

GRAnulomatous MAstitis REGistry study

(EUBREAST-15)

NCT07422870

A retrospective / prospective Cohort Study to evaluate the Incidence, Diagnostic Features, Clinical Course and Treatment Strategies in histologically confirmed Idiopathic Granulomatous Mastitis

eCRF USER MANUAL
for Study Sites

1.

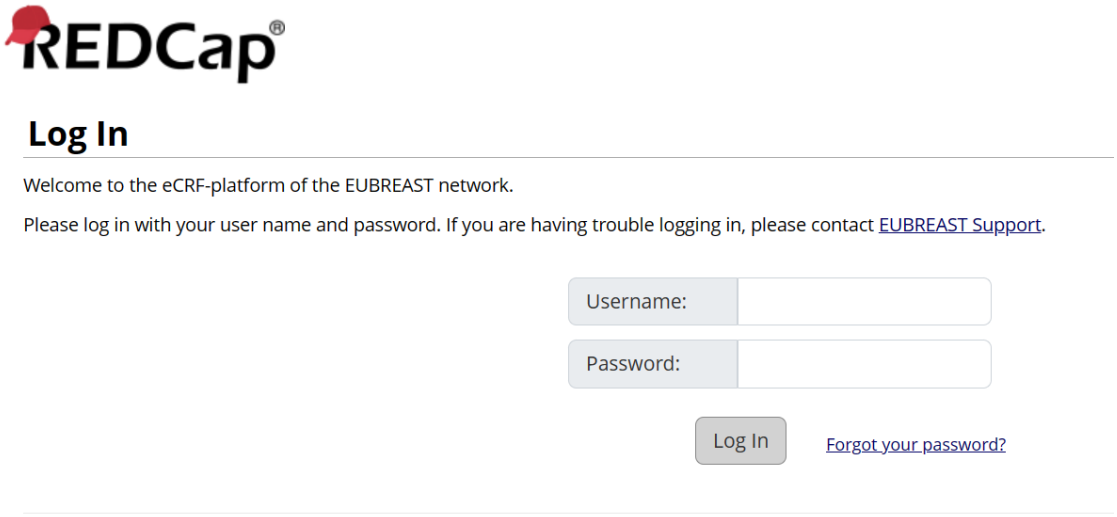
Each study site staff member receives his/her own login and password. In order to receive login credentials, fill in the Signature & Delegation Log (available at https://www.eubreast.org/gramareg/ and follow the instructions at the bottom of page 1. Each study site staff member will receive an e-mail with login information separately.

2.

Open the eCRF at:

https://eubreast-axsana.com

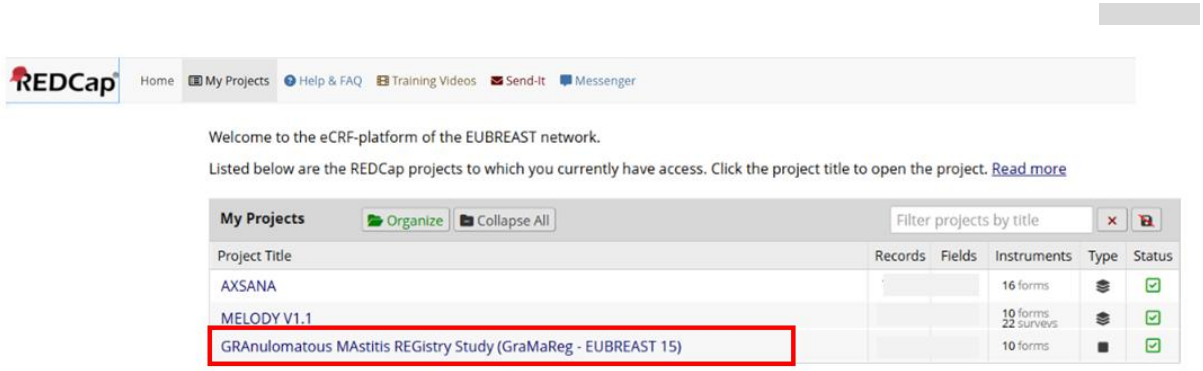
3.



Log in using your personal username and password.

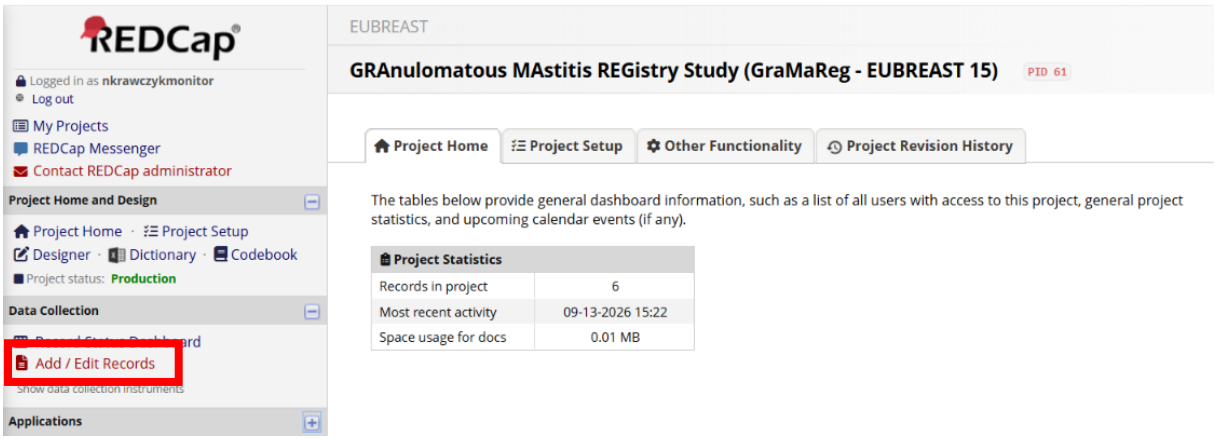
4.

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



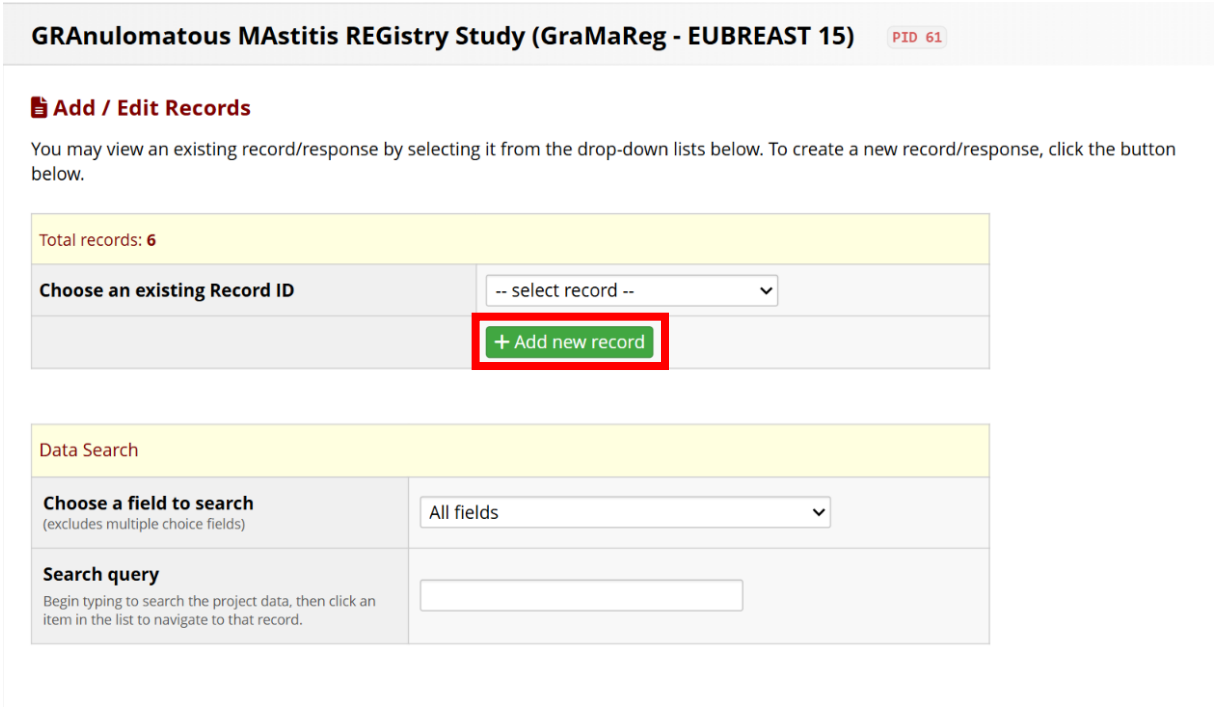
5.

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



6.

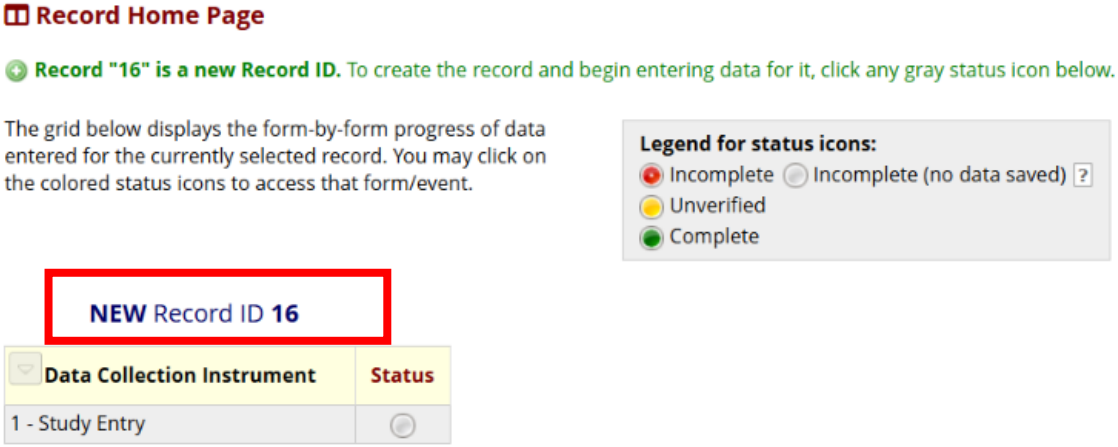
To add a new patient, choose “Add new record”.



7.

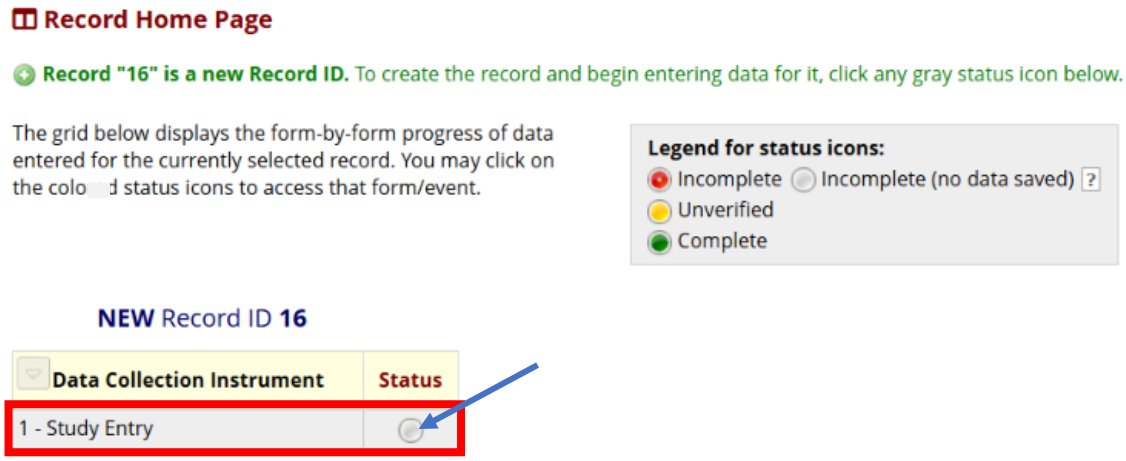
A new patient has been created.

Please keep in mind that the Record ID (in our example: 16) is a record number created by RedCap and it is <u>not</u> the Patient-ID!



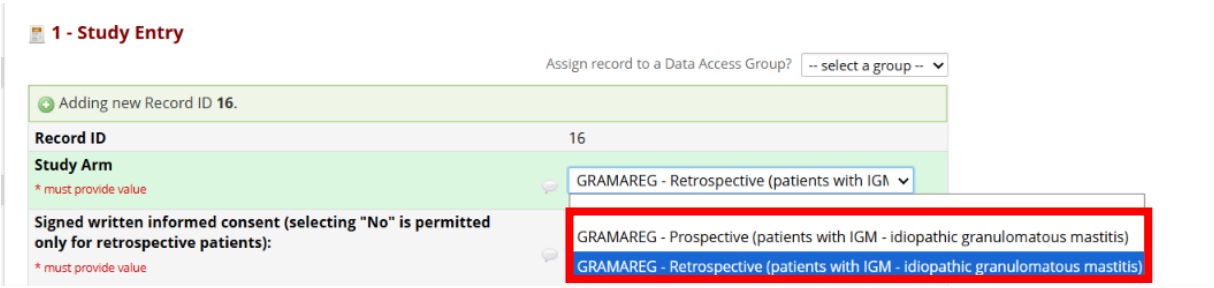
8.

At the beginning, you can only see the “Study Entry” form. Please open the “Study Entry” form by clicking the gray button.



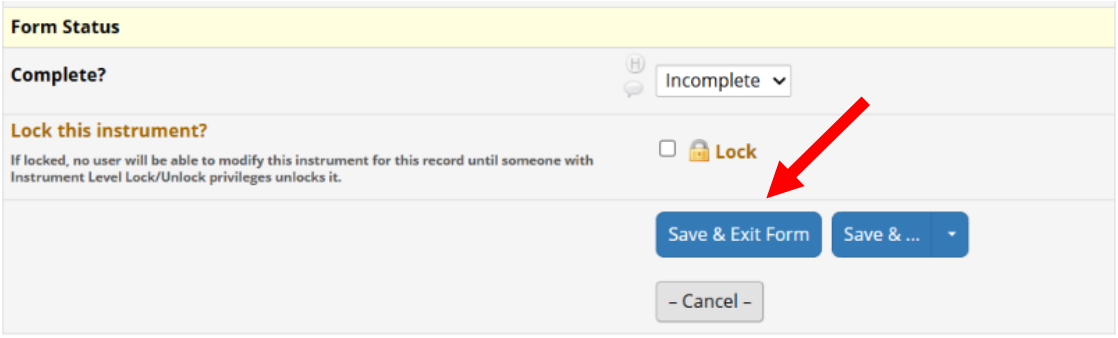
9.

Choose one of the following study arms: retrospective or prospective.



10

As soon as you have chosen the study arm and saved the form by clicking “Save & Exit Form” at the bottom of the page, you will be able to see all CRF forms for your patient.



11.

The number of CRF forms depends on the selected study arm.

CRF forms for the retrospective study arm: CRF forms for the prospective study arm:

Record ID **16**

Data Collection Instrument	Status
1 - Study Entry	
2a - Onset of current episode	
3 - Treatment	
4 - End of treatment	
5a - Post-treatment Outcome	
8 - End of Observation	

Record ID **16**

Data Collection Instrument	Status
1 - Study Entry	
2a - Onset of current episode	
3 - Treatment	
4 - End of treatment	
5 - Follow up after 1 year	
6 - Follow up after 3 years	
7 - Follow up after 5 years	
8 - End of Observation	

11.

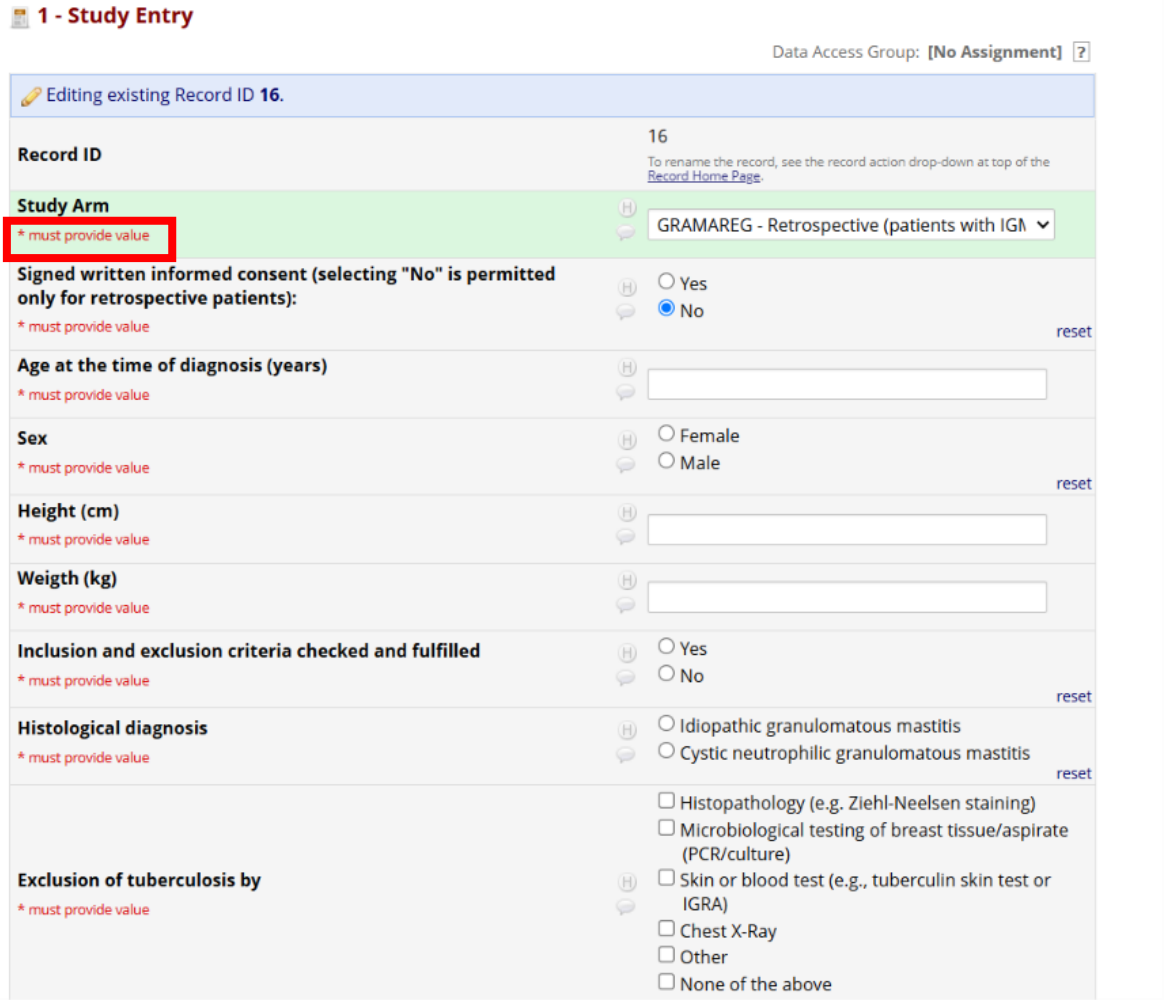
Choose the form you would like to open.

Record ID **16**

Data Collection Instrument	Status
1 - Study Entry	
2a - Onset of current episode	
3 - Treatment	
4 - End of treatment	
5 - Follow up after 1 year	
6 - Follow up after 3 years	
7 - Follow up after 5 years	
8 - End of Observation	

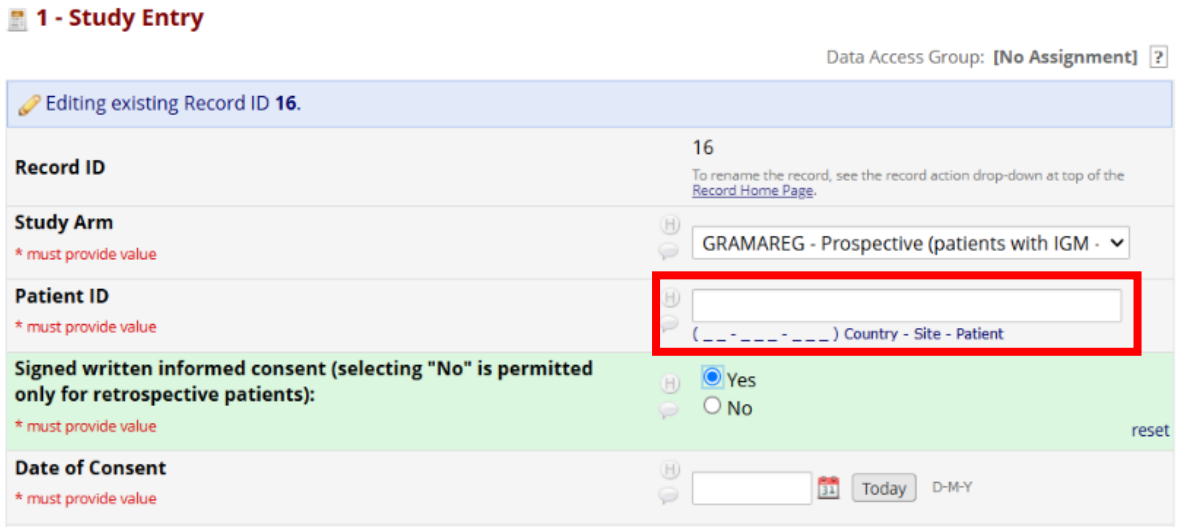
12.

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



13.

If you have chosen the prospective study arm, do not forget to enter the Patient ID that you created according to the instructions in the Subject & Identification Log (Country Code – Site ID – consecutive patient number).

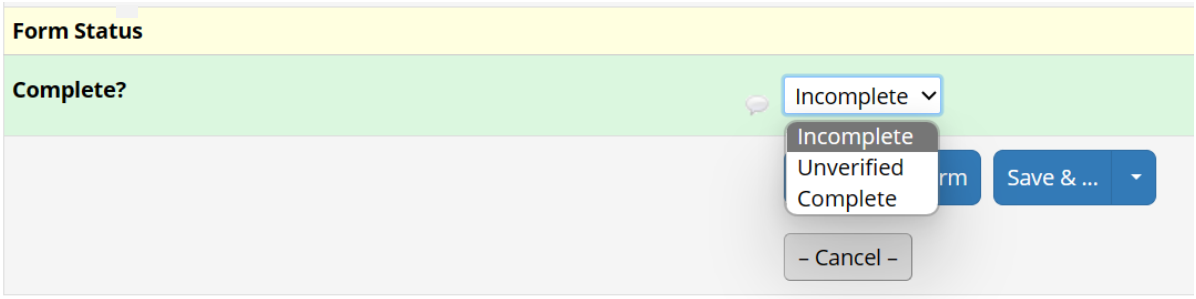


For the retrospective study arm, there is no ‘Patient ID’ field, as the data are collected anonymously.



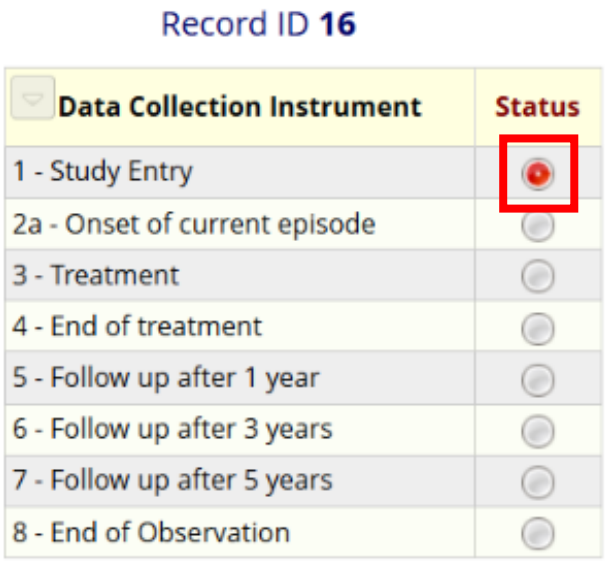
14.

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

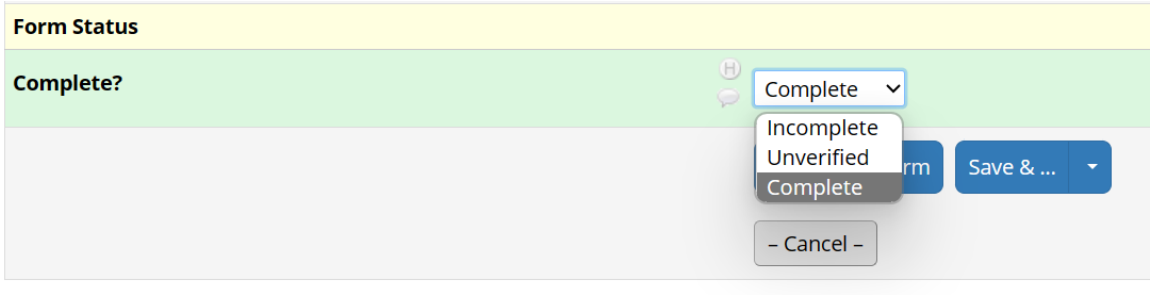


15.

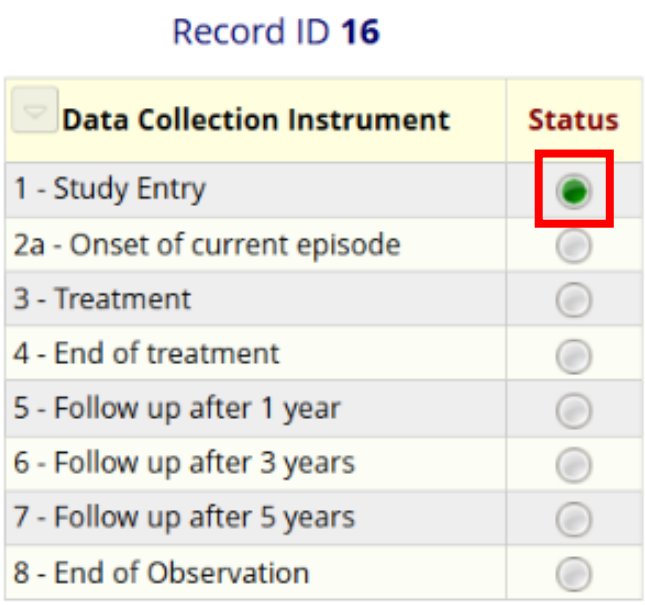
If you have saved the form as “Incomplete,” the CRF form will be displayed in red (“Incomplete”):



16. Once you have completed the form, select “Complete” at the bottom of the page and save the form.

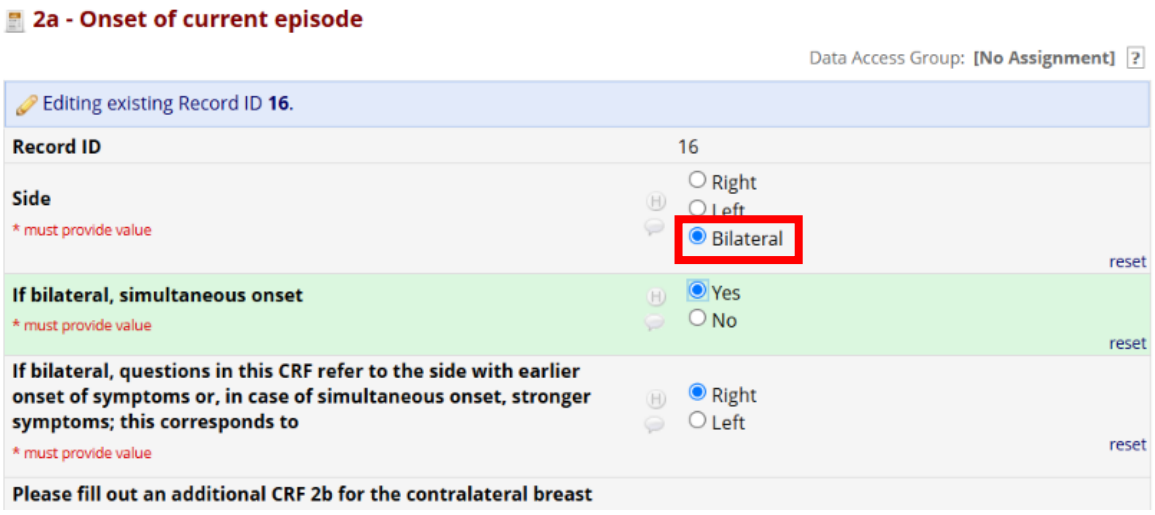


Now the CRF form is green (“complete”):



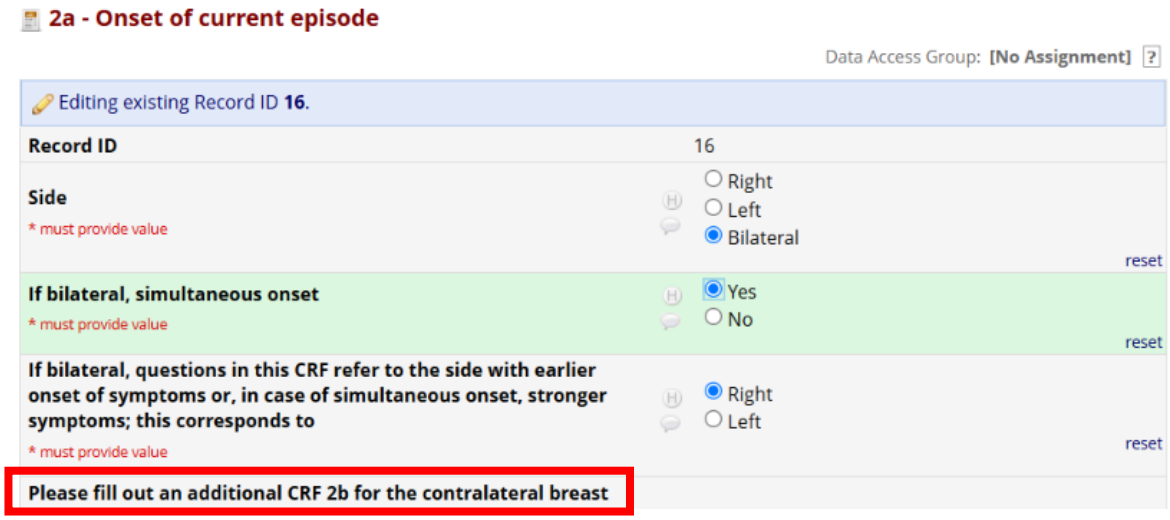
17.

If your patient had IGM on both sides, please select “Bilateral” in CRF Form 2a, “Onset of Current Episode”.



You will then be asked to complete an additional CRF form for the contralateral breast.

The form will be generated automatically as soon as you select “Bilateral,” and you do not have to create it yourself.



You can see the additional CRF Form 2b on the patient’s dashboard:



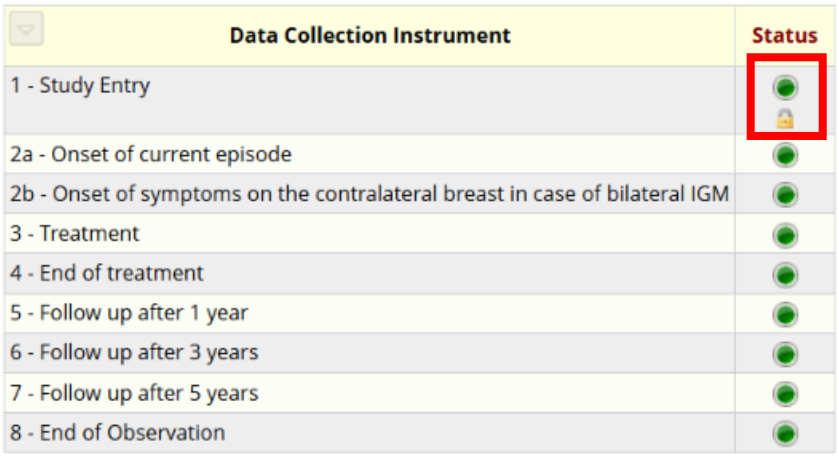
18.

Once a CRF form has been saved as “Complete,” monitoring can begin. You can recognize forms that have been locked by the monitors by the small lock icon.

Monitoring may begin as soon as individual CRF forms are completed and does not necessarily require the entire case to be completed.

If you wish to edit a form that has already been locked, please send an e-mail to:

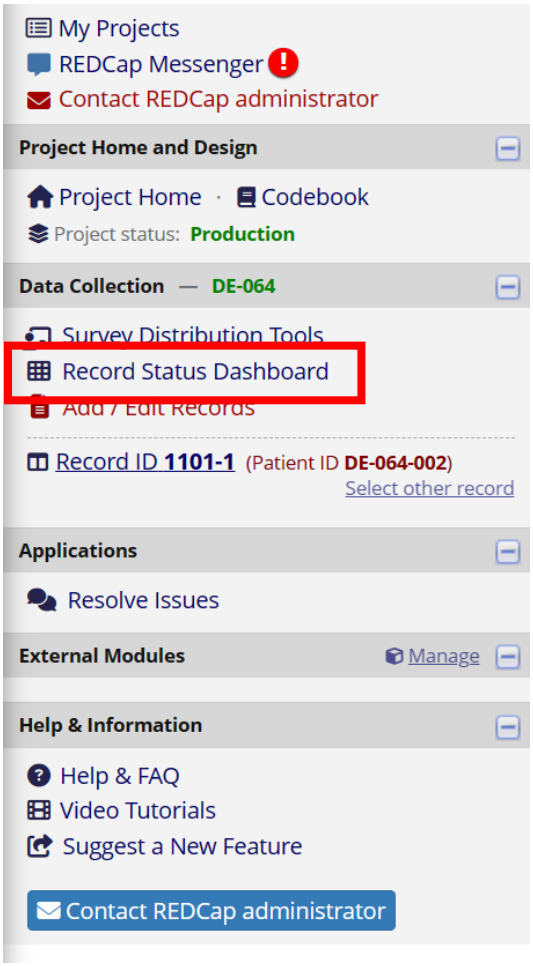
gramareg@eubreast.org



Data Collection Instrument	Status
1 - Study Entry	
2a - Onset of current episode	
2b - Onset of symptoms on the contralateral breast in case of bilateral IGM	
3 - Treatment	
4 - End of treatment	
5 - Follow up after 1 year	
6 - Follow up after 3 years	
7 - Follow up after 5 years	
8 - End of Observation	

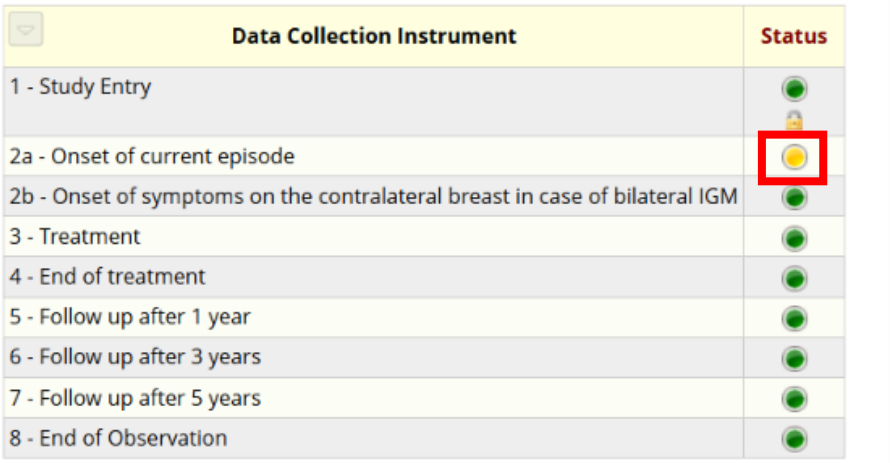
19.

You can see all patients recruited at your Study Site by choosing “Record Status Dashboard”.



20.

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.

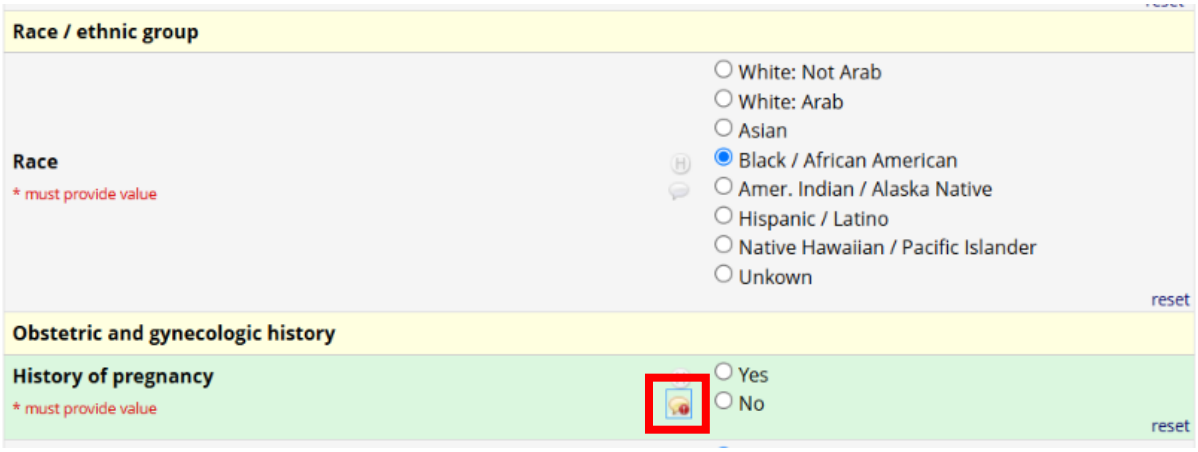


Data Collection Instrument	Status
1 - Study Entry	
2a - Onset of current episode	
2b - Onset of symptoms on the contralateral breast in case of bilateral IGM	
3 - Treatment	
4 - End of treatment	
5 - Follow up after 1 year	
6 - Follow up after 3 years	
7 - Follow up after 5 years	
8 - End of Observation	

PLEASE NOTE THAT NO QUERIES WILL BE ISSUED FOR RETROSPECTIVE CASES, AS THE DATA ARE COLLECTED ANONYMOUSLY. THEREFORE, PLEASE ENSURE THAT THE FORMS ARE COMPLETED AS THOROUGHLY AND ACCURATELY AS POSSIBLE. THE STUDY MONITORS WILL NOT BE ABLE TO VERIFY THE ENTERED DATA OR REQUEST CORRECTIONS.

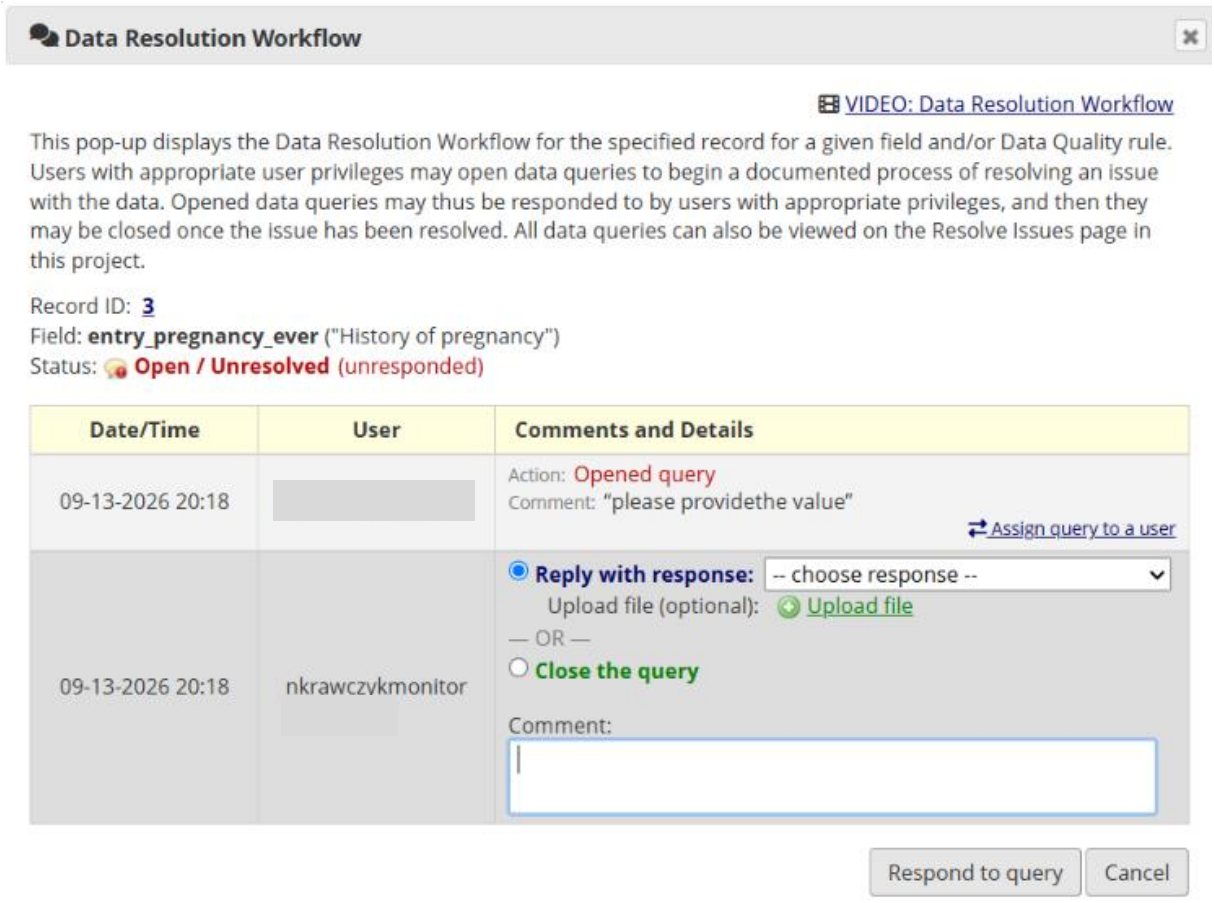
21.

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.



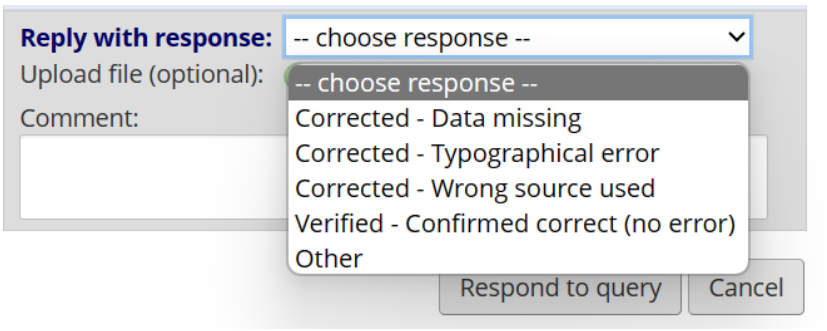
22.

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



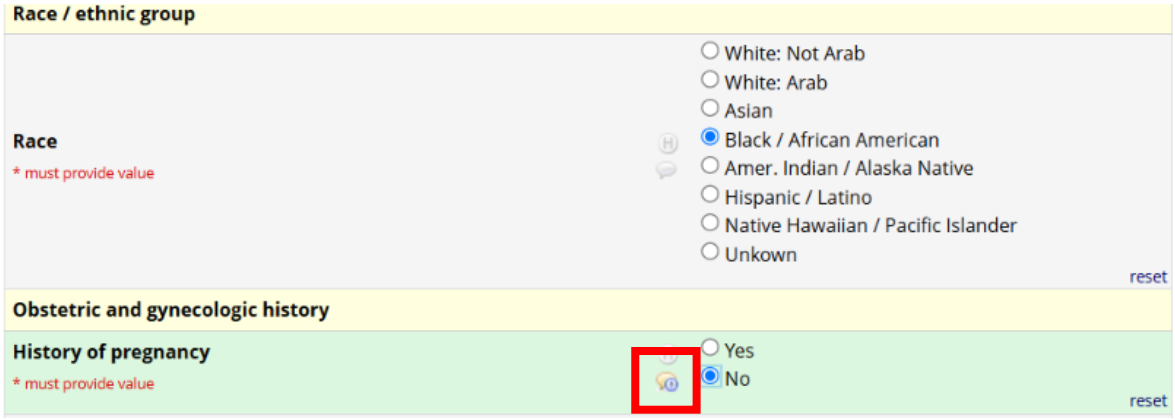
23.

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

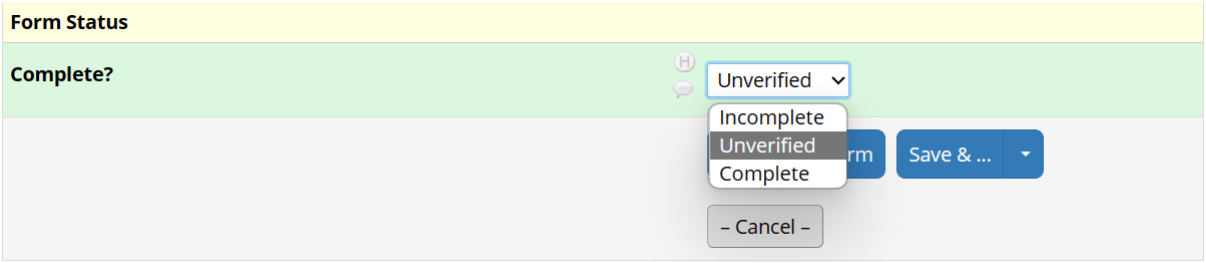


24.

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

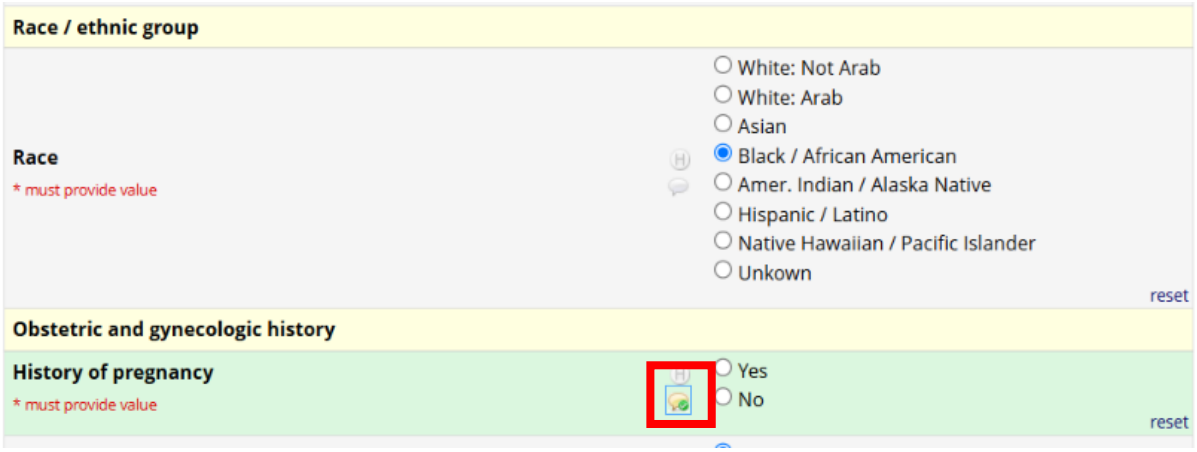


IMPORTANT: Do not change the status of the CRF form. It should remain “Unverified” until the monitor has closed the query. Once the query has been closed by the monitor, the status of the CRF form will be changed to “Complete” (green) and the form will be locked.



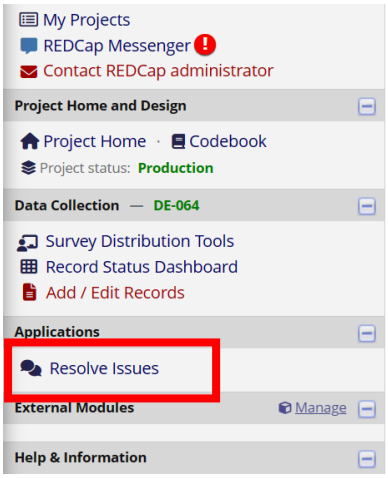
25.

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

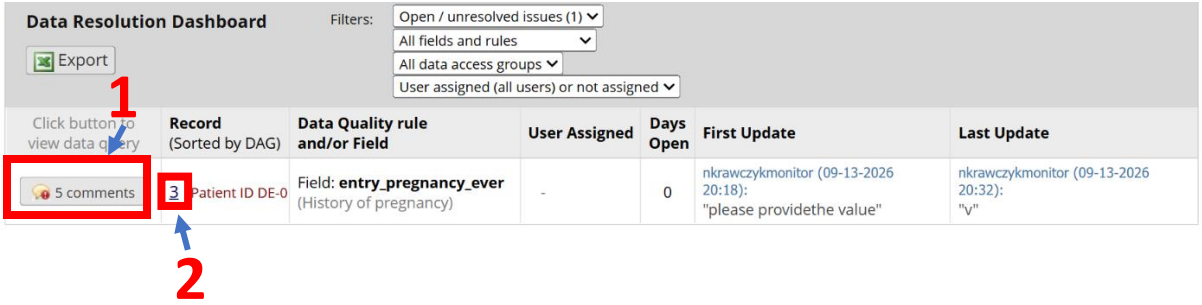


26.

To see all queries/comments, click on “Resolve Issues”.



If you click on the query/comment (No. 1), you will see the monitor’s comment directly. If you click on the Record Number (No. 2), you will be taken directly to the CRF form that the query refers to.



27.

Once you are finished, you can log out.



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

gramareg@eubreast.org