoadjuvant chemotherapy (NACT)							
CRF 1b - Study entry: Status before neoadjuvant chemotherapy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

Legend for status icons:

-  Incomplete
-  Incomplete (no data saved) ?
-  Unverified
-  Complete

16.

You can see all patients recruited by your study site by choosing “Record Status Dashboard”.



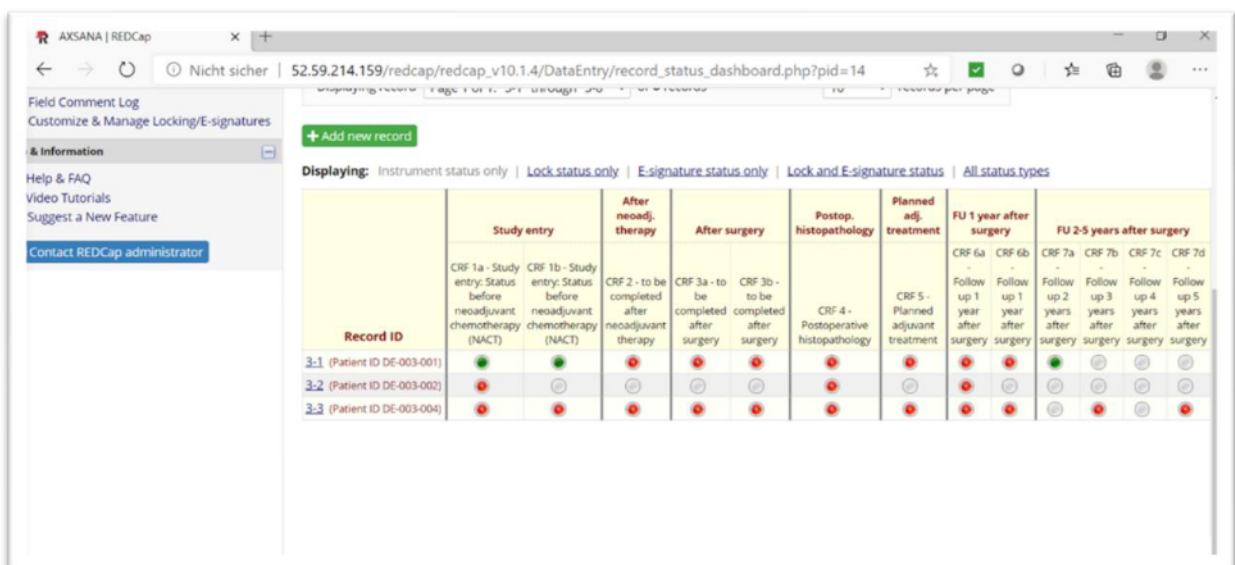
The screenshot shows the REDCap interface for the EUBREAST e.V. project. The left sidebar contains a menu with the following items: My Projects, REDCap Messenger, Project Home and Design, Project Home, Codebook, Project status: Production, Data Collection, Test-Site, Record Status Dashboard (highlighted with a red box), Add / Edit Records, Applications, Field Comment Log, Customize & Manage Locking/E-signatures, Help & Information, Help & FAQ, Video Tutorials, Suggest a New Feature, and Contact REDCap administrator. The main content area displays the Project Home page with a list of current users and project statistics.

User	Expires
ajursik (Angelika Jursik)	never
banyys (Maggie Banyys)	never
investigator (Test Investigator)	never
investigatortest (Test Investigator)	never
jshabbir (Jana Shabbir)	never
jzeppenfeld (Jeannette Zeppenfeld)	never
mmangold (Marina Mangold)	never
tkuehn (Thorsten Kühn)	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

17.

Now you can see all CRF forms of all patients.



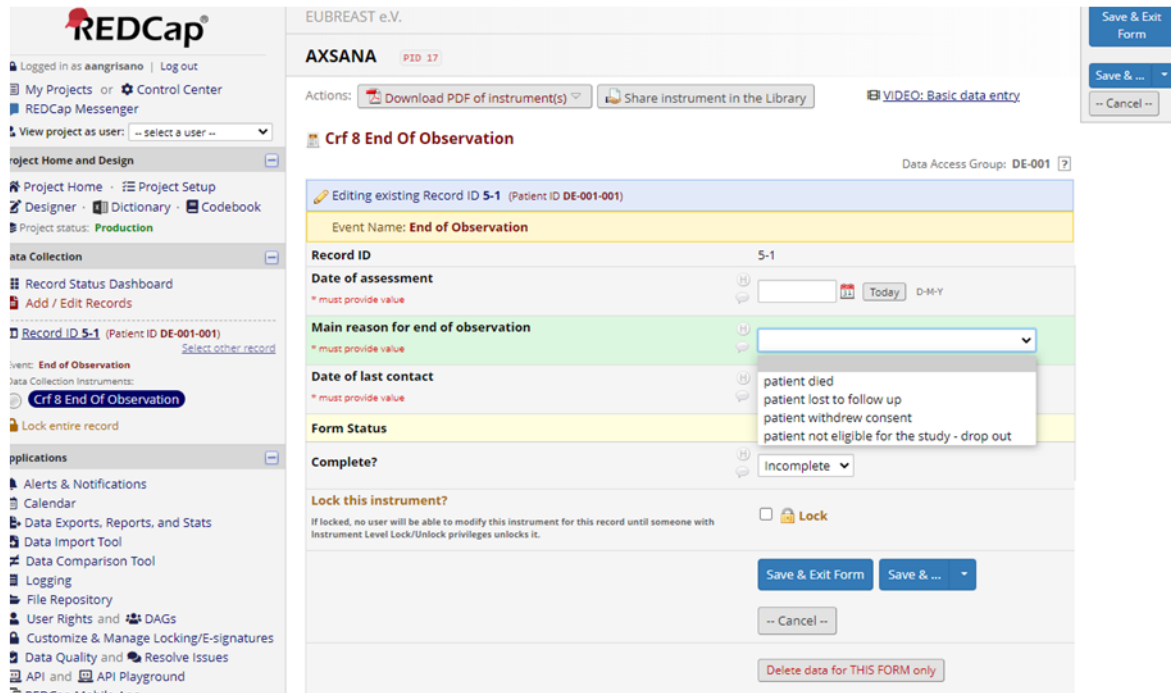
The screenshot shows the REDCap Record Status Dashboard for the EUBREAST e.V. project. The interface displays a table of patient records and their CRF form completion status. The table has columns for Record ID, Study entry, After neoadj. therapy, After surgery, Postop. histopathology, Planned adj. treatment, and Follow-up. The table shows three patients (3-1, 3-2, 3-3) and their completion status for various CRF forms.

Record ID	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	Follow-up
3-1 (Patient ID DE-003-001)	CRF 1a - 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
3-2 (Patient ID DE-003-002)	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
3-3 (Patient ID DE-003-004)	CRF 1a - 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

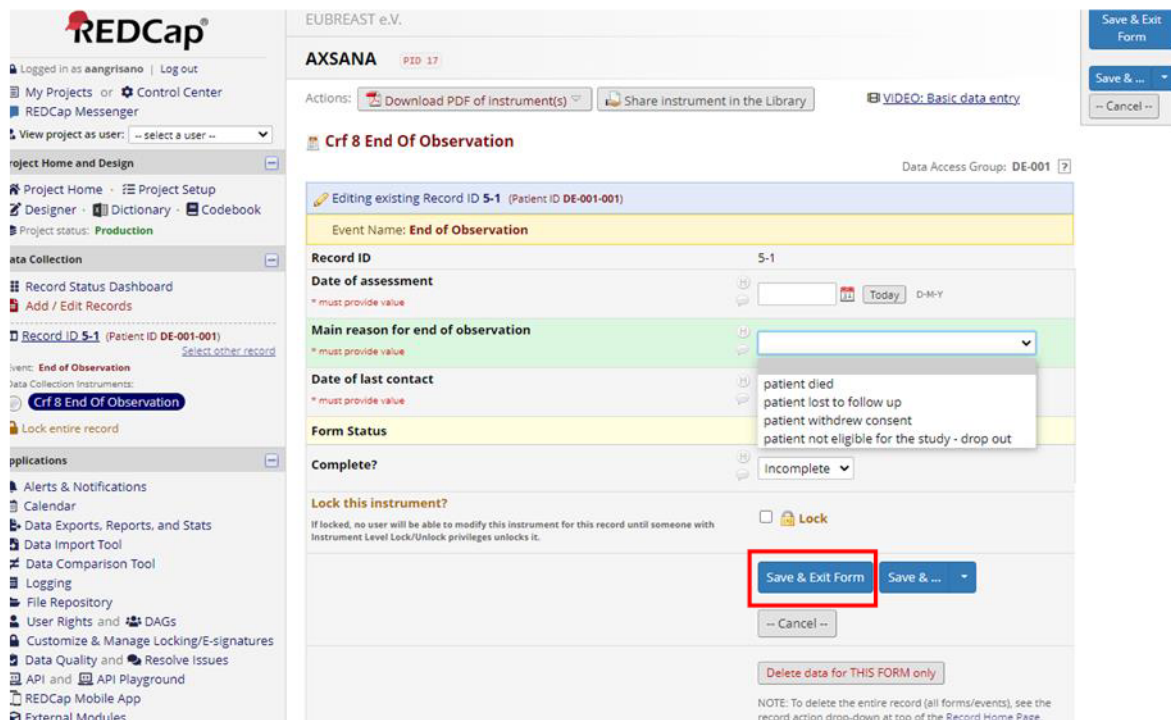
18.

The eCRF includes a page called “End of observation”. Please document all patients in this section that leave the study, due to withdrawal, death, drop out, or lost to follow up.

Fill in the form and choose a cause for “End of Observation”.



19. Do not forget to save the form before leaving.



19.

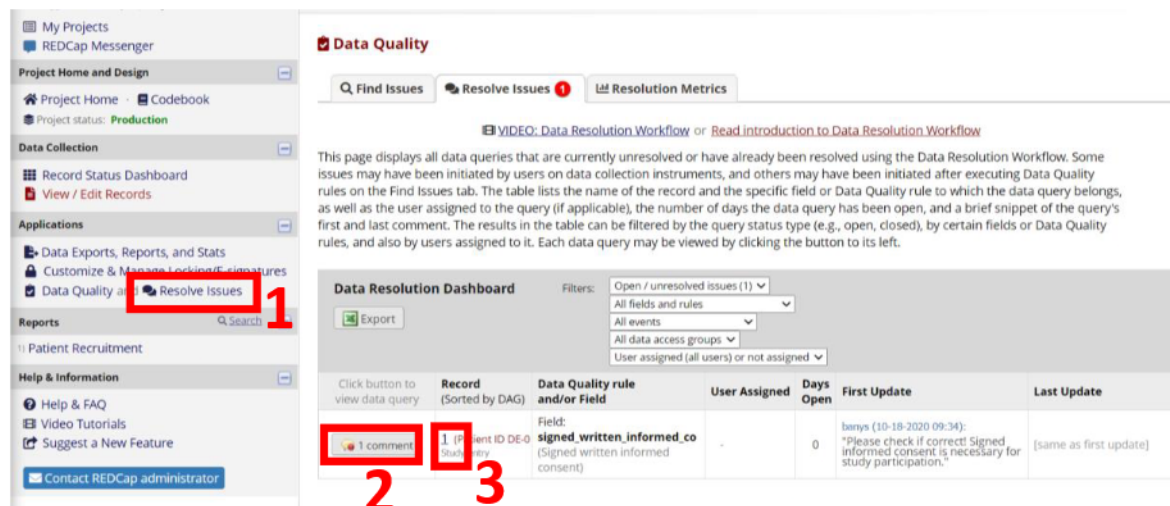
In case of inconclusive or missing data, you might receive a query from one of the monitors. Forms with open queries are shown as yellow.

Data Collection Instrument	Study entry	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 ID	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adj. treatment	FU 1 year after surgery	FU 2-5 years after surgery
1 (Patient ID 111111111111)							
5-1 (Patient ID DE-001-001)							

20.

To see all queries/comments, first click on “Resolve Issues” (No. 1 in the screenshot below) and afterwards on the query/comment you would like to see (No. 2). To see the CRF form the query refers to click on the Record Number (No. 3).



Data Quality

Find Issues | Resolve Issues | 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 (1) | 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-001-001)	Field: signed_written_informed_co (Signed written informed consent)		0	banys (10-19-2020 09:34): "Please check if correct! Signed informed consent is necessary for study participation."	[same as first update]


21.

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.


Editing existing Record ID 1 (Patient ID DE-001-001)

Event Name: After neoadj. therapy


Record ID 1

Quality of life questionnaires completed by the patient within 4 weeks before surgery?  Yes No rese

* must provide value

Neoadjuvant systemic therapy administered  Yes No rese

* must provide value

Planned axillary staging  rese

* must provide value

☒ ALND (Axillary lymph node dissection)
☐ TAD (Targeted axillary dissection = SLNB + TLNB)
☐ SLNB (Sentinel lymph node biopsy)
☐ TLNB (Target lymph node biopsy)
☐ other


22.

Once you have checked or corrected the data in the CRF form, you can respond to the query.

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.

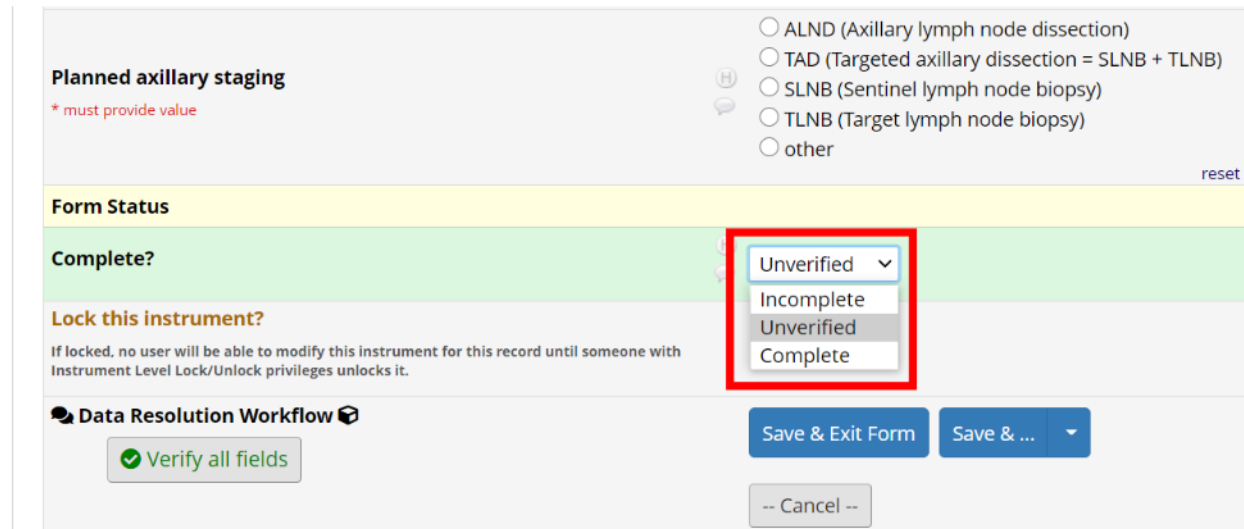
Record ID: 1
 Event: Study entry
 Field: signed_written_informed_co ("Signed written informed consent")
 Status:  Open / Unresolved (unresponded)

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)'
10-18-2020 09:36	banys	<input checked="" type="radio"/> Reply with response: -- choose response -- Upload file (optional): -- choose response -- — OR — <input type="radio"/> Close the query Comment: <div> Corrected - Data missing Corrected - Typographical error Corrected - Wrong source used Verified - Confirmed correct (no error) Other </div>

Respond to query Cancel

23.

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.



Planned axillary staging
* must provide value

☐ ALND (Axillary lymph node dissection)
☐ TAD (Targeted axillary dissection = SLNB + TLNB)
☐ SLNB (Sentinel lymph node biopsy)
☐ TLNB (Target lymph node biopsy)
☐ other

Form Status

Complete? Unverified

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.

Data Resolution Workflow

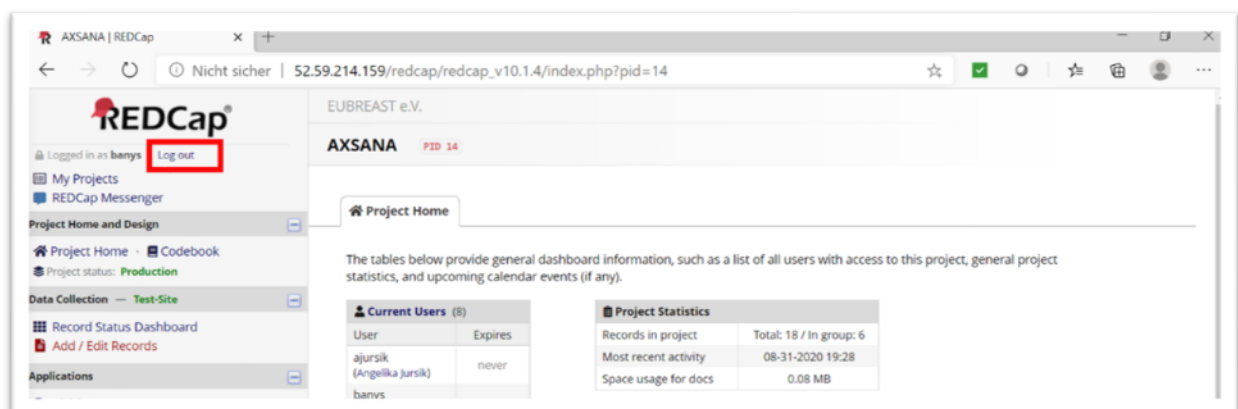
Verify all fields

Save & Exit Form Save & ...

-- Cancel --

24.

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



AXSANA | REDCap

Logged in as banys Log out

My Projects
REDCap Messenger

Project Home and Design

Project Home Codebook
Project status: Production

Data Collection Test-Site

Record Status Dashboard
Add / Edit Records

Applications

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).

Current Users (8)	
User	Expires
ajursik	never
(Angelika Jursik)	
banys	

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

In case of questions concerning the use of eCRF, you can contact:

Ms. A. Jursik: jursik@eubreast.com

Ms. J. Shabbir: shabbir@eubreast.com

PD Dr. M. Banys-Paluchowski: m.banys@outlook.com

Dr. S. Hartmann: steffi.hartmann@kliniksued-rostock.de