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.

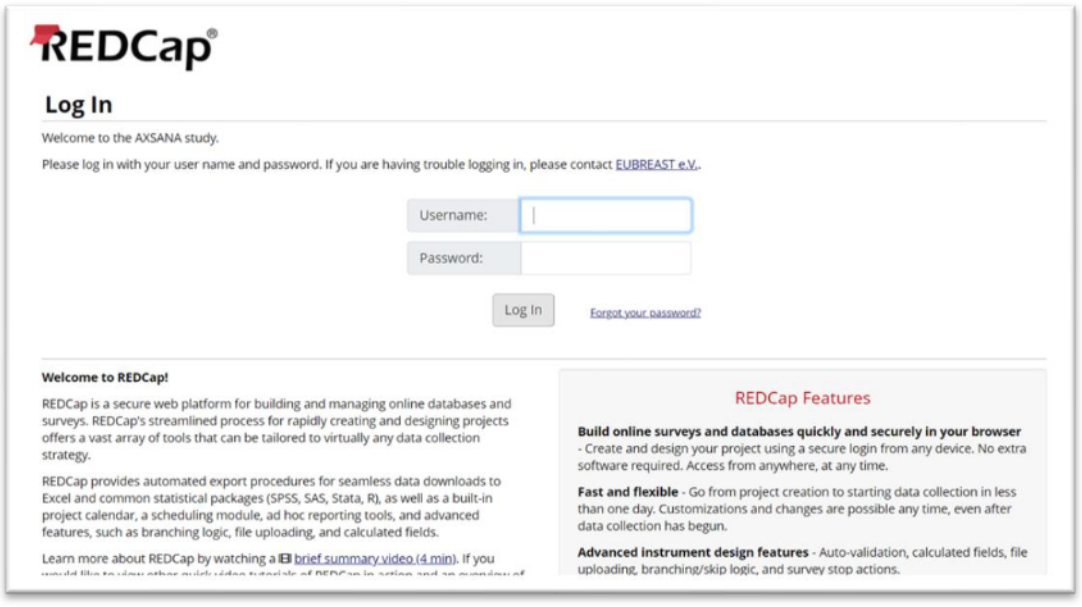
Updated version of user manual includes: “End of observation”. Please document all patients in this section that leave the study, due to withdrawal, death, drop out, or lost to follow up.

2.

Open the eCRF at:

https://eubreast-axsana.com/

3.

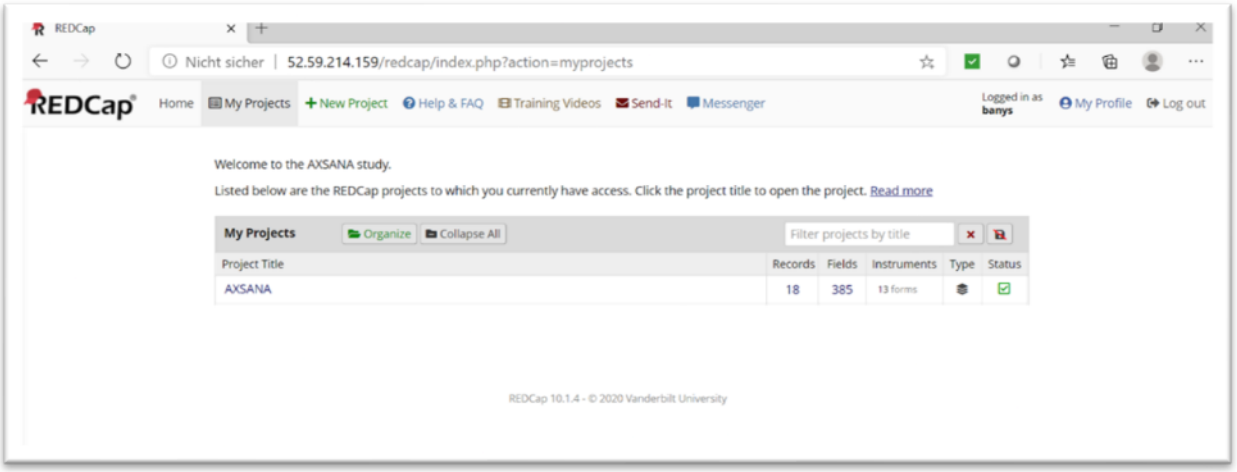


Log in using your personal username and password.

4.

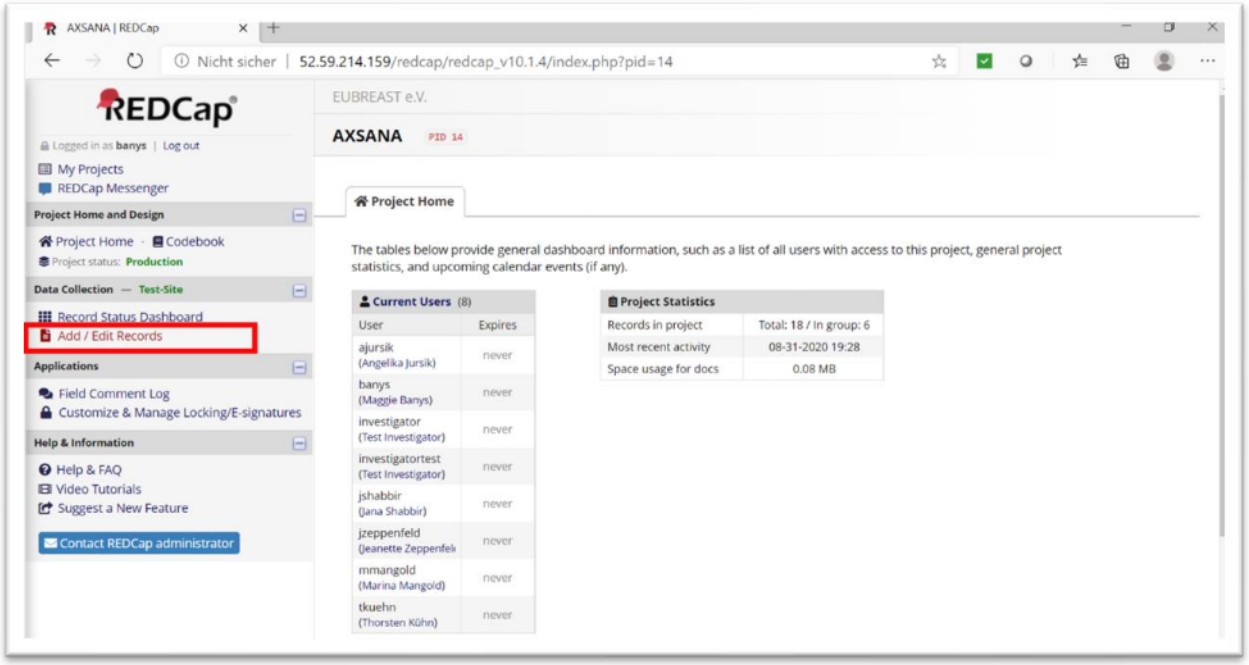
Now you can see the list of open projects. Choose AXSANA.

Do not click on “New Project”.



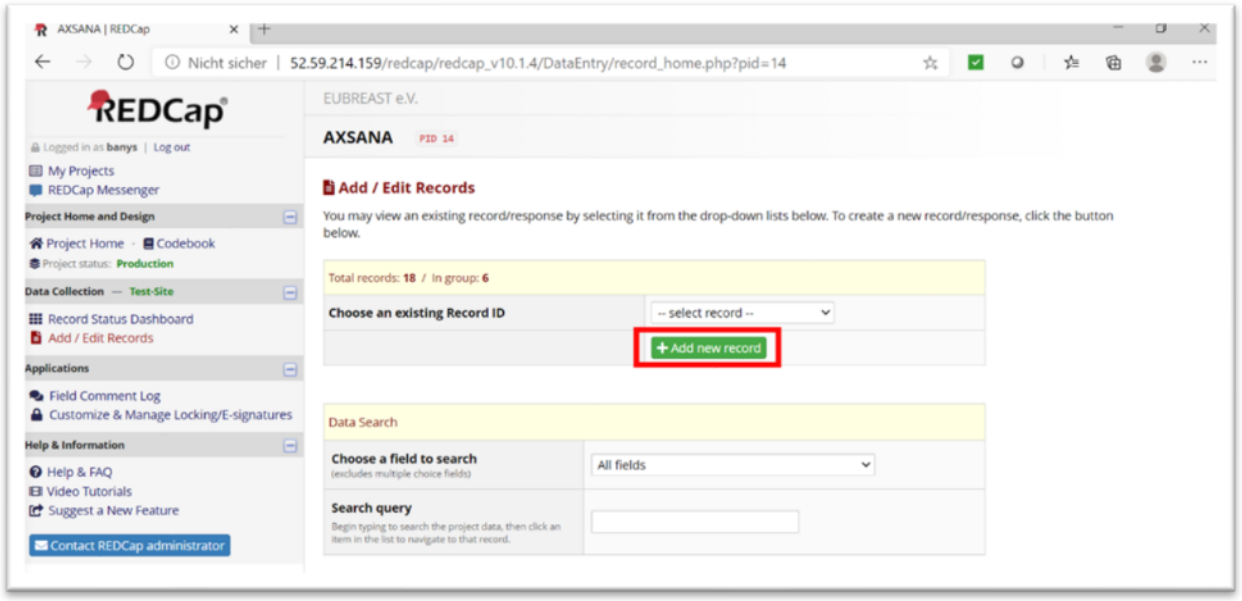
5.

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



6.

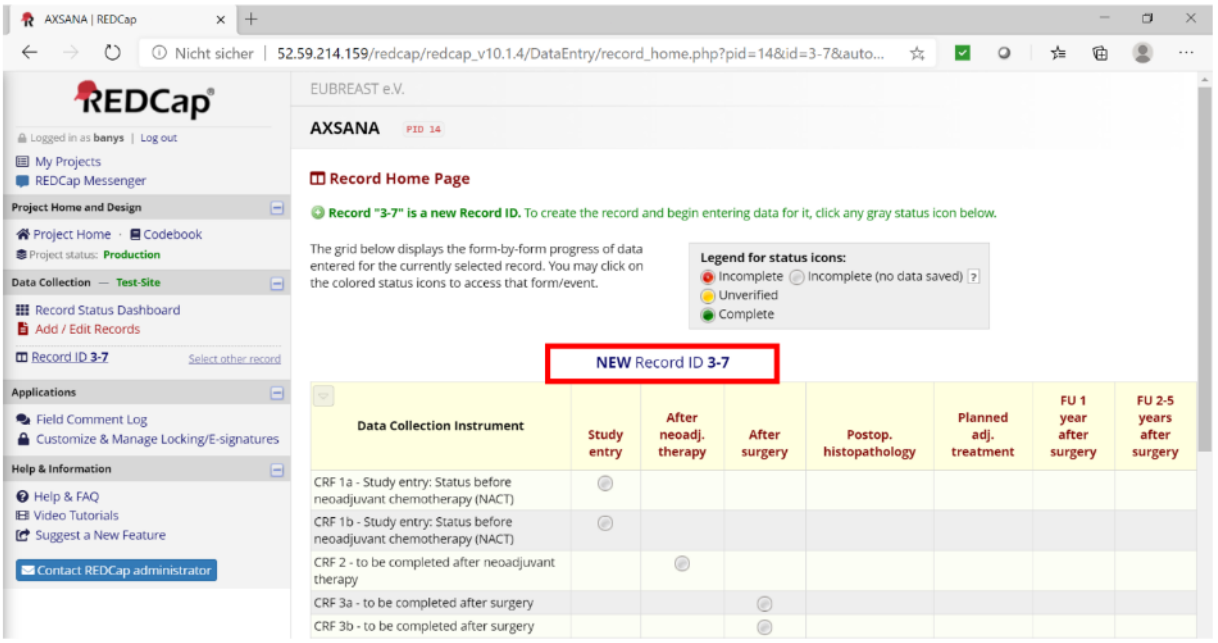
To add a new patient, choose “Add new record”.



7.

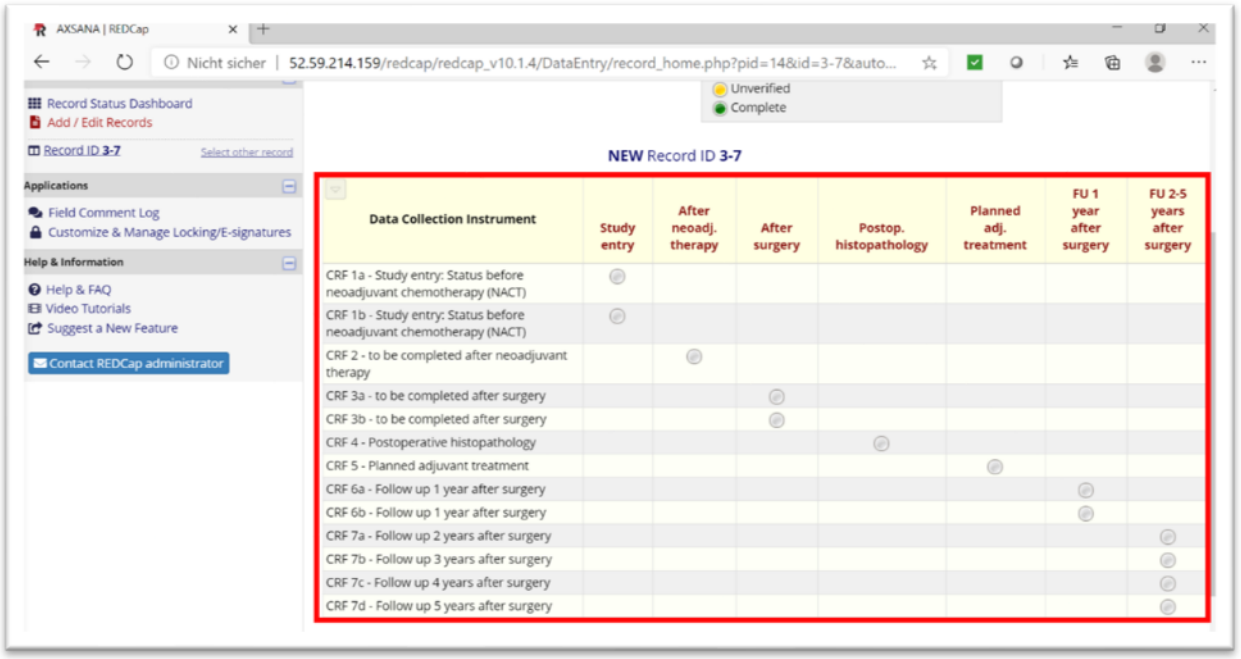
A new patient has been created.

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



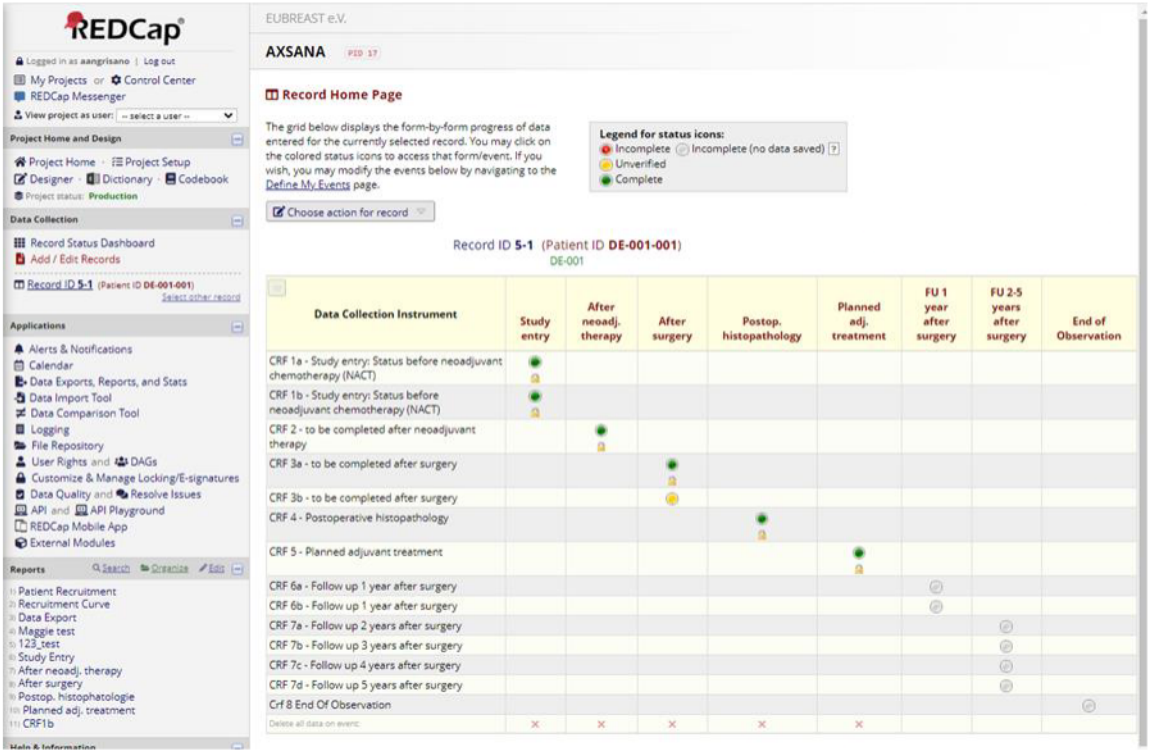
8.

Now you can see all CRF forms of your patient.



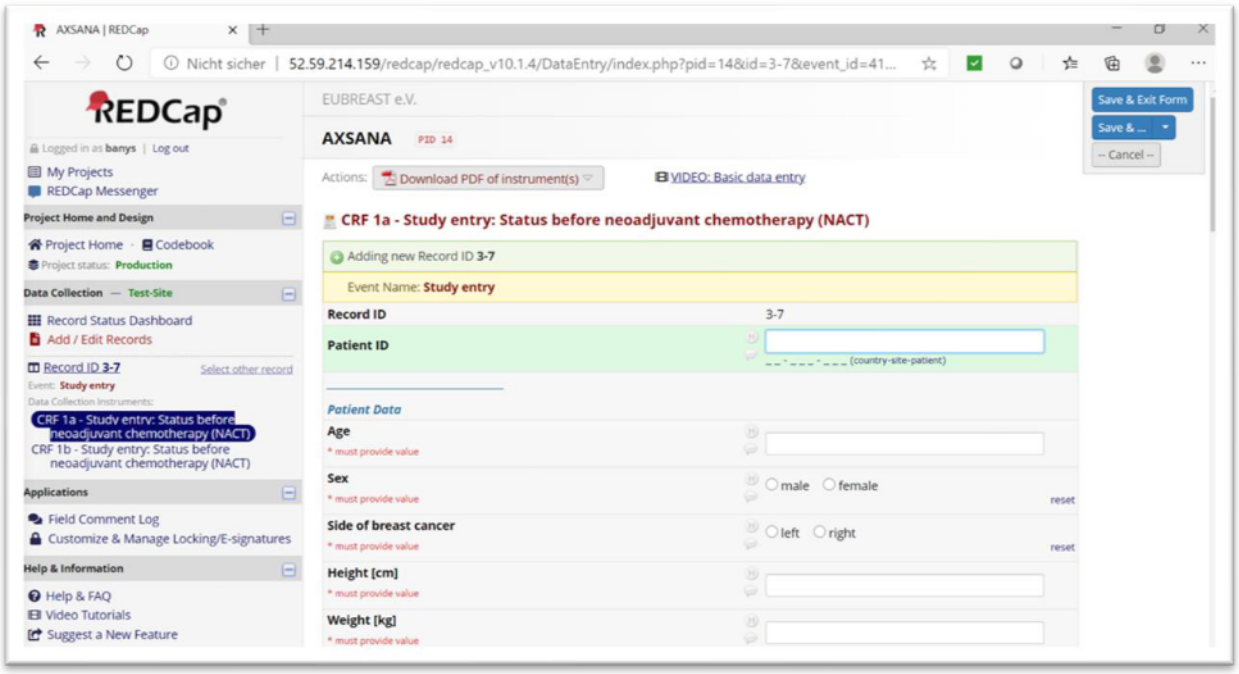
9.

Choose the form you would like to open.



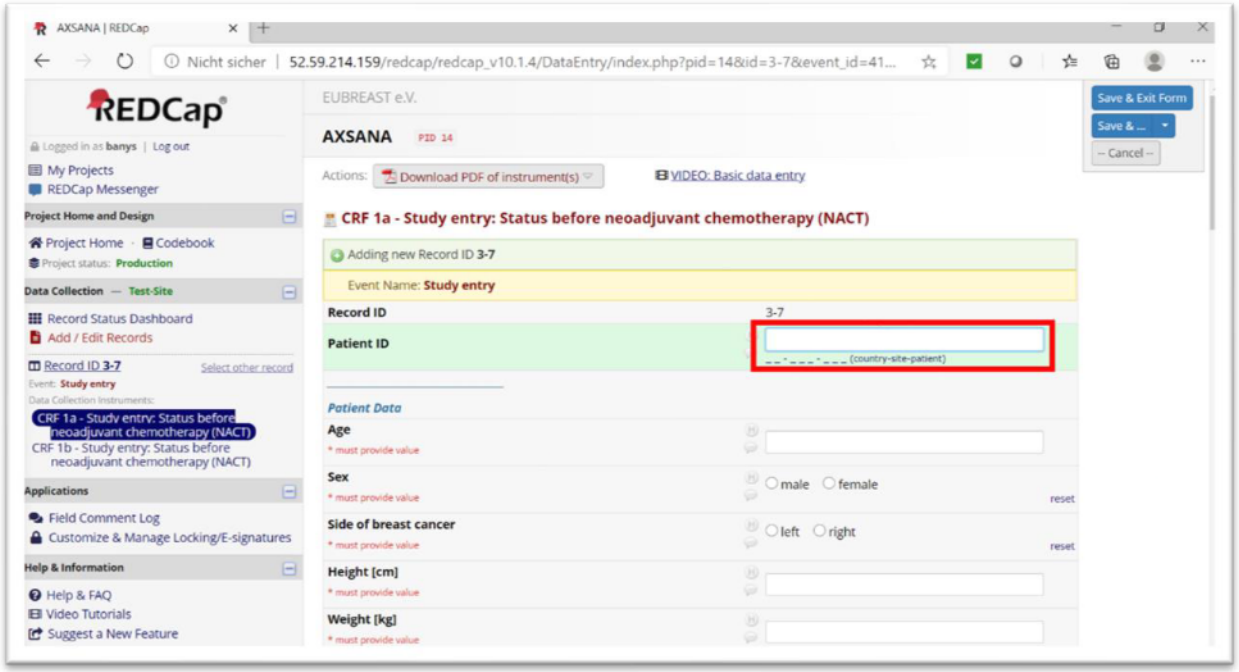
10.

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



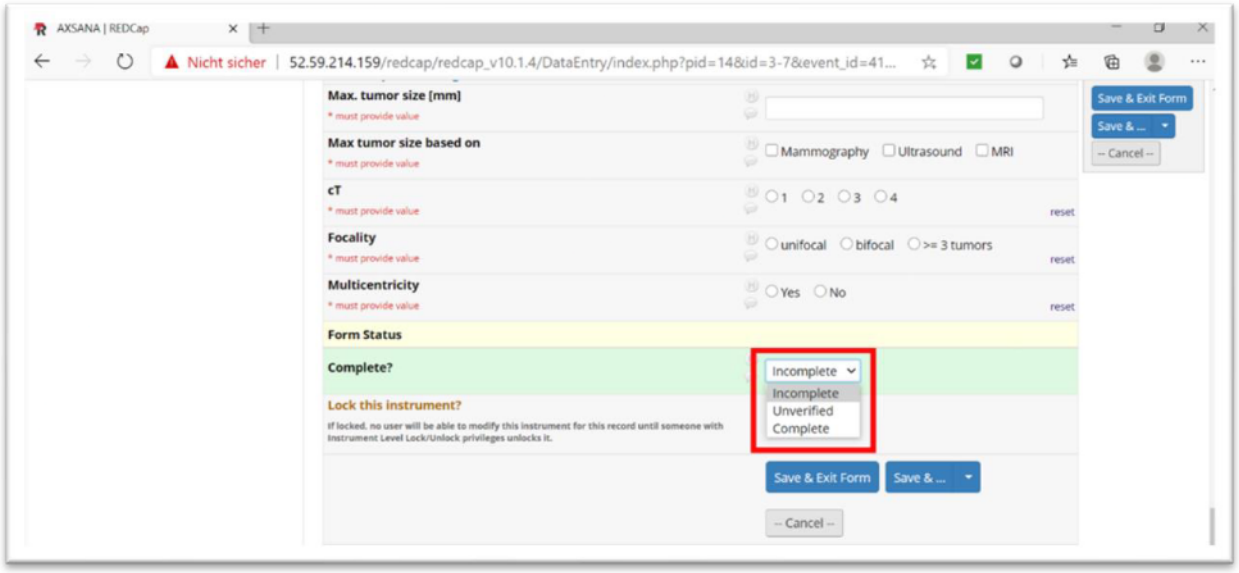
11.

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



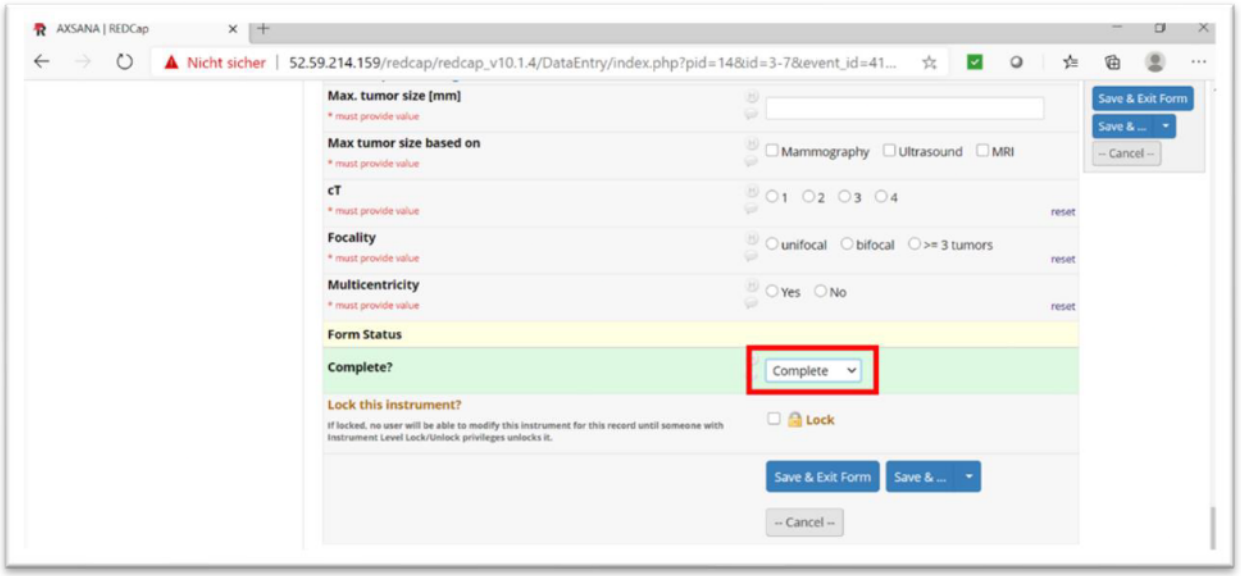
12.

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



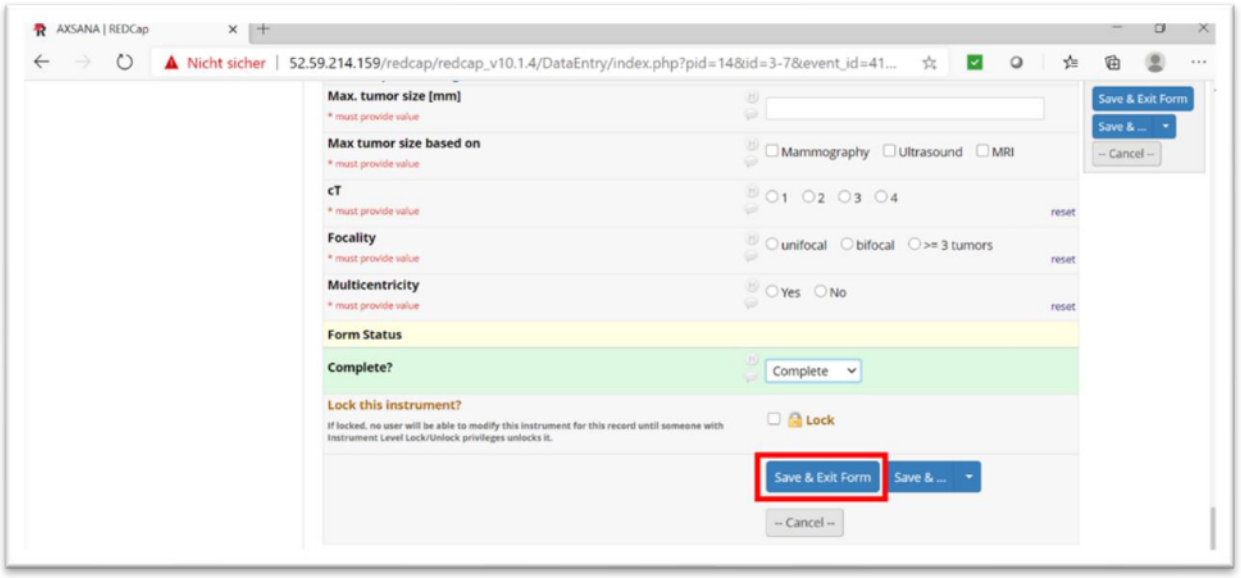
13.

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



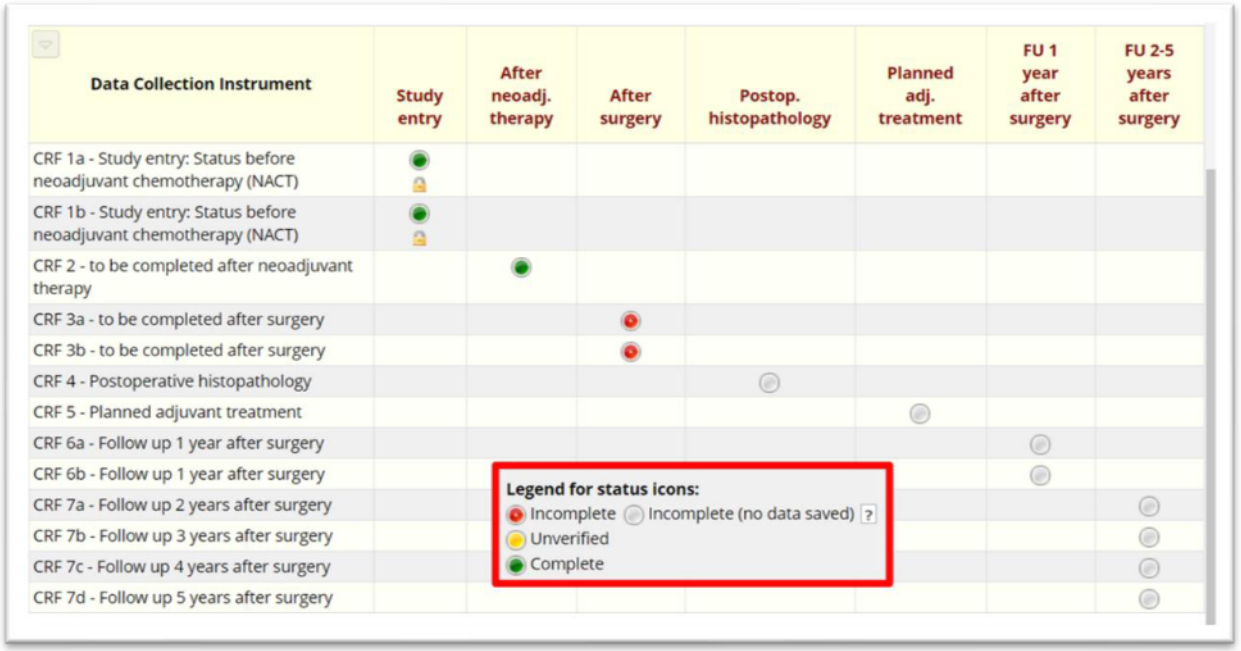
14.

Do not forget to save the form before leaving.



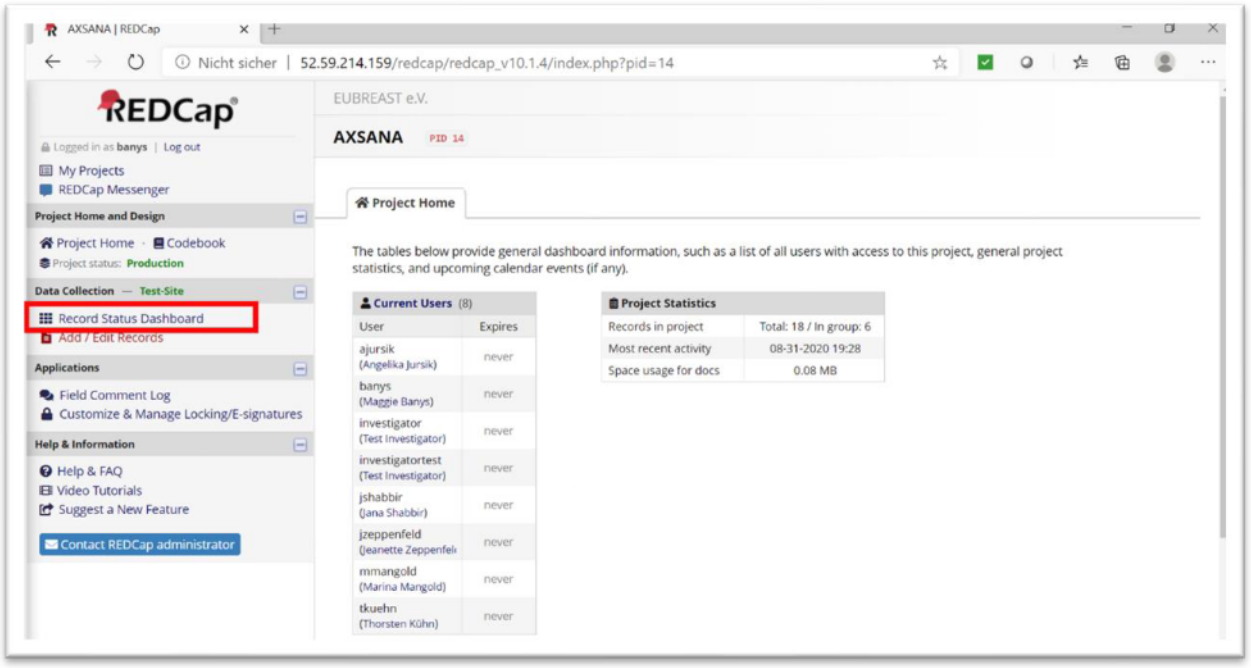
15.

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



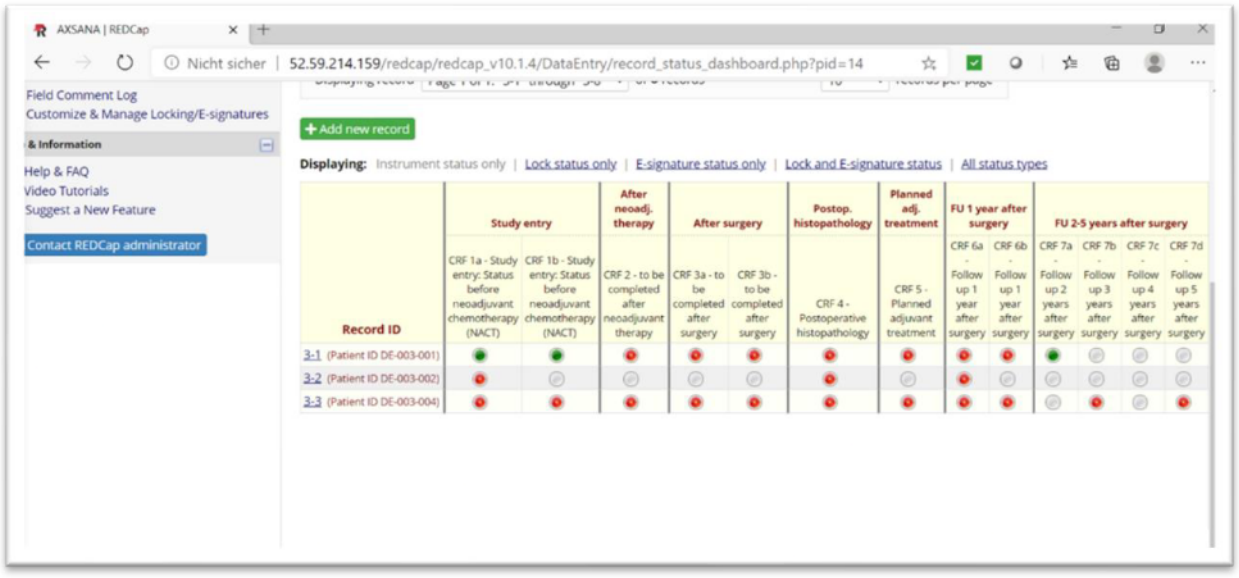
16.

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



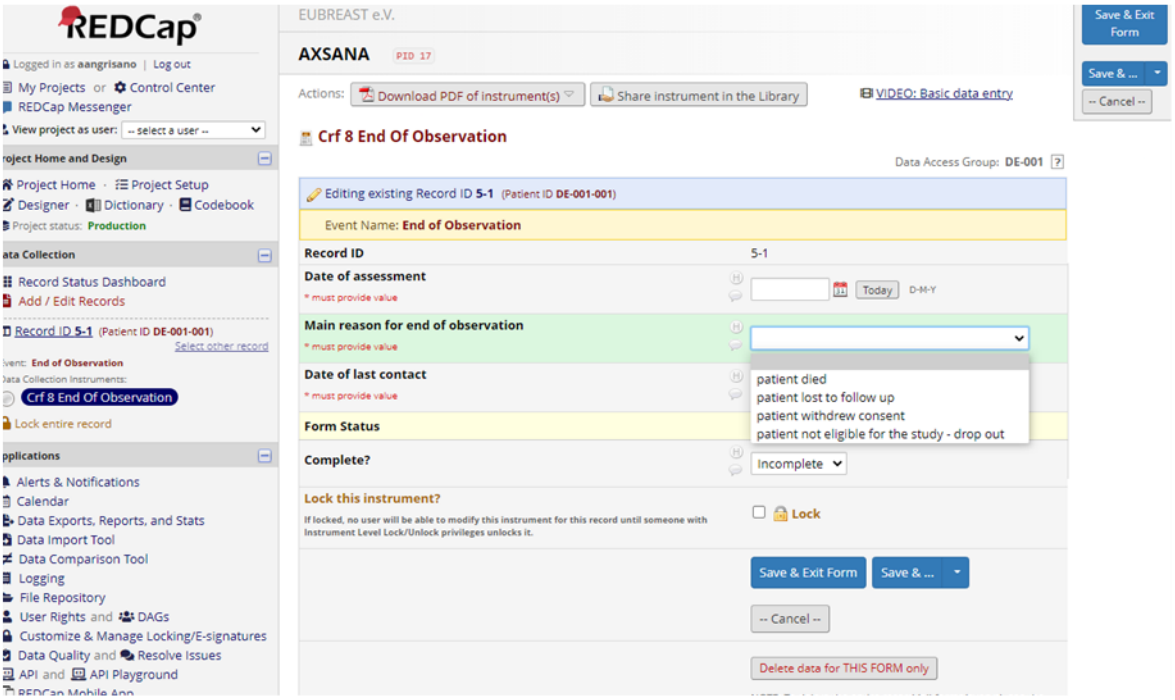
17.

Now you can see all CRF forms of all patients.

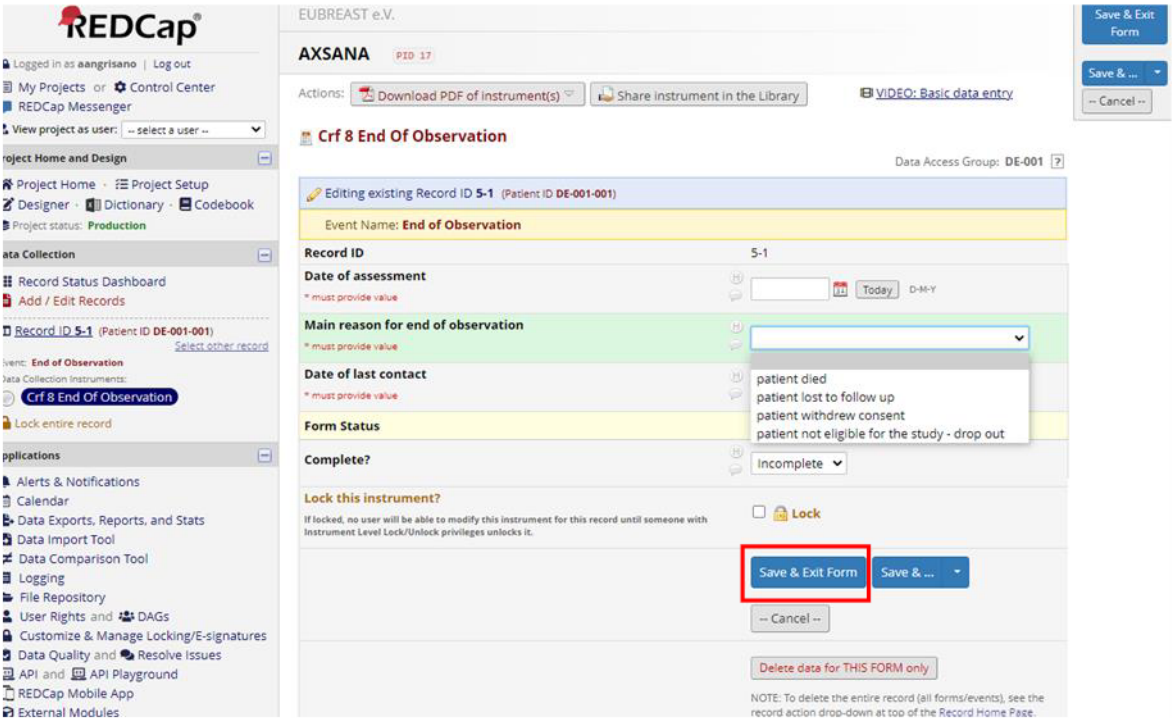


18.

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.

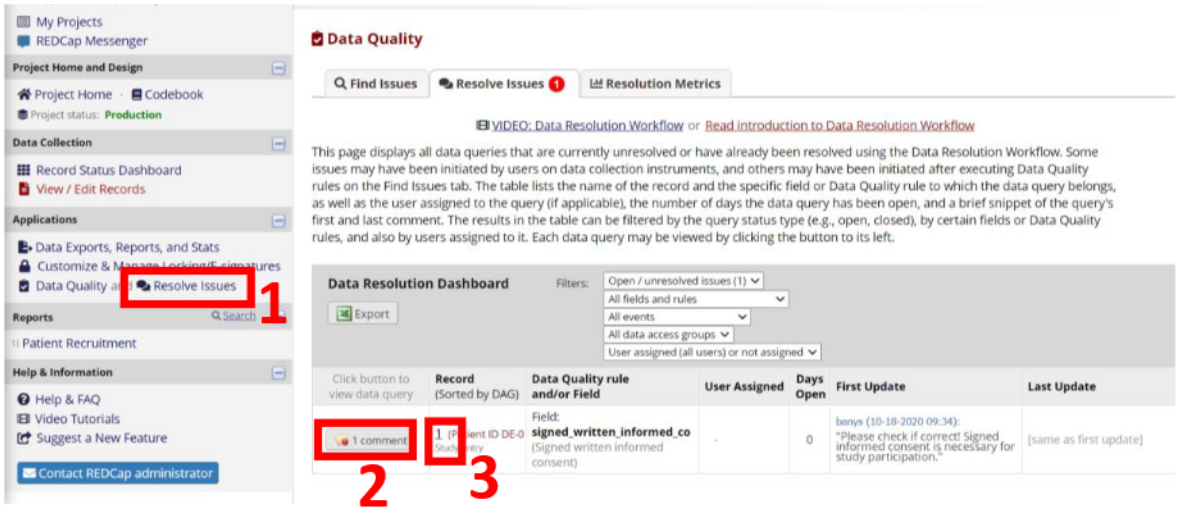
In case of inconclusive or missing data, you might receive a query from one of the monitors. Forms with open queries are shown as yellow.

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			
	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 11111111111)													
5-1 (Patient ID DE-001-001)													

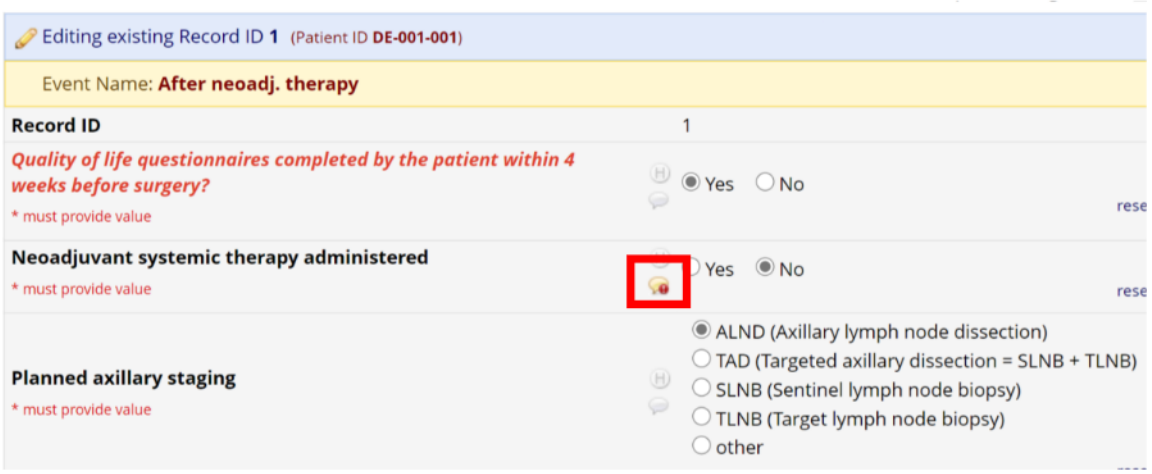
20.

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).



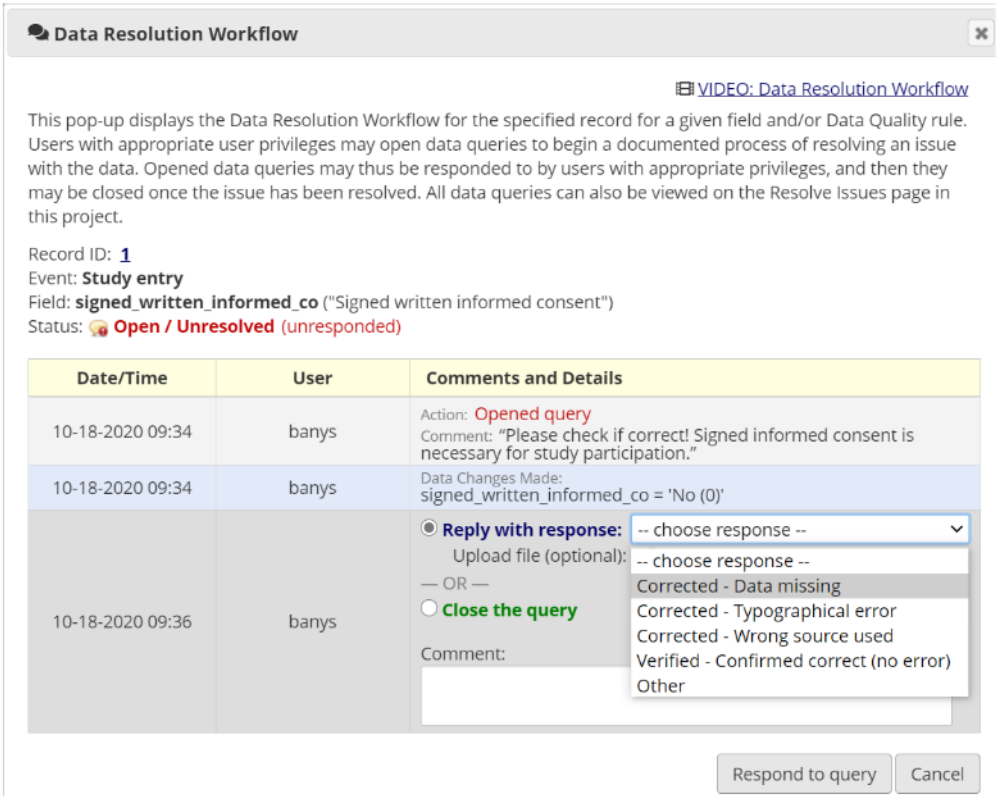
21.

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



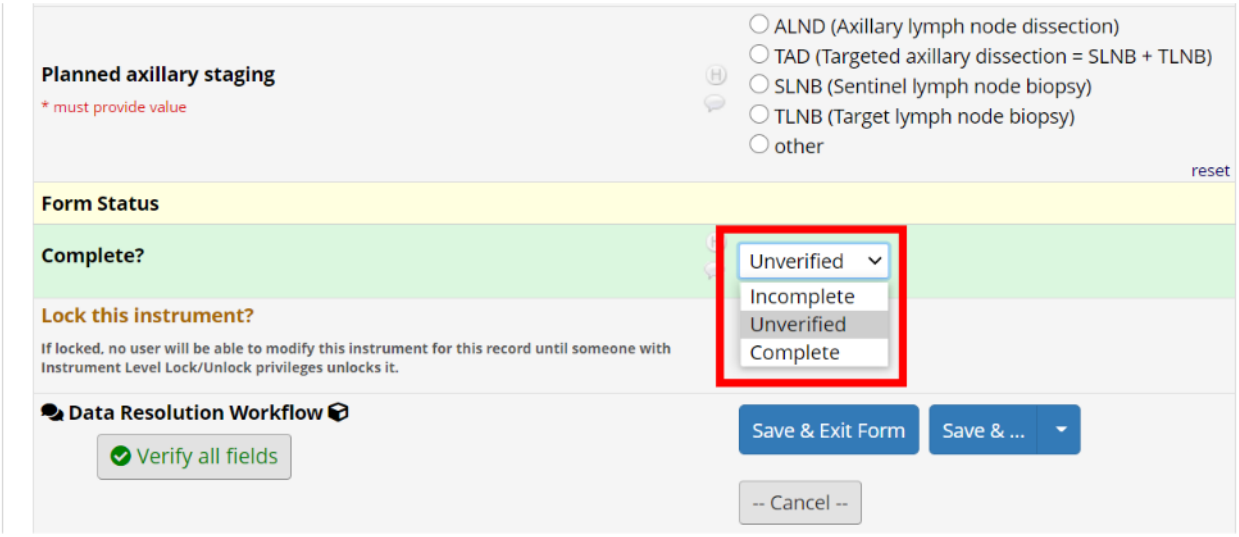
22.

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



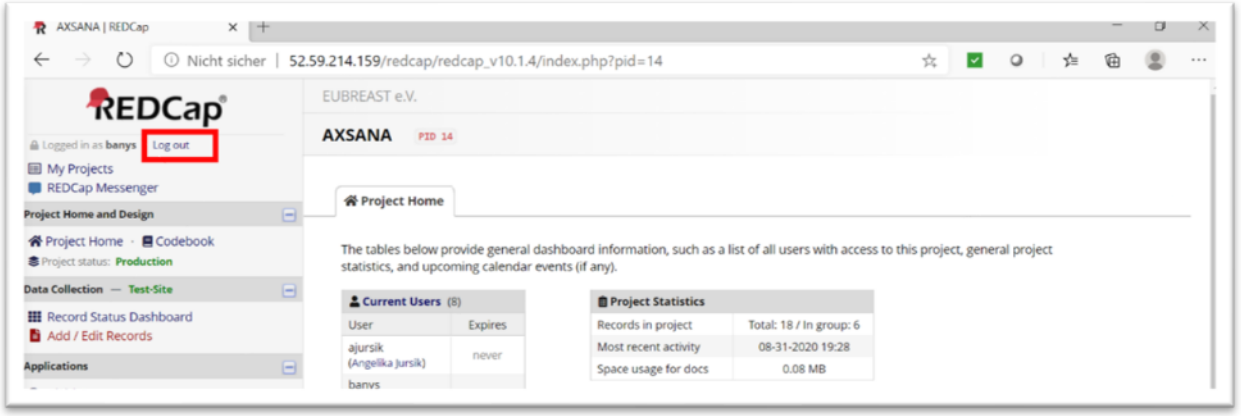
23.

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.



24.

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



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