

## 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](mailto: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.

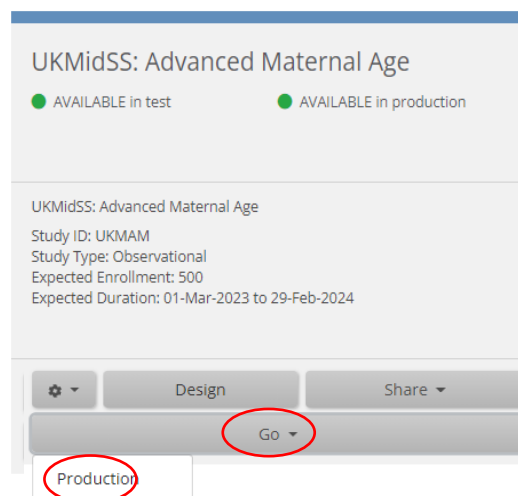
## 1- Data entry

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.

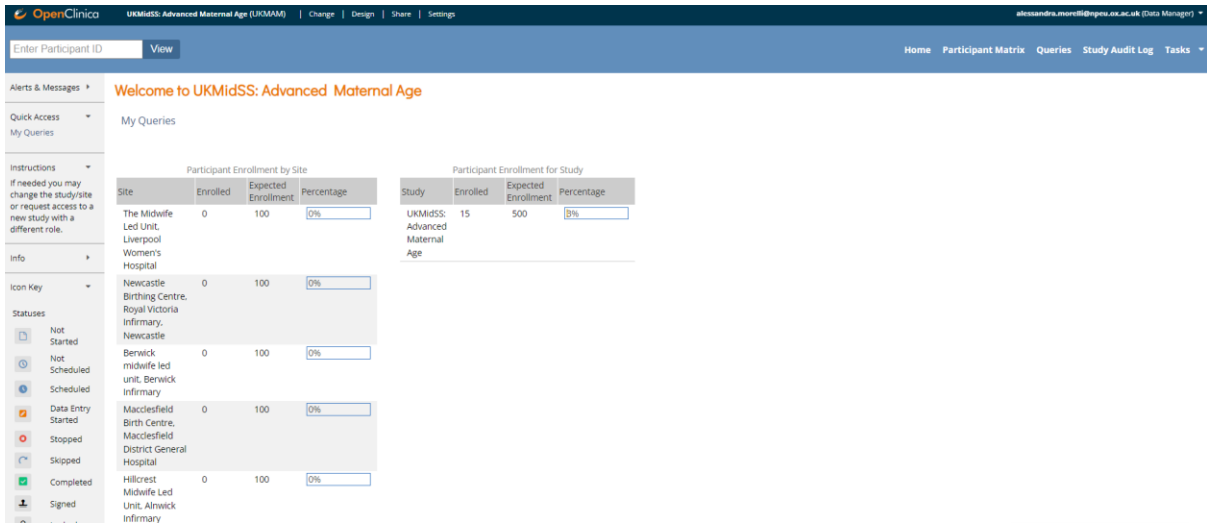
- 1- Go to <https://npeu.openclinica.io/>, add your username and password and click “log in”.  
If you don't have any log-in details, please email [ukmidss@npeu.ox.ac.uk](mailto:ukmidss@npeu.ox.ac.uk)



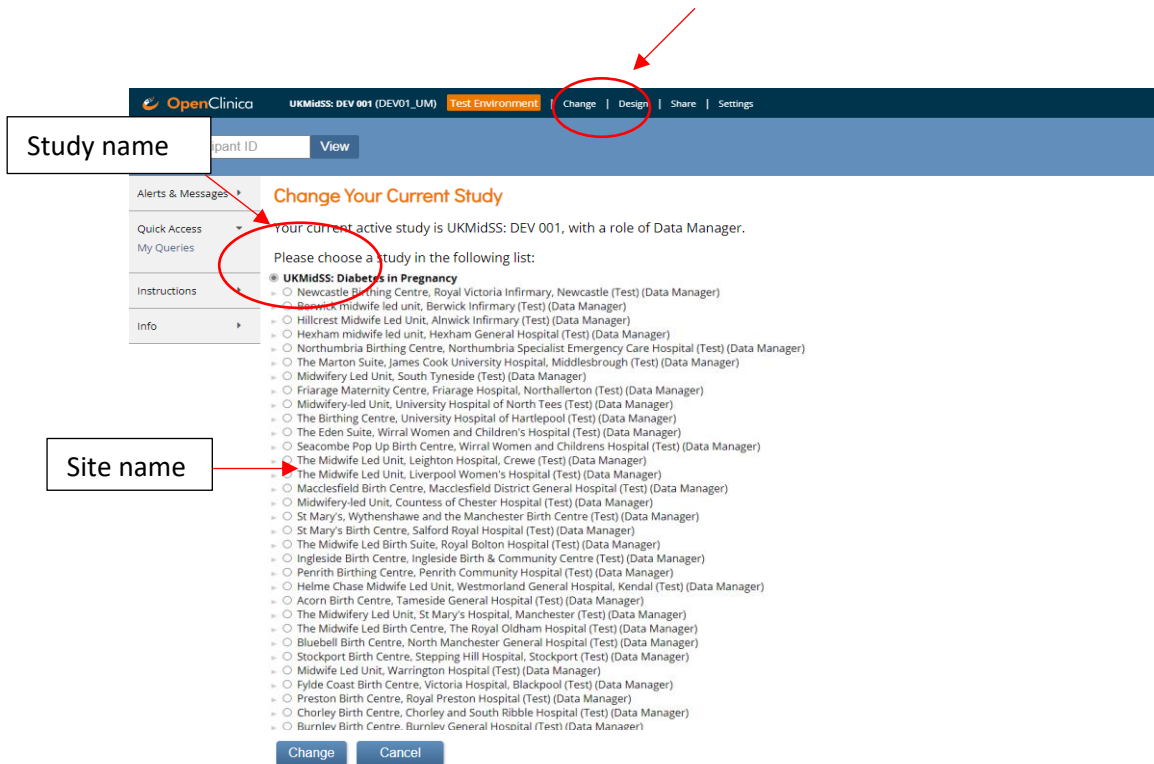
- 2- You will be redirected to a page which will be similar to this one. The name of the study will be **“Advanced Maternal Age”**. You should click on **“Go” “Production”**



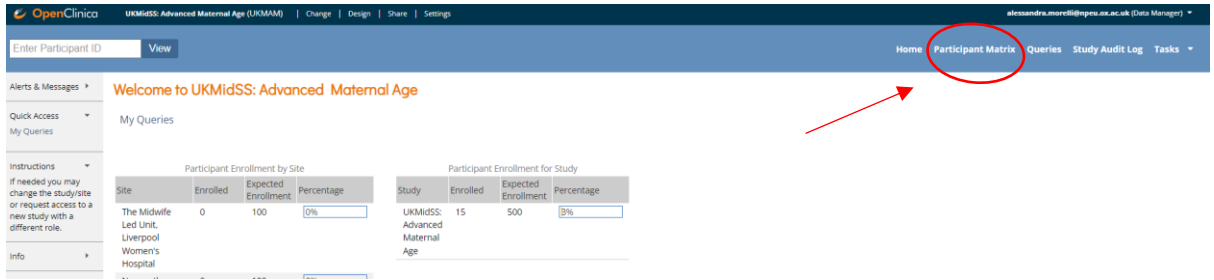
3- You be directed to a page that looks similar to the one below






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.



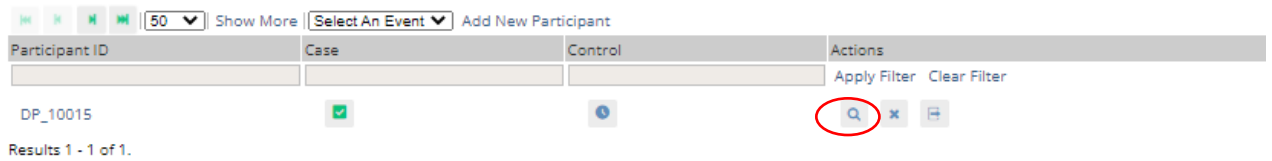
- 5- In order to identify the case/ control you wish to do the data entry for, you need to click on **“Participant Matrix”** on the right side of the screen.



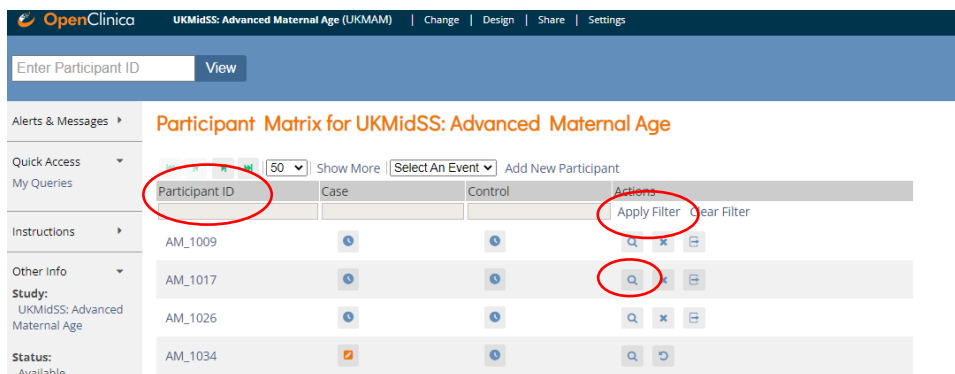
On the Participant Matrix page you will see the study “Participant IDs” for your cases and the associated controls. Each line represents a case, with its associated control. For cases and controls where no data have been entered you will see a blue icon  alongside the Participant ID. Where a form has 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.

### Participant Matrix for UKMidSS: Diabetes in pregnancy



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.

Participant **AM\_1009**

**General Information**


Edit

Participant ID	AM_1009	Status	Available
Study Name	UKMidSS: Advanced Maternal Age	Site Name	Portsmouth Maternity Centre, St Mary's Community Health Campus

**Visits**

Sort by Date

<b>Control</b>	Control
01-Mar-2023	
<b>Case</b>	Case
01-Mar-2023	

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.

Participant **AM\_1009**


**General Information**

Edit

Participant ID	AM_1009	Status	Available
Study Name	UKMidSS: Advanced Maternal Age	Site Name	Portsmouth Maternity Centre, St Mary's Community Health Campus

**Visits**

Sort by Date

<b>Control</b>	Control
01-Mar-2023	
<b>Case</b>	Case
01-Mar-2023	

Edit Case

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

AM\_1009: UKMidSS: Advanced Maternal Age - CASE

Event type

Section 1: Case definition

Participant ID

Study name

Case Definition:  
Any woman of advanced maternal age, defined as 41 years of age or older when giving birth, and admitted for labour care in a midwifery unit.  
Please complete this section first. These questions will confirm whether this woman fits our case definition or not. If your responses indicate that this woman is NOT a case you will not need to enter any further data and should contact the UKMidSS office.

1.1 Please confirm that this woman was admitted for labour care in the midwifery unit/birth centre? \*

Yes

No

All changes saved.

- 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” .

## AM\_1009: UKMidSS: Advanced Maternal Age - CASE

### Section 1: Case definition

Case Definition:  
Any woman of advanced maternal age, defined as 41 years of age or older when giving birth, and admitted for labour care in a midwifery unit.  
Please complete this section first. These questions will confirm whether this woman fits our case definition or not. If your responses indicate that this woman is NOT a case you will not need to enter any further data and should contact the UKMidSS office.

1.1 Please confirm that this woman was admitted for labour care in the midwifery unit/birth centre? \*

Yes

No

All changes saved.

Close

Next →

Return to Beginning      Go to End

- 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.

2.2 What was the woman's ethnic group?

- White British
- White Irish
- Any other white background
- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed background
- Indian
- Pakistani
- Bangladeshi
- Any other Asian background
- Black Caribbean
- Black African
- Any other black background
- Chinese
- Any other ethnic group
- Not recorded

Please select woman's ethnicity

View All History

Queries + New

Annotations + New

not known

Add a new query

missing data, unable to retrieve

Assign to: Alessandra Mor  Email? Add Query

No History

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.

## AM\_1009: UKMidSS: Advanced Maternal Age - CASE

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Section 7. Any other information

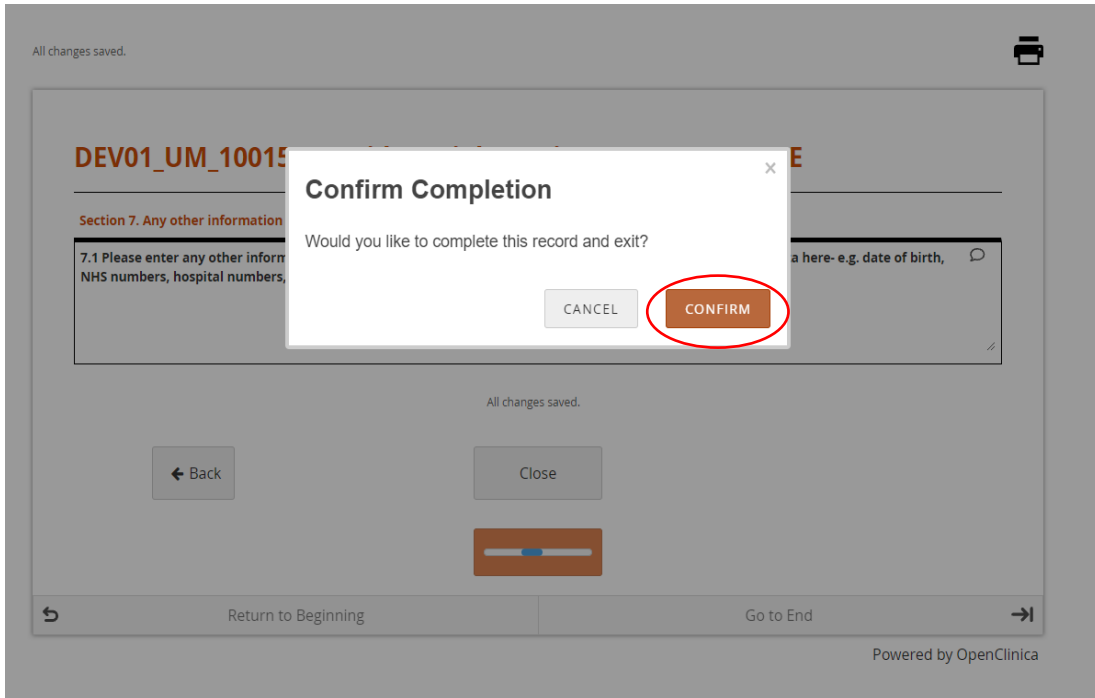
7.1 Please enter any other information you feel may be important (please do not add any personal identifiable data here- e.g. date of birth, NHS numbers, hospital numbers, etc. )

← Back
Close

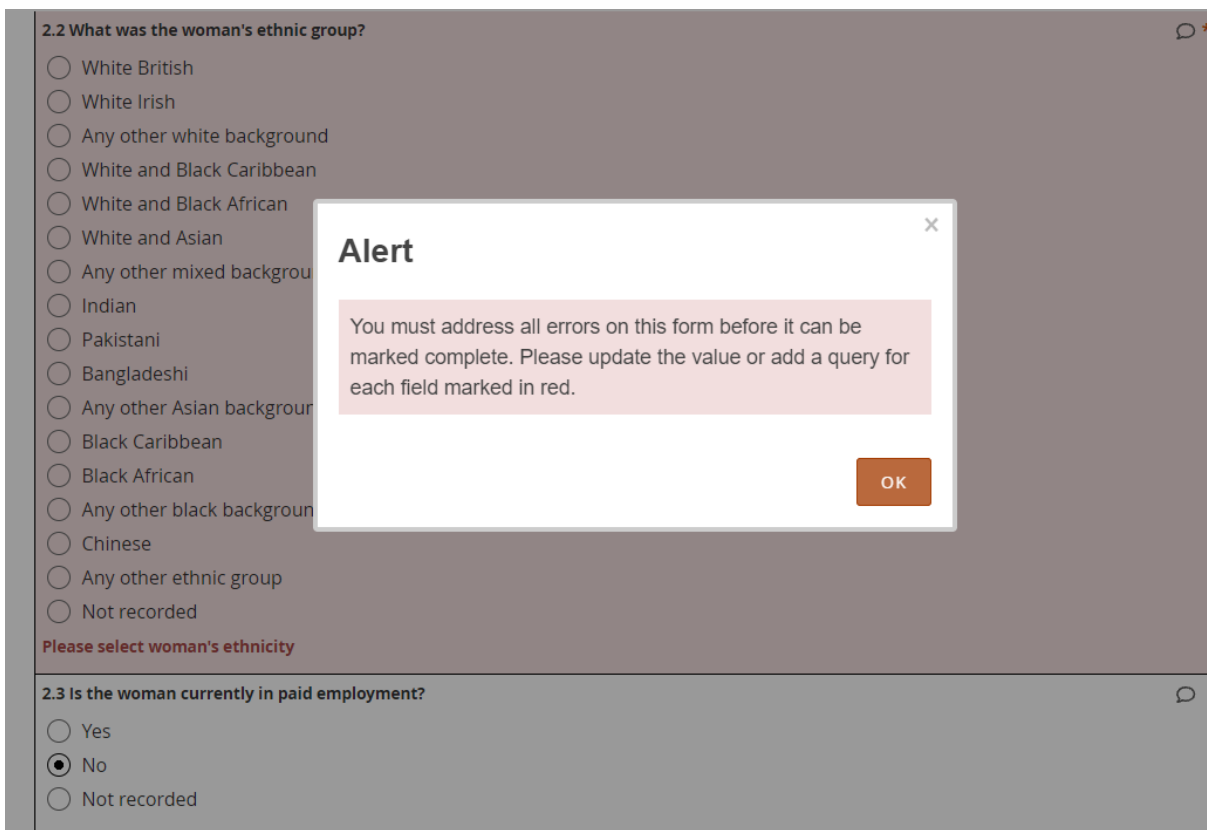
✓ Complete

↶ Return to Beginning
Go to End ↷

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.

### Participant AM\_1009

General Information

Edit			
Participant ID	AM_1009	Status	Available
Study Name	UKMidSS: Advanced Maternal Age	Site Name	Portsmouth Maternity Centre, St Mary's Community Health Campus

Visits

Sort by Date

<b>Control</b>	✔	Control	✔	
17-Nov-2021	⋮	02-Dec-21 by...	⋮	
<b>Case</b>	✘	Case	✘	
17-Nov-2021	⋮	25-Nov-21 by...	⋮	

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.

## Participant Matrix for UKMidSS: Advanced Maternal Age

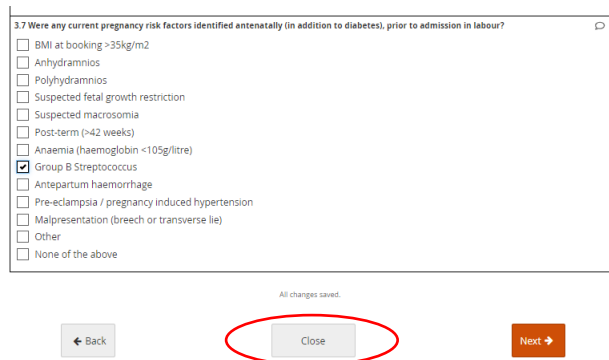
⏪ ⏩ ⏴ ⏵ | 50 ▼ | Show More | Select An Event ▼ | Add New Participant

Participant ID	Case	Control	Actions
			Apply Filter Clear Filter
AM_1009	✘	⌚	🔍 ✕ 🗑️
AM_1017	⌚	⌚	🔍 ✕ 🗑️
AM_1026	⌚	⌚	🔍 ✕ 🗑️
AM_1034	✘	⌚	🔍 ↻
AM_1041	⌚	⌚	🔍 ↻
AM_1053	✔	✔	🔍 ✕ 🗑️

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.



3.7 Were any current pregnancy risk factors identified antenatally (in addition to diabetes), prior to admission in labour?

- BMI at booking >35kg/m2
- Anhydramnios
- Polyhydramnios
- Suspected fetal growth restriction
- Suspected macrosomia
- Post-term (>42 weeks)
- Anaemia (haemoglobin <105g/litre)
- Group B Streptococcus
- Antepartum haemorrhage
- Pre-eclampsia / pregnancy induced hypertension
- Malpresentation (breech or transverse lie)
- Other
- None of the above

All changes saved.


← Back      Close      Next →

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.

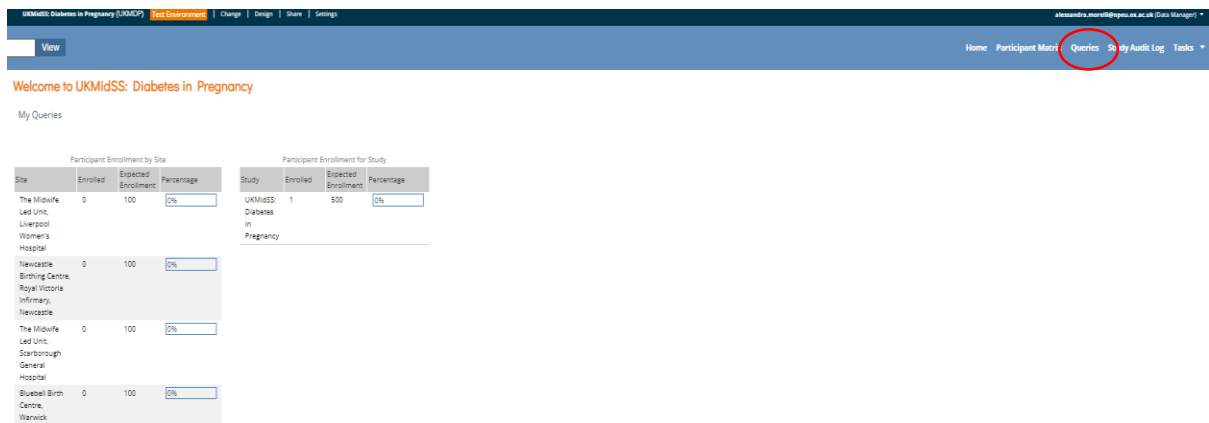
## 2- How to deal with data queries

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:

<b>New</b>	
<b>Updated</b>	
<b>Closed</b>	
<b>Not Applicable</b>	
<b>Closed Modified</b>	

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



UKMidSS: Diabetes in Pregnancy (UKMDP) **Test Environment** | Change | Design | Run | Settings

View Home Participant Mgmt **Queries** Study Audit Log Tasks

Welcome to UKMidSS: Diabetes in Pregnancy






My Queries










Participant Enrollment by Site				Participant Enrollment for Study			
Site	Enrolled	Expected Enrollment	Percentage	Study	Enrolled	Expected Enrollment	Percentage
The Midwife Led Unit, Liverpool Women's Hospital	0	100	0%	UKMidSS Diabetes in Pregnancy	1	500	0%
Newcastle Birthing Centre, Royal Victoria Infirmary, Newcastle	0	100	0%				
The Midwife Led Unit, Scarborough General Hospital	0	100	0%				
Bluebell Birth Centre, Warwick	0	100	0%				


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

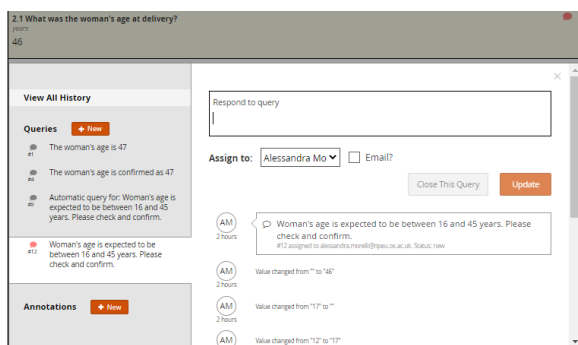
**Queries**


Summary counts by status (based on table filters)

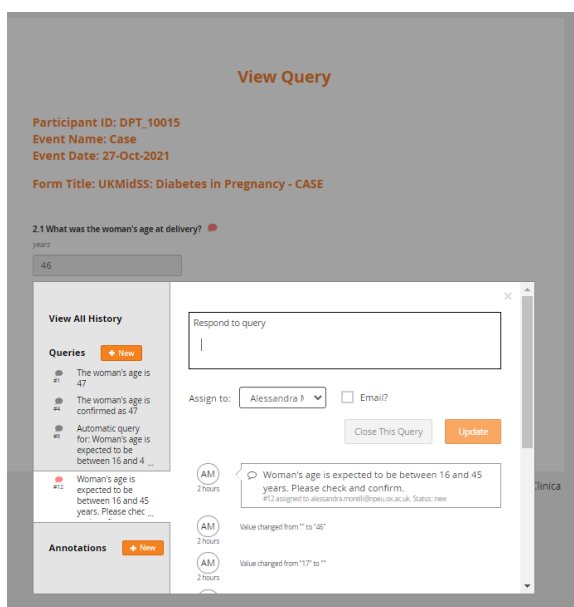
<b>New</b>		4
<b>Updated</b>		..
<b>Closed</b>		..
<b>Not Applicable</b>		..
<b>Closed Modified</b>		10
<b>Total</b>		14

Query ID	Participant ID	Site ID	Type	Resolution Status	Days Open	Days Since Updated	Event Name	CRF	Item Name	Item Value	Detailed Notes	Assigned User	Actions
11	DPT_10015	UKMDP	Query	 New	0	0	Case	Case	BIRTH_LOC	3	Midwifery unit, under midwifery care cannot be selected if Q4.7.1 is answered Before birth. Please check and confirm.	Alessandra Morelli (alessandra.morelli@npeu.ox.ac.uk)	 
12	DPT_10015	UKMDP	Query	 New	0	0	Case	Case	AGE_AT_DEL	46	Woman's age is expected to be between 16 and 45 years. Please check and confirm.	Alessandra Morelli (alessandra.morelli@npeu.ox.ac.uk)	 
13	DPT_10015	UKMDP	Query	 New	0	0	Case	Case	GLUC_MON_WHY_OTH		Please give details of...	0	 

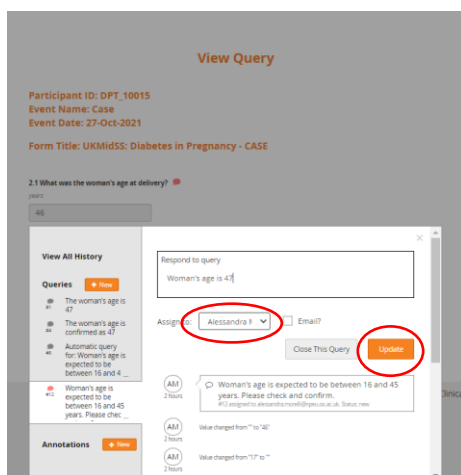
3- Click on the  icon to view the query within the actual record.






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.

### Participant Matrix for UKMidSS: Advanced Maternal Age

Navigation:     | 50 | Show More | Select An Event | Add New Participant

Participant ID	Case	Control	Actions
			Apply Filter Clear Filter
AM_1009			  
AM_1017			  
AM_1026			  
AM_1034			 
AM_1041			 
AM_1053			  
AM_1060			  
AM_1078			  
AM_1085			  

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

## Participant AM\_1009

### General Information

Edit

Participant ID	AM_1009	Status	Available
Study Name	UKMidSS: Advanced Maternal Age	Site Name	Portsmouth Maternity Centre, St Mary's Community Health Campus

### Visits

Sort by Date

<b>Control</b>	<input checked="" type="checkbox"/>	<b>Control</b>	<input checked="" type="checkbox"/>
01-Nov-2021	⋮	02-Jan-22 by...	⋮
<b>Case</b>	<input checked="" type="checkbox"/>	<b>Case</b>	<input checked="" type="checkbox"/>
01-Nov-2021	⋮	29-Dec-21 by...	⋮

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.

3.10 Did the woman receive any medication for diabetes control in pregnancy?	🗨
<input type="radio"/> Yes	
<input checked="" type="radio"/> No	
3.11 During pregnancy, before admission in labour, was the woman admitted to hospital for glycaemic control not related to steroids?	🗨
<input checked="" type="radio"/> Yes	
<input type="radio"/> No	
Please enter a reason for change at bottom of page.	

Looks like you've made some updates. Please tell us why:

Enter a reason for your changes	<input type="checkbox"/> Apply to all
3.11 During pregnancy, before admission in labour, was the woman admitted to hospital for glycaemic control not related to steroids?	
Enter a reason for changing this value	

All changes saved.

← Back

Close

Next →

Return to Beginning

Go to End



## 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.

### AM\_1009: UKMidSS: Advanced Maternal Age - CASE

#### Section 2: Woman's details

2.1 What was the woman's age at delivery?  
years

15

Woman's age is expected to be between 16 and 45 years. Please check and confirm.

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.

2.1 What was the woman's age at delivery?  
years

15

Woman's age is expected to be between 16 and 45 years. Please check and confirm.

**View All History**

**Queries** + New

**Annotations** + New

Add a new query

I confirm the age of 15 is correct

Assign to: Alessandra Mor  Email?

Add Query

- AM Value changed from "55" to "15"  
13 minutes
- AM Value changed from "" to "55"  
13 minutes
- AM Value changed from "44" to ""  
33 minutes
- AM Value changed from "" to "44"  
3 hours


Show value changes

## 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

2.5 Please enter the Children in Low-income Families Measure (CLFM) score. For the Children Low-income Families Measure score [click here](#)  \*

CLFM score which should be a value between 0 and 1 with 3 decimal places

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

# UKMidSS

Please enter a postcode:

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[About this app](#)