UKMidSS quick Data entry guide

Introduction

This data entry guide has been developed to guide UKMidSS reporters through the data entry process. If you need a 1:1 training session or support, please email us at ukmidss@npeu.ox.ac.uk.

This guide is divided into 3 sections:

1- Data entry: This will give you an overview of the data entry process

2-How to deal with data queries: This section will give you an overview of how to respond to data queries once they have been raised.

3- Other relevant information: This section will give you an overview of how to enter the CLFM score, how to deal with errors and how to edit a completed form.

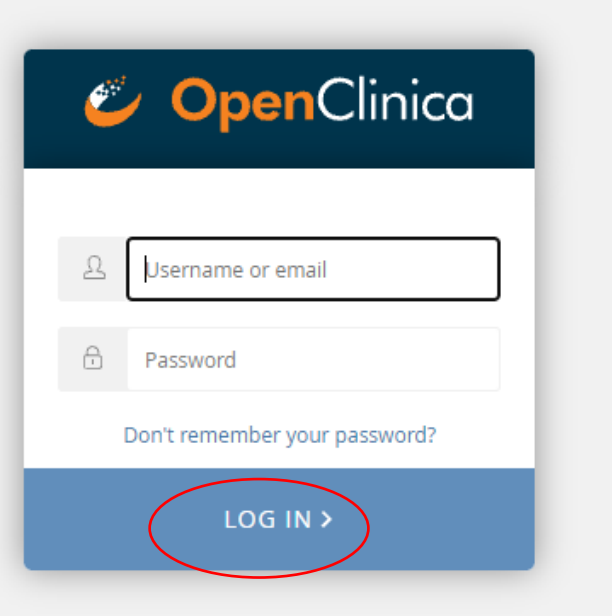
Key Points

- As soon as you submit a monthly report with at least one 'case' for the Advanced Maternal Age study you will receive an email listing the Participant IDs' for those cases.
- Each "Participant ID" will start with **AM_**
- The **case** and the associated **control have the same Participant ID**, with separate forms for the case and control. **You must enter data for both the case and the control.**
- **Case:** Any woman with a diagnosis of diabetes during pregnancy (gestational or pre-existing) and admitted for labour care to a midwifery unit.
- **Control:** woman who was admitted to the midwifery unit immediately before the case, did not fit the case criteria and it's not a case herself.
- There are **7 sections** to complete for both Case and Control. Controls will require less data to be captured.
- Our approvals for UKMidSS only permit us to collect unidentifiable, anonymous data. Please do not enter any identifiable information (e.g. NHS number, hospital number, date of birth, postcode) anywhere in OpenClinica or send us any identifiable information by email or through the monthly report. Please do not share any identifiable information with the research team.

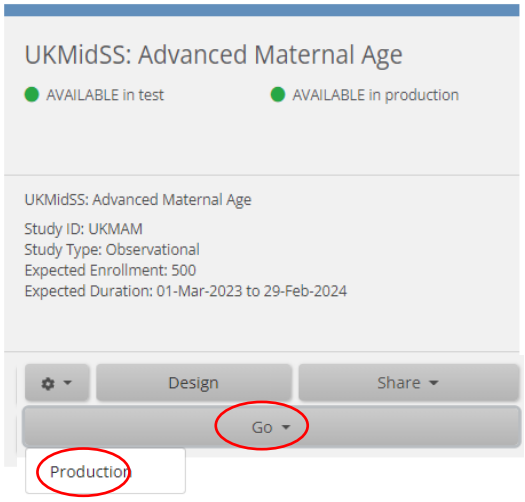
1- Data entry

Please note that this data entry guide has been created in developer mode of OpenClinica, therefore the study name and ID are different to what you will be able to see.

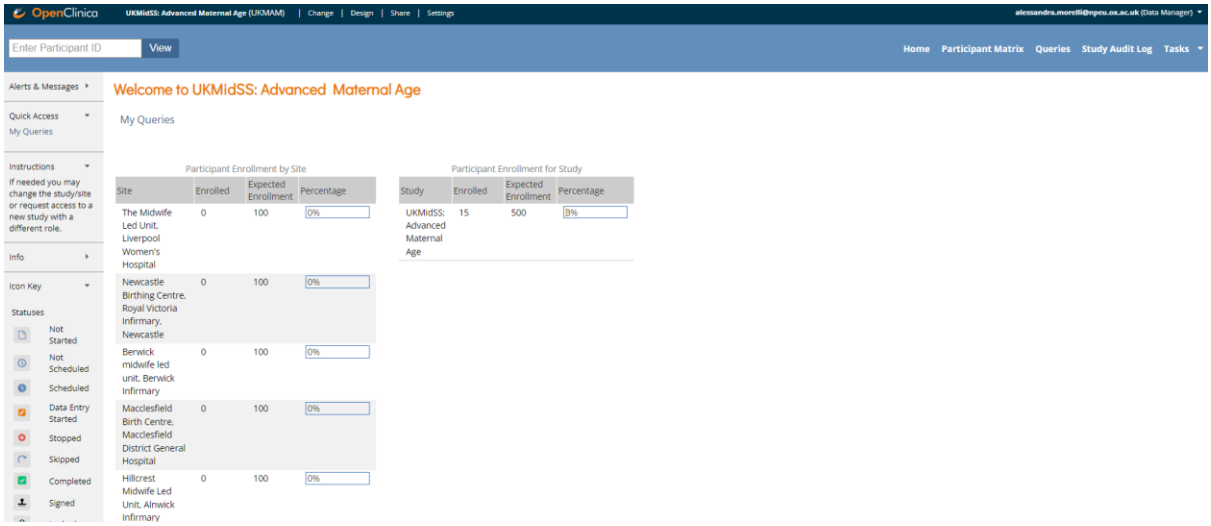
1- Go to https://npeu.openclinica.io/ , add your username and password and click “log in”.
If you don’t have any log-in details, please email ukmidss@npeu.ox.ac.uk



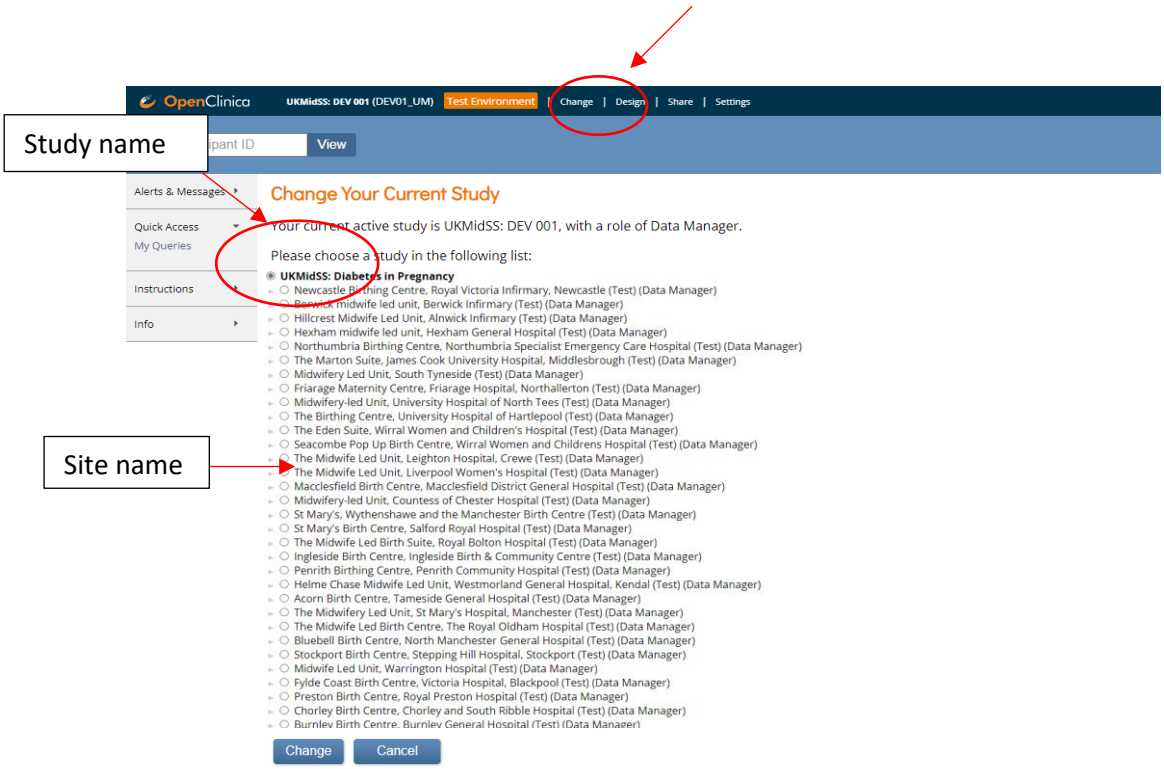
2- You will be redirected to a page which will be similar to this one. The name of the study will be **“Advanced Maternal Age”.** You should click on **“Go” “Production”**



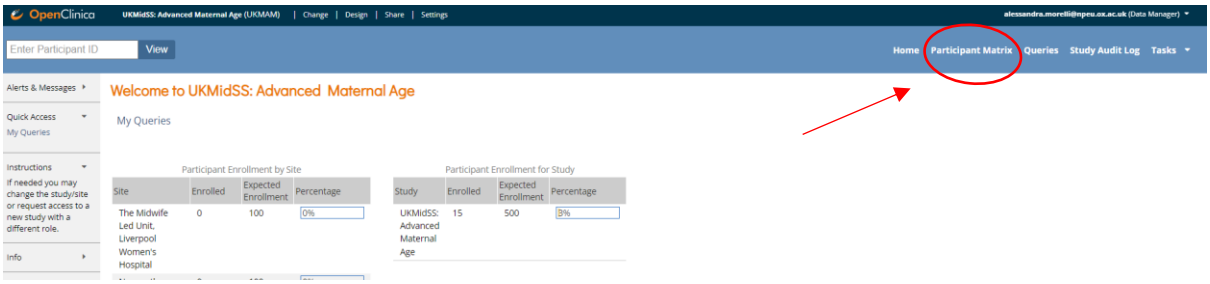
3- You be directed to a page that looks similar to the one below



4- If you are a **reporter for more than one site** or **more than one study** that uses OpenClinica as a database management system, you can select the appropriate study/site by clicking the **"Change"** tab at the top and selecting the appropriate study/site. The study must be **"Diabetes"**. And click on **"Change**" at the bottom of the screen.

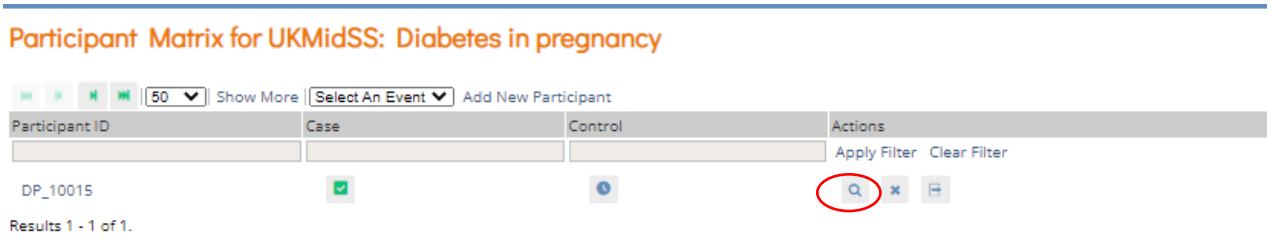


5- In order to identify the case/ control you wish to do the data entry for, you need to click on **"Participant Matrix"** on the right side of the screen.

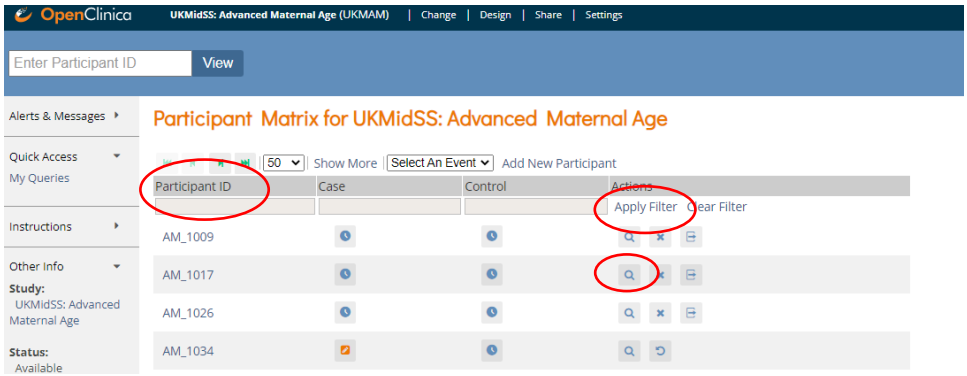


On the Participant Matrix page you will see the study "Participant IDs" for your cases and the associated controls. Each line represents a case, with its associated control. For cases and controls where no data have been entered you will see a blue icon alongside the Participant ID. Where a form has been started, but not completed, there will be an amber icon . Forms which have been completed have a green icon .

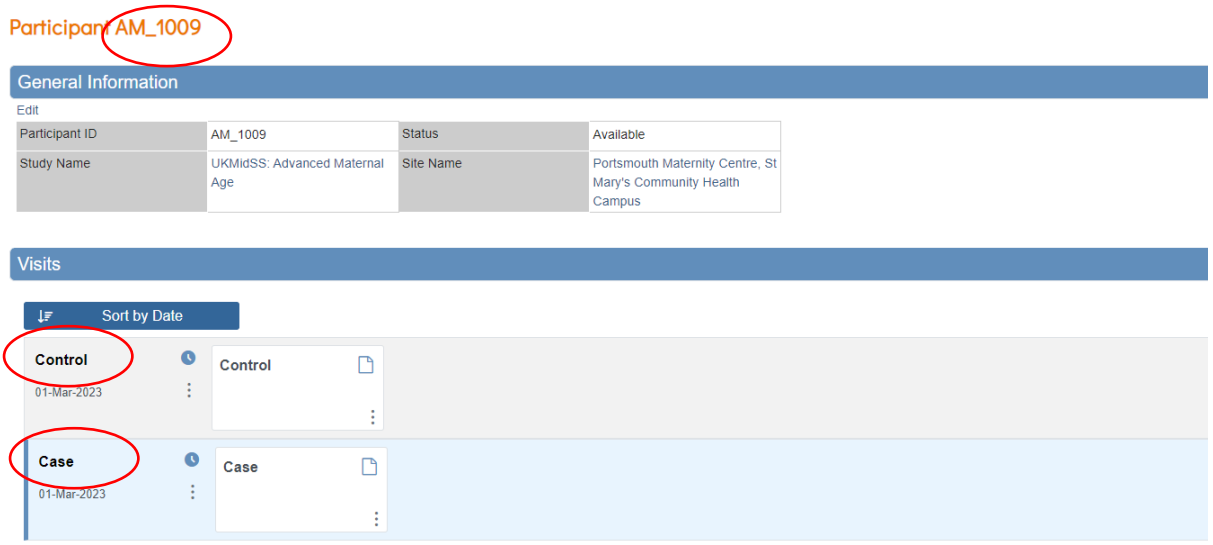
6- Click on the **magnifying lens** alongside the participant ID you wish to enter data for.



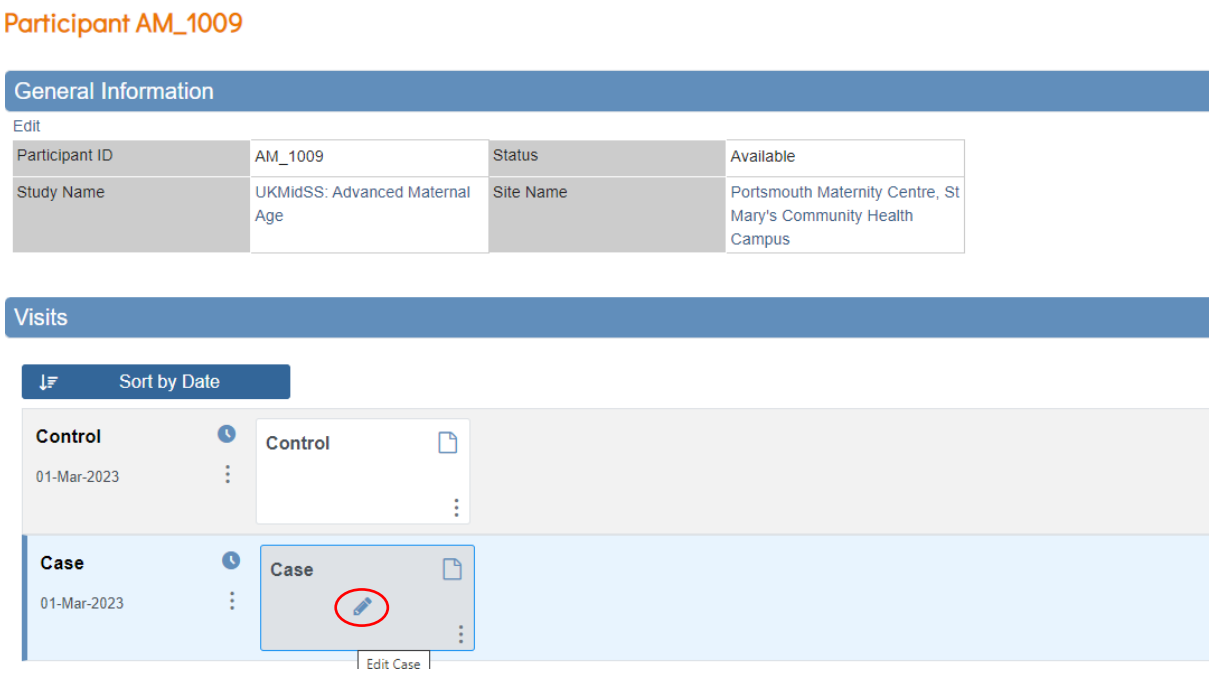
If you have a long list of cases and wish to select a specific Participant ID, add the participant ID number (**AMA_XXXXX**) you received in your email under **"Participant ID"** and click **"Apply Filter"**. Then then click on the **magnifying lens** to select that participant ID.



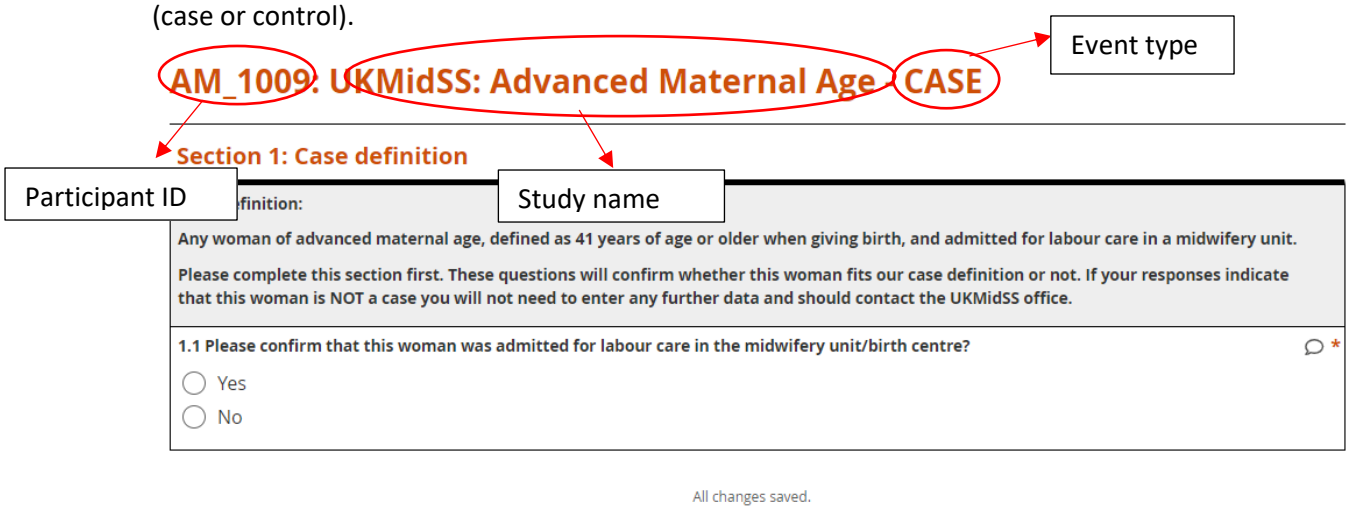
7- You will then reach this screen where you can see the case and the associated control with the same ID.



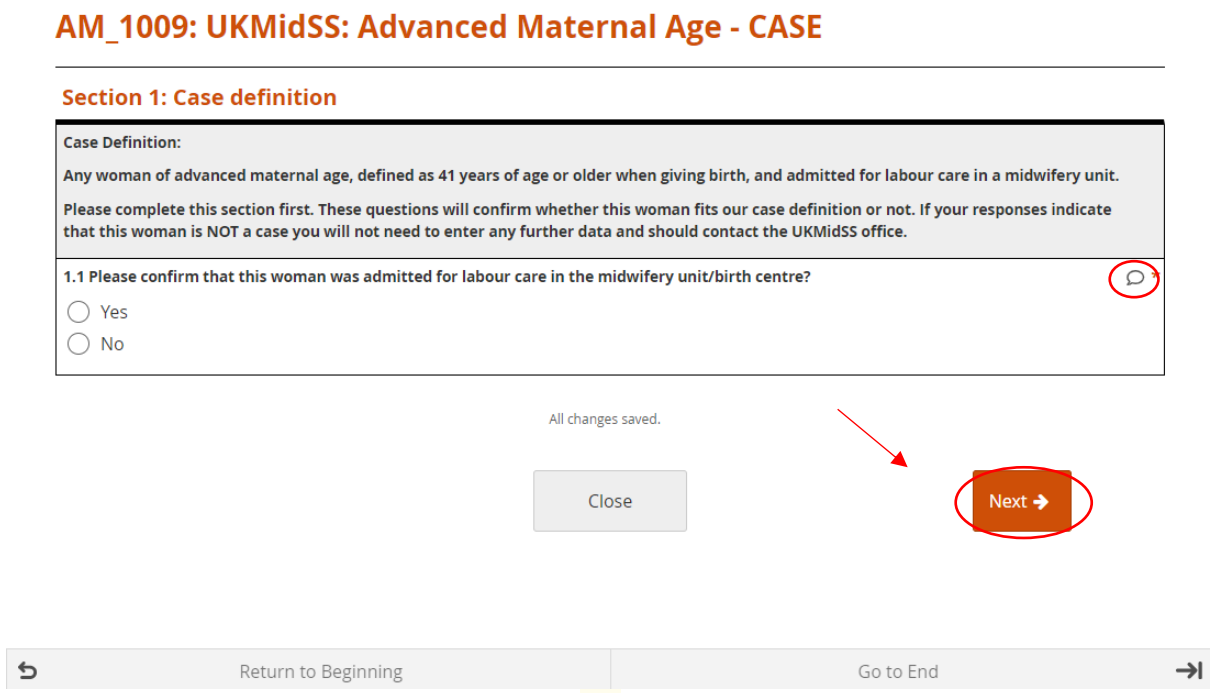
8- To enter data, click on the **pen** sign that will appear when you place the cursor in the right box below the case or the control. It doesn't matter whether you start the data entry with the case or the control, but make sure you enter the data for the case in the case form and the control data in the control form.



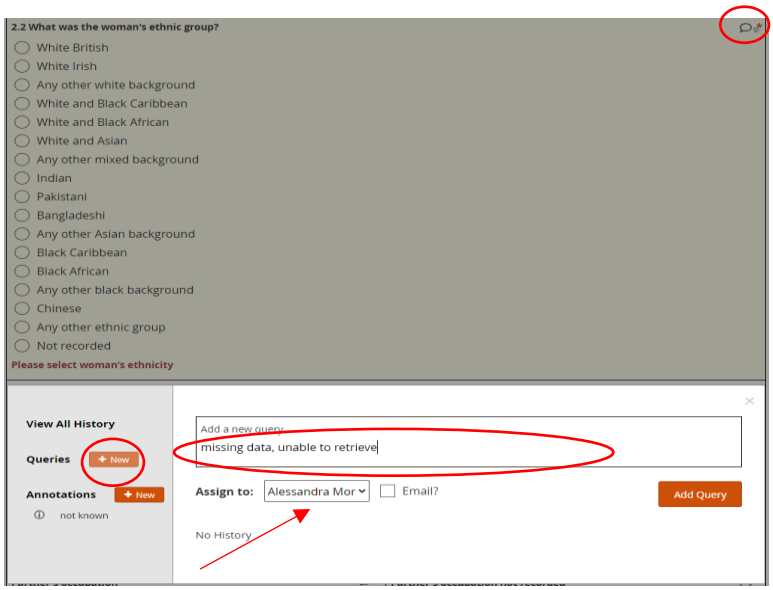
9- At the top of your form, you will have the Participant ID, the Study name and the event type (case or control).



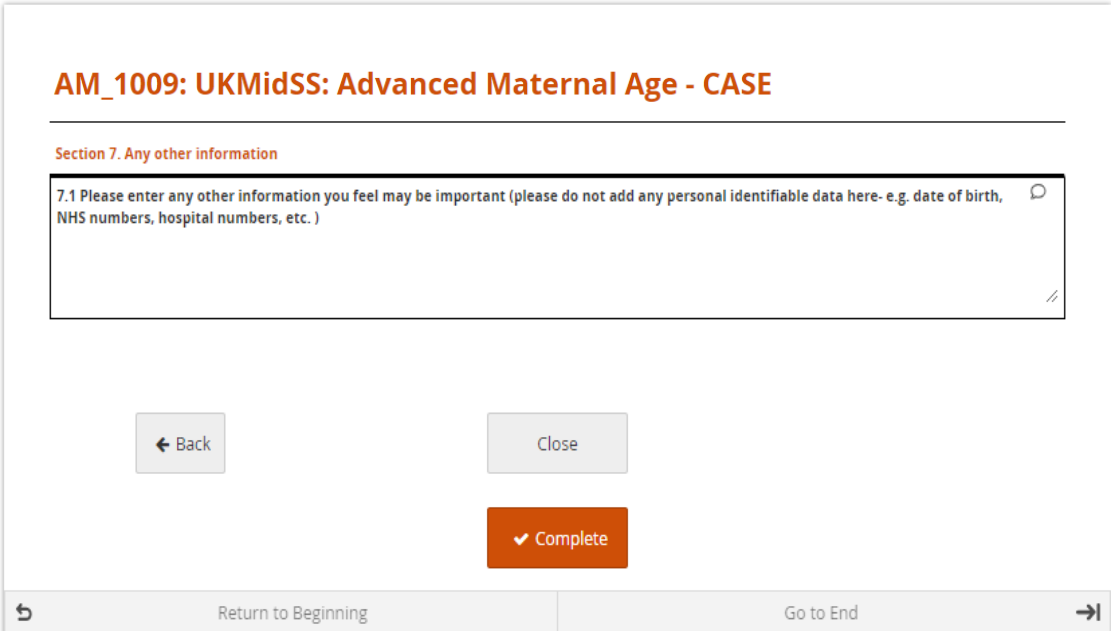
10- **All the fields marked with a star are mandatory**. There are 7 sections to complete and you can move to the next section by clicking "Next" .



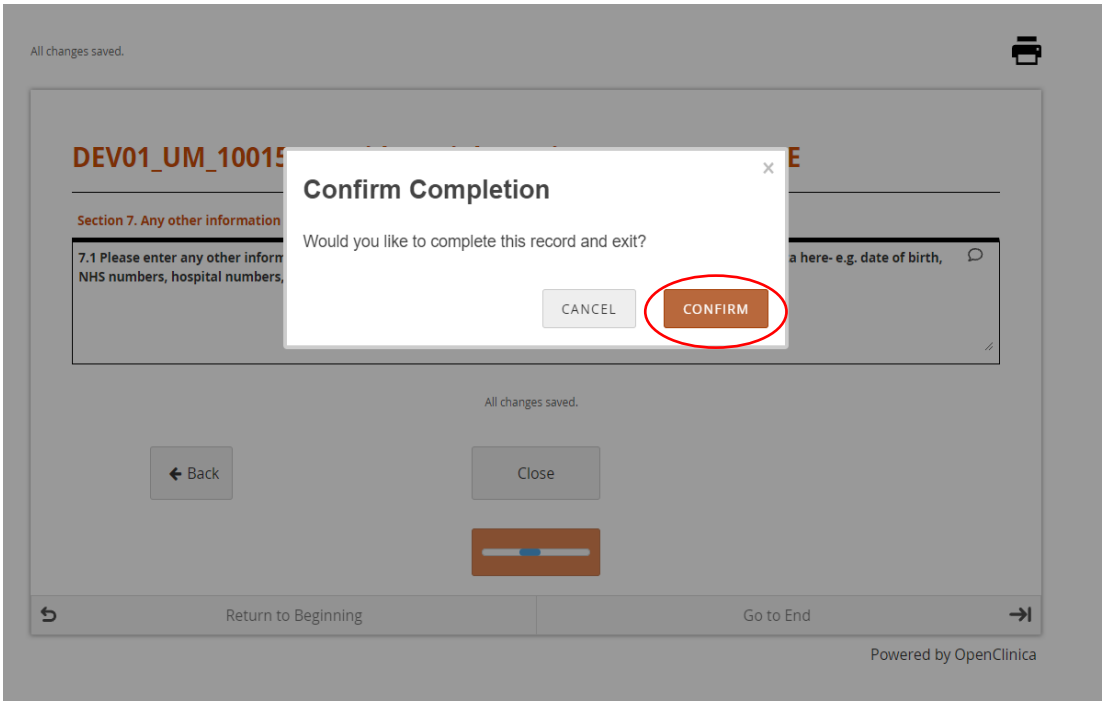
11- If you have missing data, click on the **cloud icon** on the right side, click on **"New"** query, **"Assign to"** yourself and then **"Add query"**. If you think you are able to retrieve this data somehow, just make a note in the query box. We will close queries for missing data that you are unable to retrieve, but keep queries open if you are still tracking down the data. For those queries we are unable to close, you will receive a monthly reminder that some data is outstanding.
If you leave any mandatory field blank without adding a query you will **not** be able to complete data entry. There is more information about how to deal with data queries in Section 2.



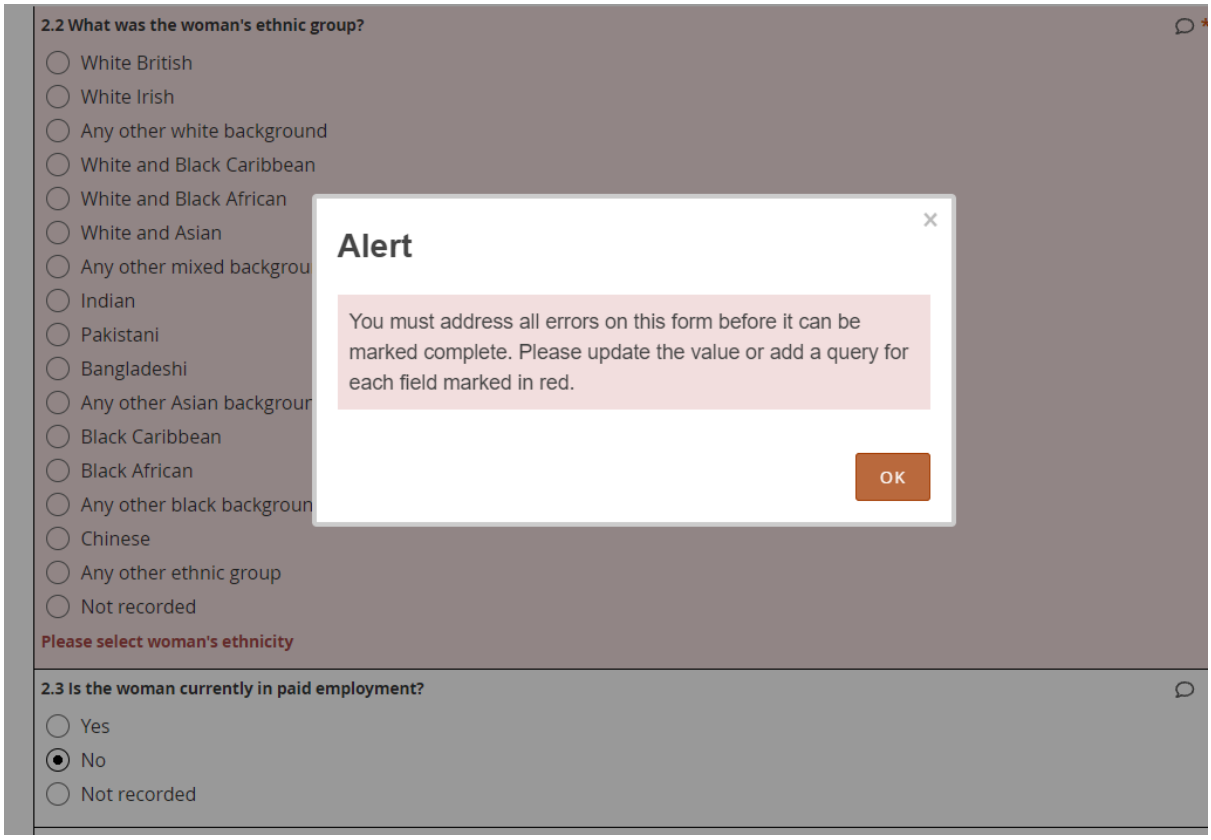
12- Once you have entered all the data and you reach **section 7**, click on **"Complete"** to mark the data entry in that form as completed.



13- You then need to click **"Confirm",** if you are sure all the data is correct.



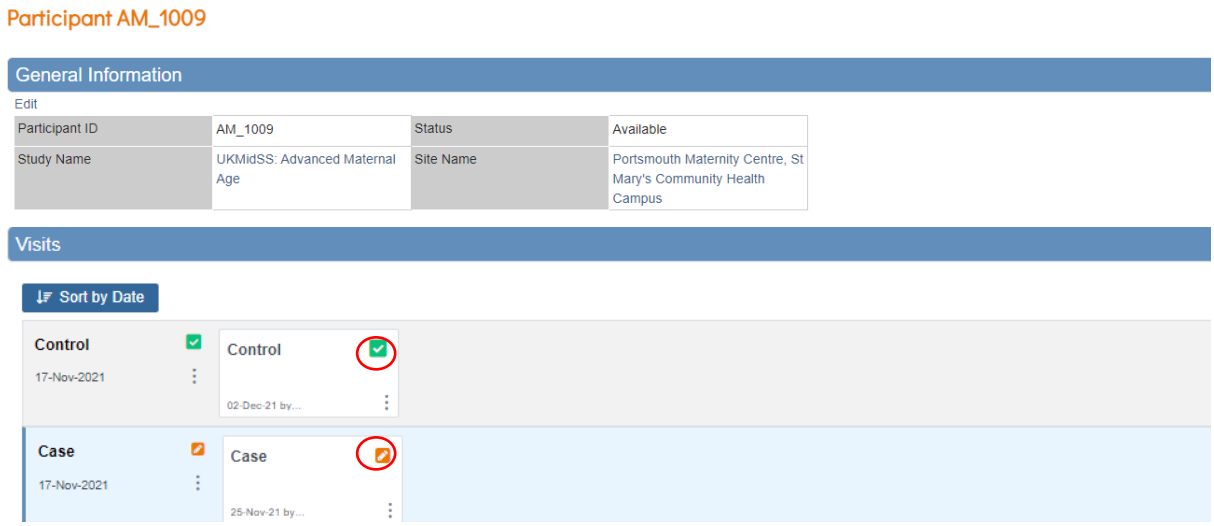
14- If you **forgot to complete a mandatory field**, you **will not be able to complete the data entry** and you will receive an **"Alert"** message. You will be pushed back to the part of the form that is



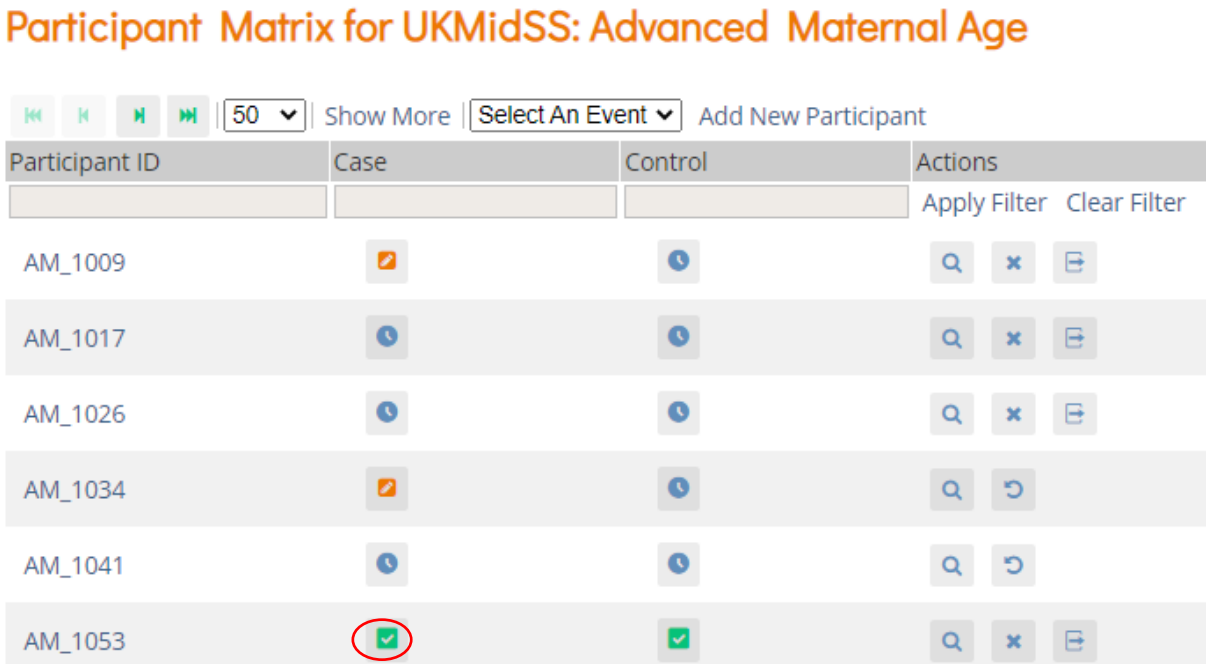
not completed or completed incorrectly. If you don't have the data or the data is incomplete, add a query as shown in step 11.

15- After you have addressed the error, remember that **you need to go again to section 7** to complete the data entry as shown in step 11 and 12, or it will show as incomplete on our system.

16- If you have completed the data entry appropriately, there will be a green tick under **"Visits"**, otherwise it will appear as orange.



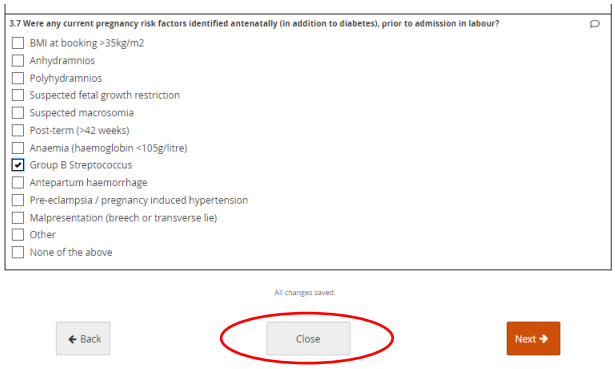
Once you have completed the data entry for any form, there will also be a green tick showing that the record is complete on the **Participant matrix** page.



17- Repeat all the steps above from point 10 to enter data for the **Control.**

Reminder

You can stop the data entry at any point without completing it simply by clicking on “Close” at the bottom of the page, which is quite useful when you don’t have all the data available. OpenClinica will automatically save any data entered.

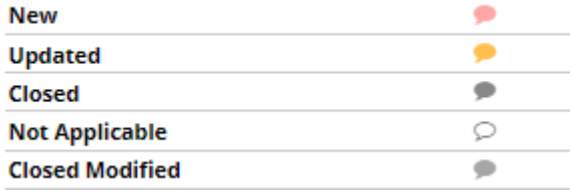


But remember that the data entry will not be completed and you will need to go back into the record, update it and go up to section 7 as shown in steps 12 and 13 of this guide. Otherwise, the status will remain orange.

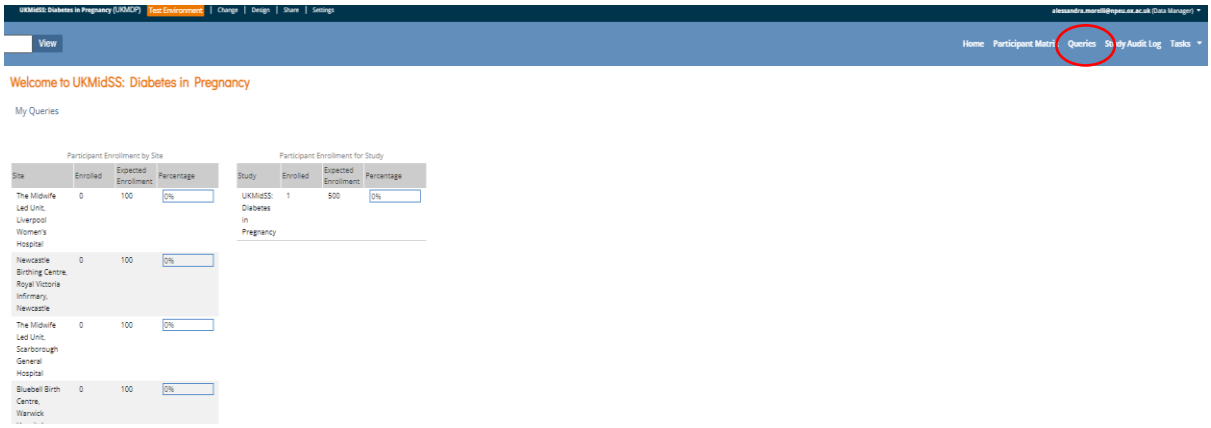
2- How to deal with data queries

So that the studies we carry out using UKMidSS are as reliable as possible, it is important that we have complete and accurate data about cases and controls. When data are missing, or an unexpected or inconsistent value has been entered in OpenClinica, we will highlight these queries in your monthly UKMidSS Status Report. Please remember, do not enter any identifiable information (e.g. NHS number, hospital numbers, date of birth, postcode) anywhere in OpenClinica. If you have problems or questions about this process please contact us: ukmidss@npeu.ox.ac.uk or 01865 17823.

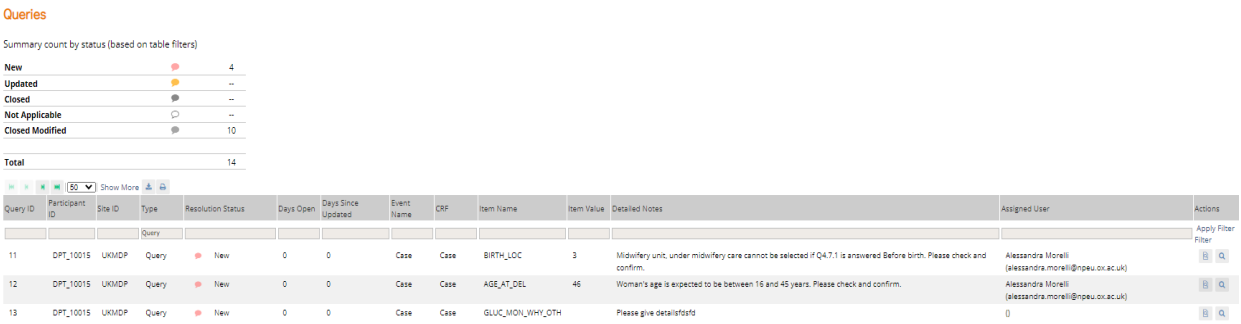
Queries are categorised as below:



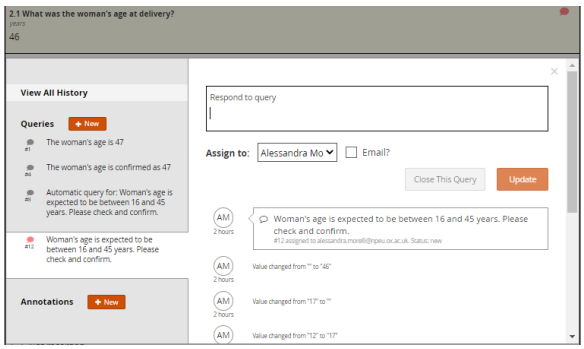
1- Click on queries on the top right corner of the page



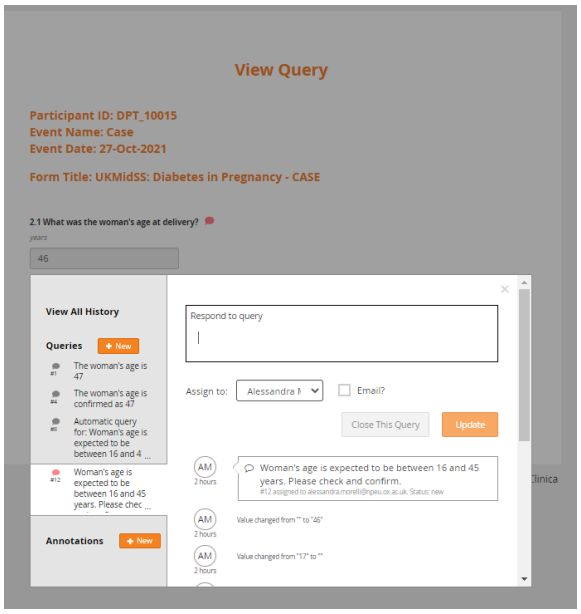
2- A list of queries will appear (if you have any).



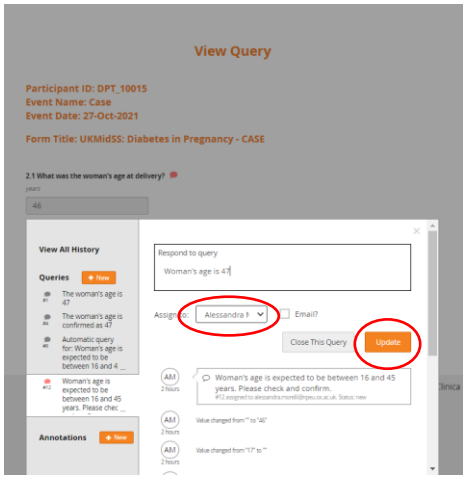
3- Click on the icon to view the query within the actual record.



Or click to only view the query.



4- Once you have reviewed your query, assign it to yourself or a colleague that works with you and then click on “Update”.



5- The query status will then change from red to orange . The UKMidSS team will review the queries monthly and close all the queries that have been answered. Once a query is closed, the icon will change to black .

For previous reporters

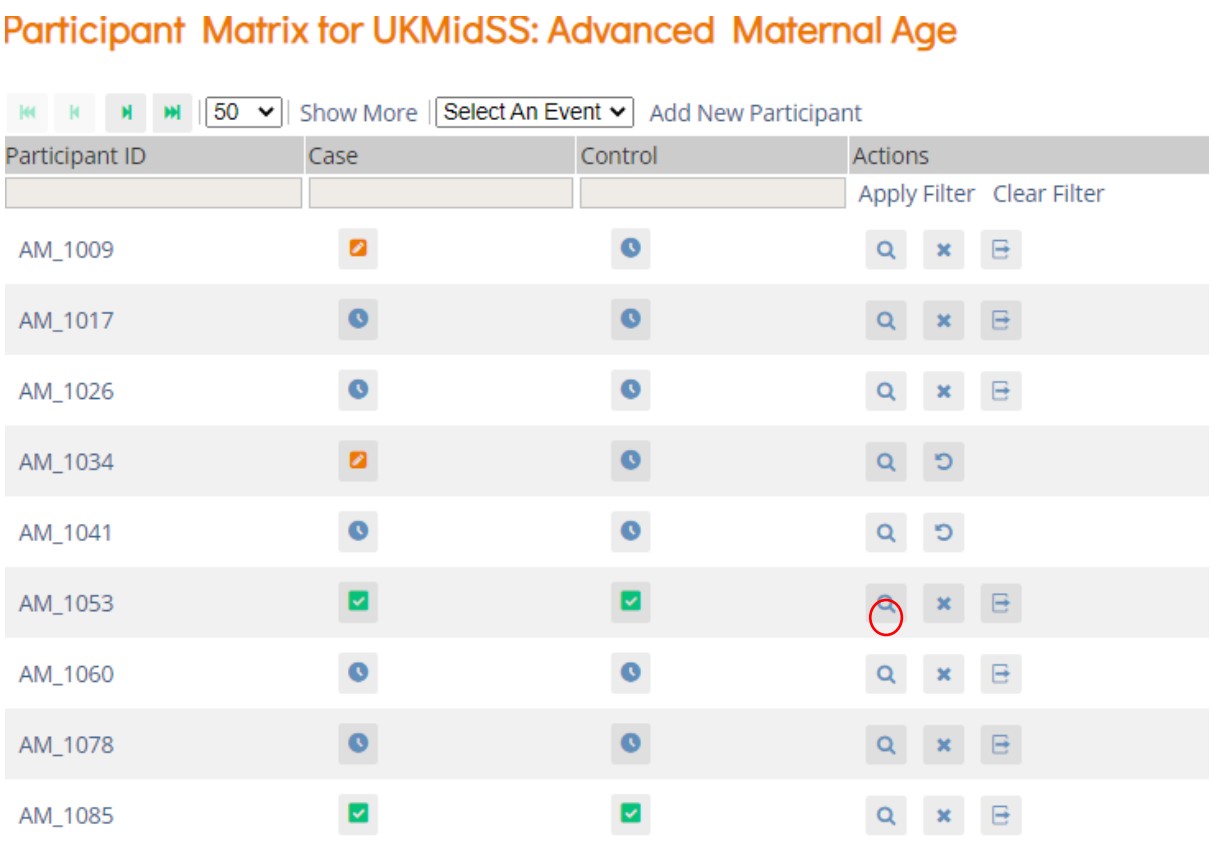
Discrepancy notes have been removed and integrated into the data entry form itself. When data that are missing or unexpected are saved in OpenClinica, now you will just treat it as a data query . Flags will no longer appear on OpenClinica.

3- Other relevant information

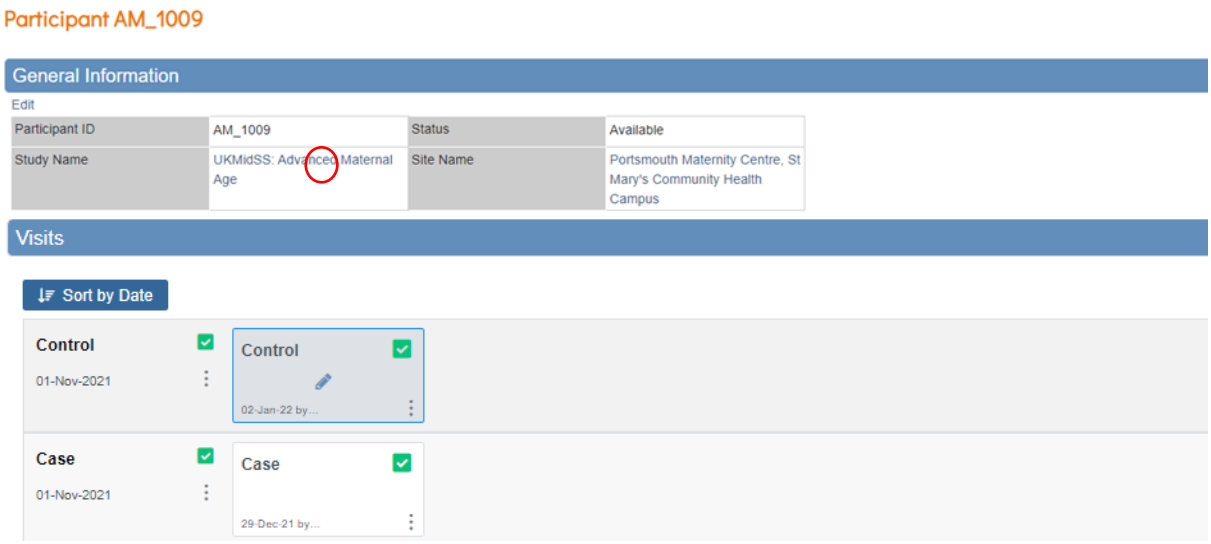
1- Editing a completed form

If you have marked a form as complete you can still go back and edit the data you have entered. For example, you may wish to change the data because you left an item blank the first time or you realise you entered an incorrect value e.g. the woman's weight is 89kg but was entered as 98kg. To change data once a form has been marked complete you must provide a reason for the change, otherwise the edit will not be saved.

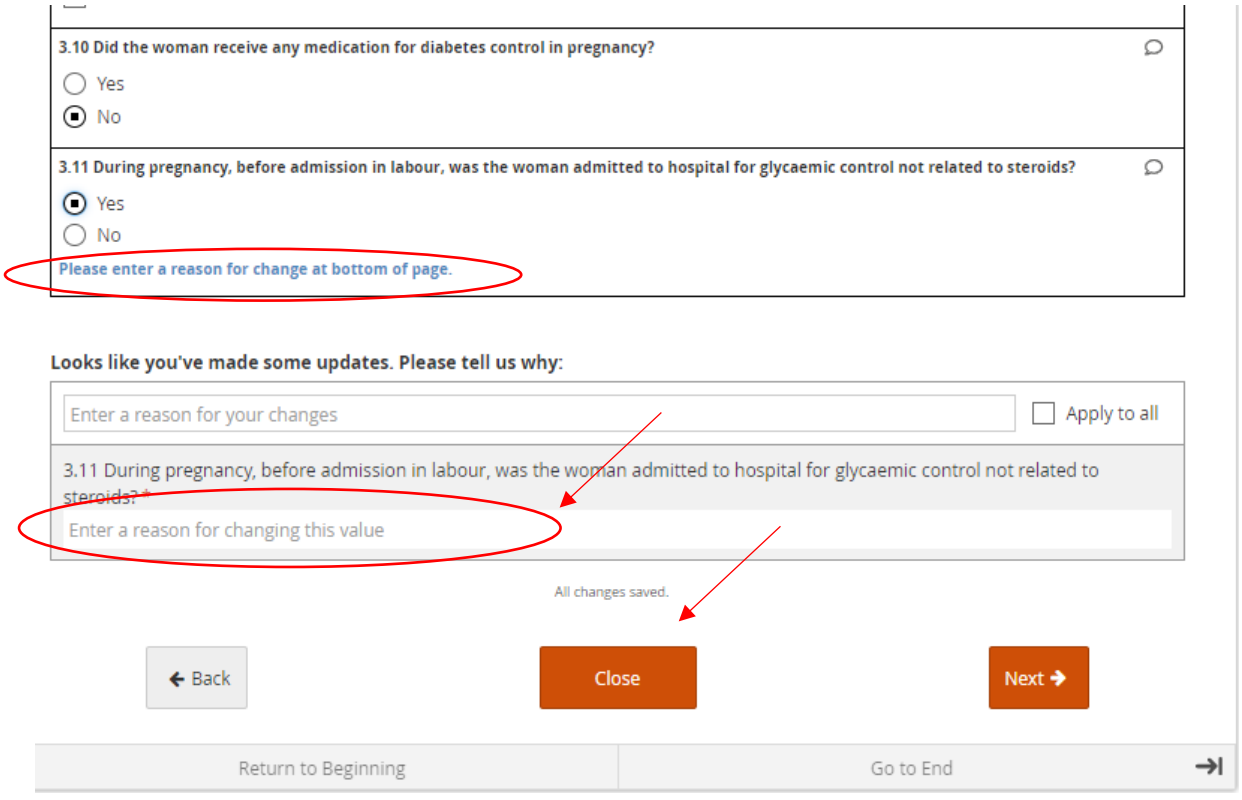
Go to **"Participant Matrix",** click on the on the left, then **click** on the magnifying glass icon.



Then click on the edit control under the record you wish to modify.

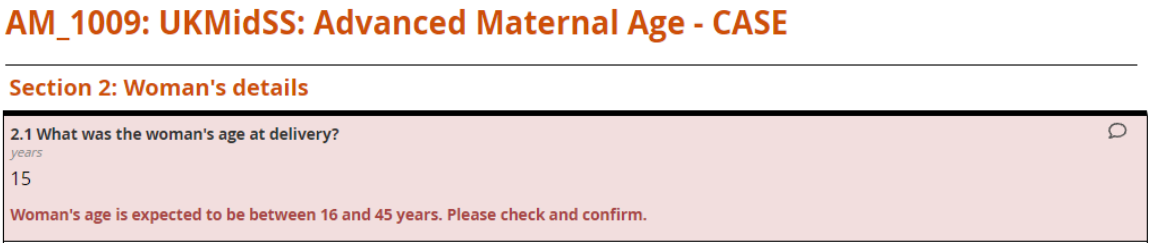


A message will appear at the bottom of the screen stating you must provide a reason for the change, before the data edited can be saved. Click on "**Close"** once you have finished all your changes.

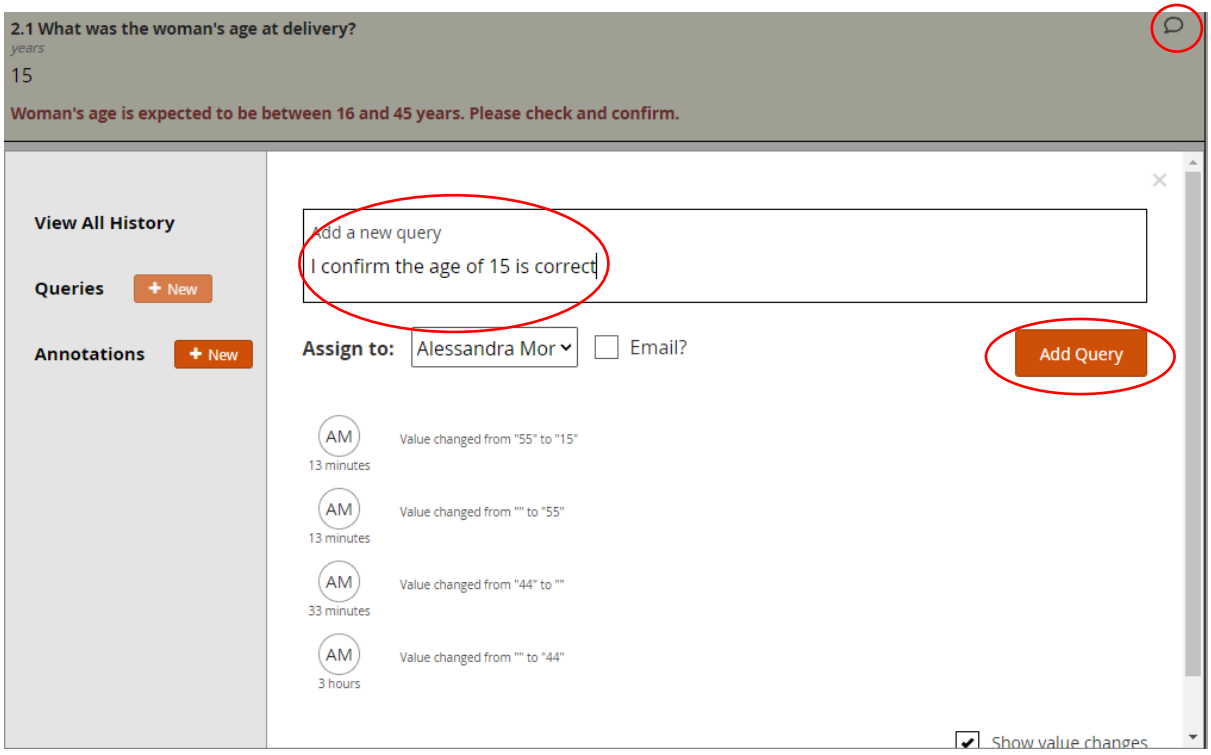


2- Errors:

Some fields have a range of values that you are allowed to enter. For example, for age, the woman's age range is expected to be between 16 and 45 years. The system will prompt you to check anything that is outside those ranges.



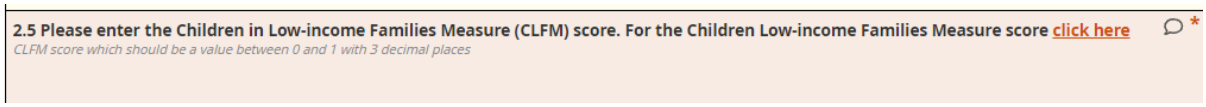
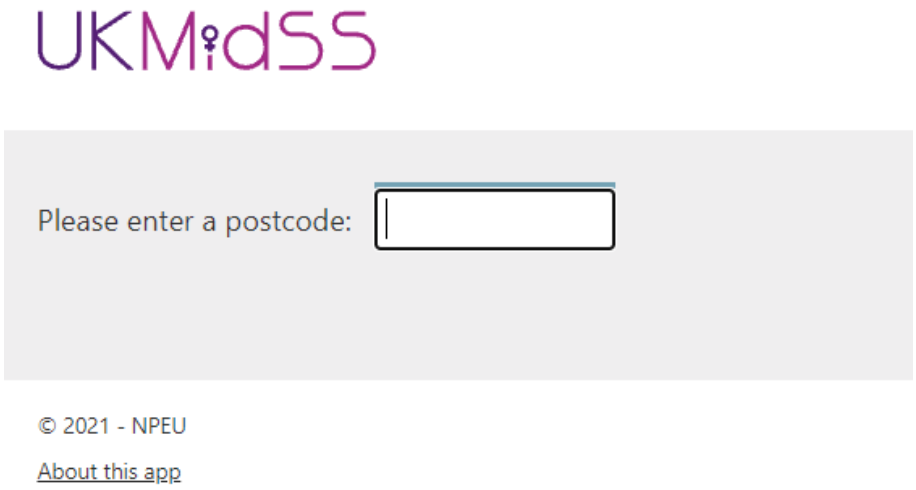
To deal with this error, if the data you entered is correct, you will need to add a query as shown at point 13 of the guide.



3- CLFM score

Question **2.5** asks for the **Children in Low-income Families Measure (CLMF) score**. This is derived from the woman's postcode. Because we are not allowed to collect identifying details there is a link

to click in the form which will take you to our postcode lookup website. Click on "click here" next to question 2.5



This will take you to a screen that like the one below. Enter the woman's postcode there and copy and paste the score for that postcode into the form at question 2.5