INOSS
The International Network of Obstetric Survey Systems

Guide for Anaphylaxis in Pregnancy Reporters

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INOSS and Anaphylaxis in pregnancy

1 Case definition

The anaphylactic reaction must occur during pregnancy or within 48 hours of delivery. Cases are those who meet the following criteria:

Anaphylaxis is defined as a severe, life-threatening generalised or systemic hypersensitivity reaction. The following two criteria must be met for a diagnosis of anaphylaxis to be made:

1. A life-threatening airway problem and/or breathing problem and/or circulatory problem

2. Sudden onset and rapid progression of symptoms

2 Case notification

Report cases to respective national system

B.OSS – report cases using the monthly reporting system.

France – report cases to Dr Marie-Pierre Bonnet (marie-pierre.bonnet@inserm.fr)

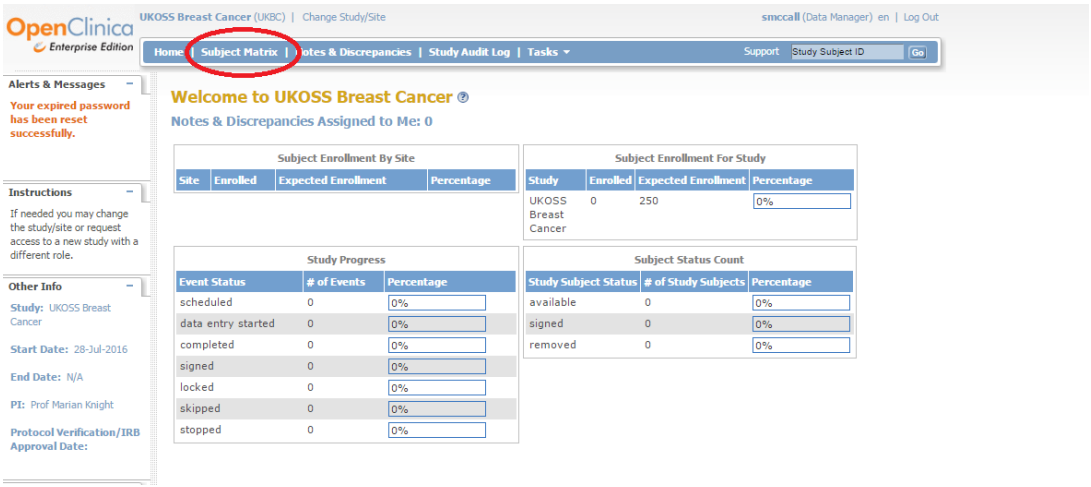
3 Open Clinica

Step 1. Once you have reported a case you will be sent login details for Open Clinica from Openclinica@npeu.ox.ac.uk.

Step 2. Login and change your password to something memorable.

Alternatively, you can also access OpenClinica® directly at https://openclinica.npeu.ox.ac.uk/OpenClinica

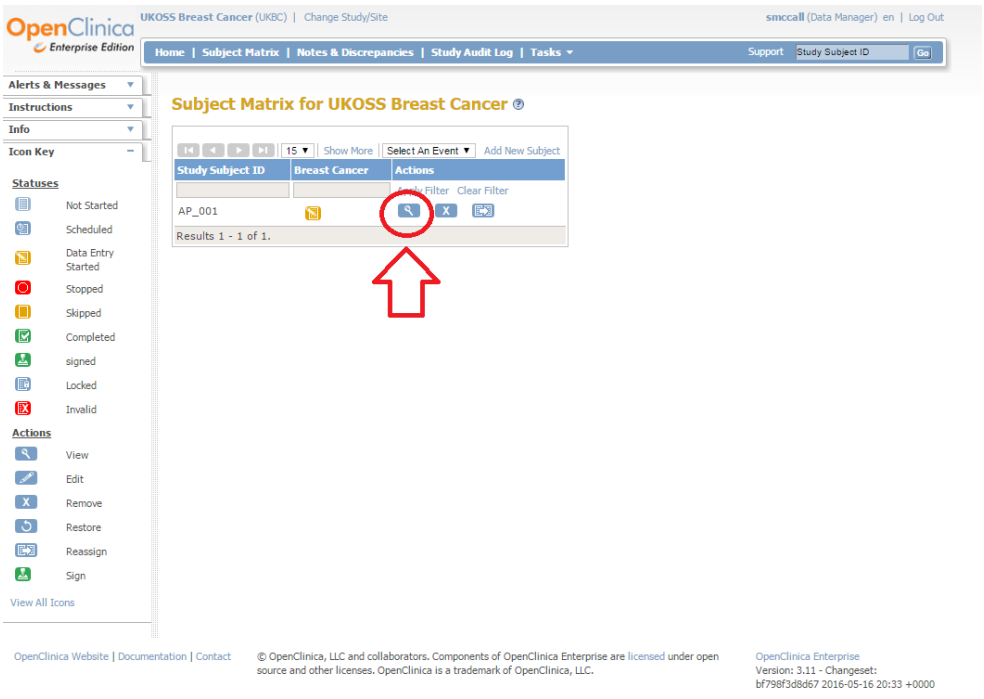
Step 3. Click on “subject matrix” to access the reported cases



Step 4. Selecting the case

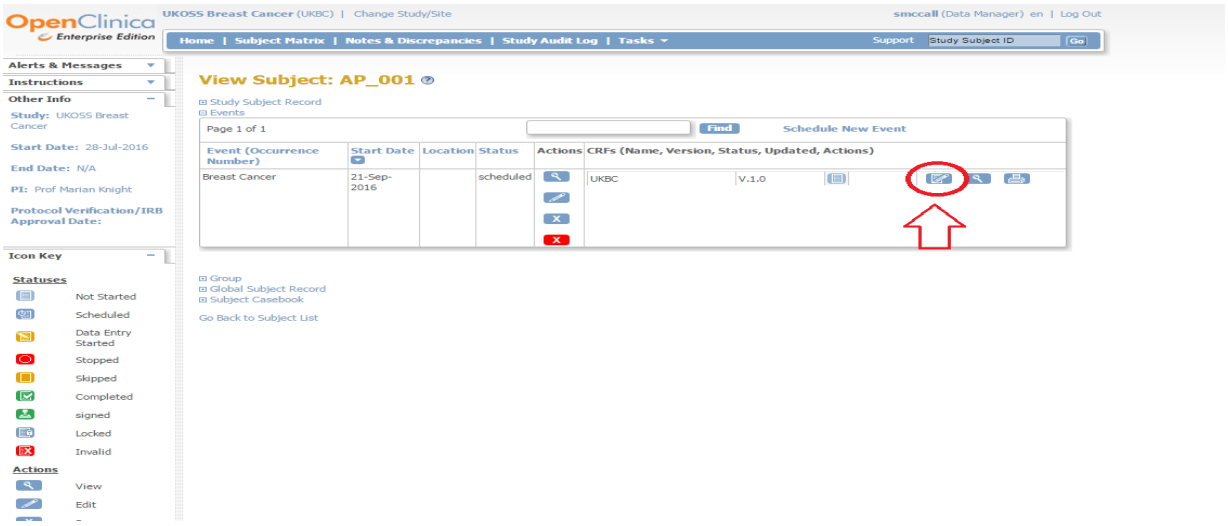
- An email will have be sent to you providing you with the Study Subject IDs (CaseID) of the case you reported e.g AP_001 .
    - **Advanced knowledge:** Beside the Case ID there will be an icon to indicate the data entry stage. Cases where no data have been entered you will see a blue icon alongside the Case ID. Where a form has been started, but not completed, there will be an amber icon. Forms which have been completed have a green icon.

- Click on the **View/Enter Data** icon beside the corresponding case to **view** the case.



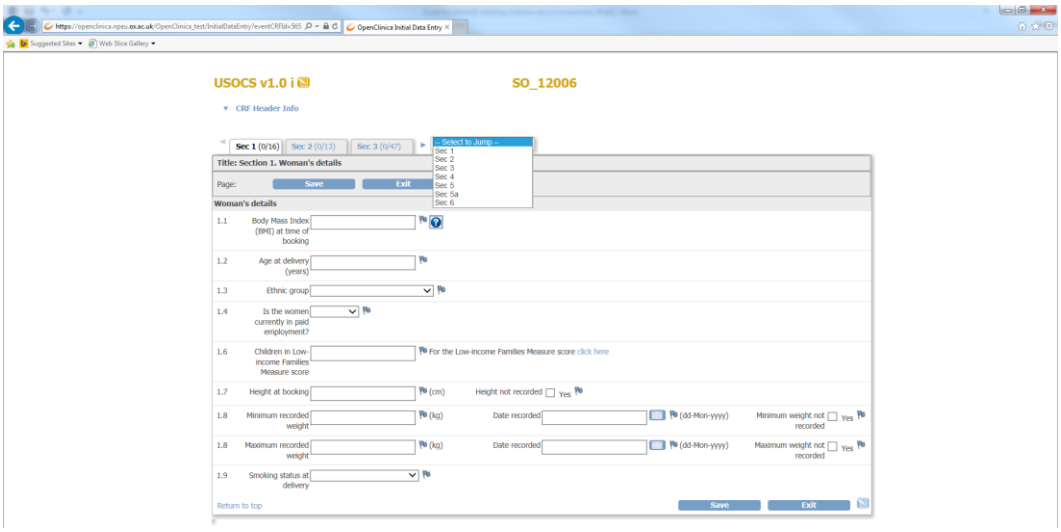
Step 5. Data entry

- Click on the **Enter Data** icon to **enter** the data collection form.



Step 6. Data collection form

Enter data on this page



You can move from question to question by using the tab key. Once you have completed a section click Save

If there are data issues or missing data a red box will appear !

Importantly, if a data issue is raised the data <u>is not yet saved.</u> You can either amend the data, or ignore the issues and click save to move onto the next section. More information on data issues is found in **step 7.**

If there are no data issues (Dis) when you click Save you will move to the next section.

If the data is missing values leave it blank and leave an annotation detailing that it is missing.

To explain any data issue or add extra information click on . In "add note" enter "**Annotation**" in the description box. In this section you can elaborate on the issue or give extra details.

Further information:

1. To enter dates in the form click on the calendar icon and select the date, or enter using the format dd-Mo n-yyyy.
2. To enter times in the form use 24 hour clock and the format hh.mm
3. Throughout the form, where you see a icon you can hover over with your mouse for question-specific guidance.

Step 7. Extra information on Data issues (DIs)

If the data you have entered contains an error (e.g. the date is formatted incorrectly), is invalid (e.g. missing or not an expected value) or needs checking (e.g. an unusual but valid response) a Data Issue (DI) will be raised.

A list of DIs will appear at the top of the screen. There are two types of DI:

1. DIs where the data are invalid and **cannot** be saved.
   These will appear first and must be resolved before you can save the data you have entered.

   - **These data MUST be edited before saving.**
   - **Please correct formatting errors or leave the item blank if it cannot be corrected.**

2. DIs where the data are invalid, but can be saved, begin with (?), e.g.
   (?) Age at delivery is expected to be between 16 and 45
   (?) Please enter a value for Ethnic group

   Step 1.Check any DIs carefully.

   Step 2. Correct any errors in the data you have entered.

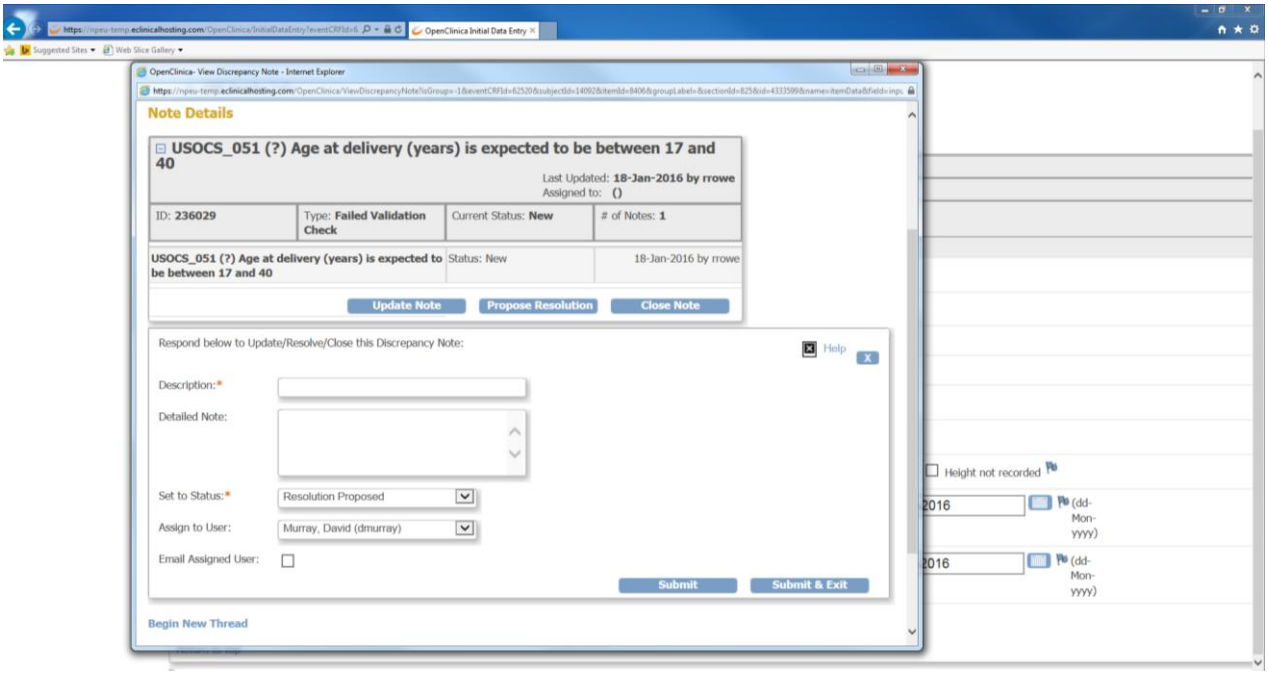
   Step 3.If the value you have entered is invalid, but you believe it to be correct you should click **and continue to the next section.**

Step 8. Discrepancy Notes (DNs)

Discrepancy Notes (DN) indicated by a red flag are created automatically if invalid data (e.g. a value that is missing or not expected) are entered and saved.

Whenever a DN is created we will contact you to check the data, so it is **really important** that you enter some extra information about each DN. This is a validation check to let us know if the data is correctly entered or truly missing.

You can enter this extra information by clicking on a red flag :



- **Click** Propose Resolution

This will open a further box where you can enter information:

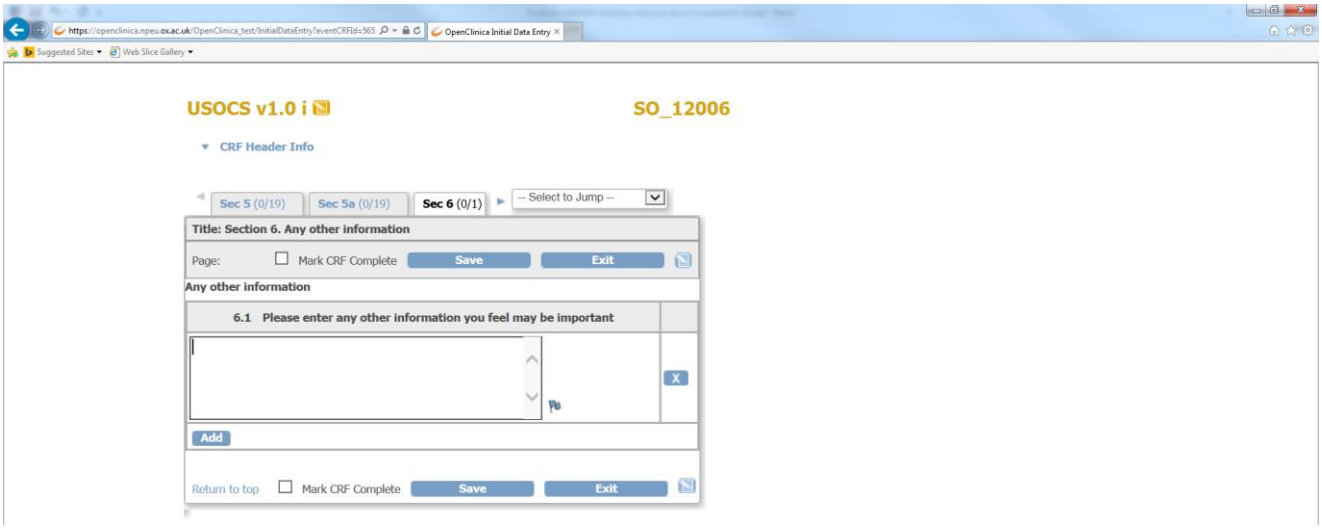
- **In the Description box enter information to clarify the data you have entered, e.g. Woman's age, 46, is correct – checked OR Data missing from notes – will never be known.**
- **In the Set to Status box, check that it says Resolution Proposed.**
- **Click** Submit and Exit

Alternatively, you can access DNs by clicking on the "Note and Discrepancies" tab if you are outside the data collection form.

Now, if you return to that section, the flag next to that question will be green indicating that you have proposed a resolution to the DN.

Step 9. Completing the form

Once the form is complete, check the complete check box. **Mark CRF Complete**



It is very important that you mark the form complete before you save. If you save the form without marking the form complete we will not be able to use the data and will have to contact you.

A pop-up box will appear asking you to confirm that the form is complete.

- **Click OK and then** Save

If you have any issues please contact:

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