

## 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 Diabetes Study you will receive an email listing the Participant IDs' for those cases.
- Each "Participant ID" will start with **DP\_**
- 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.

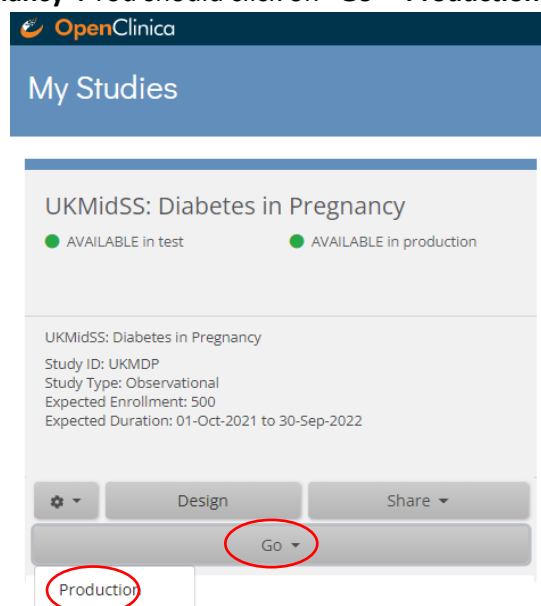
## 1- Data entry

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 “Diabetes in Pregnancy”. You should click on “Go” “Production”



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

The screenshot shows the OpenClinica interface for the study 'UKMidSS: Diabetes in Pregnancy'. The top navigation bar includes 'OpenClinica', 'UKMidSS: Diabetes in Pregnancy (UKMDP)', 'Test Environment', and 'Change | Design | Share | Settings'. Below the navigation bar, there is a search bar for 'Participant ID' and a 'View' button. The main content area is titled 'Welcome to UKMidSS: Diabetes in Pregnancy' and contains two tables:

Participant Enrollment by Site			
Site	Enrolled	Expected Enrollment	Percentage
The Midwife Led Unit, Liverpool Women's Hospital	0	100	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 Hospital	0	100	0%
Shrewsbury Midwife Led Unit, Royal Shrewsbury Hospital	0	100	0%
The Midwife Led Unit	0	100	0%

Participant Enrollment for Study			
Study	Enrolled	Expected Enrollment	Percentage
UKMidSS: Diabetes in Pregnancy	0	500	0%

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.

The screenshot shows the OpenClinica interface with the 'Change' tab highlighted in the top navigation bar. Below the navigation bar, there is a search bar for 'Participant ID' and a 'View' button. The main content area is titled 'Change Your Current Study' and contains the following text:

Your current active study is UKMidSS: DEV 001, with a role of Data Manager.




Please choose a study in the following list:

- UKMidSS: Diabetes in Pregnancy
  - Newcastle Birthing Centre, Royal Victoria Infirmary, Newcastle (Test) (Data Manager)
  - Berwick midwife led unit, Berwick Infirmary (Test) (Data Manager)
  - Hillcrest Midwife Led Unit, Alnwick Infirmary (Test) (Data Manager)
  - Hexham midwife led unit, Hexham General Hospital (Test) (Data Manager)
  - Northumbria Birthing Centre, Northumbria Specialist Emergency Care Hospital (Test) (Data Manager)
  - The Marton Suite, James Cook University Hospital, Middlesbrough (Test) (Data Manager)
  - Midwife Led Unit, South Tyneside (Test) (Data Manager)
  - Friarage Maternity Centre, Friarage Hospital, Northallerton (Test) (Data Manager)
  - Midwife-led Unit, University Hospital of North Tees (Test) (Data Manager)
  - The Birthing Centre, University Hospital of Hartlepool (Test) (Data Manager)
  - The Eden Suite, Wirral Women and Children's Hospital (Test) (Data Manager)
  - Seacombe Pop Up Birth Centre, Wirral Women and Children's Hospital (Test) (Data Manager)
  - The Midwife Led Unit, Leighton Hospital, Crewe (Test) (Data Manager)
  - The Midwife Led Unit, Liverpool Women's Hospital (Test) (Data Manager)
  - Macclesfield Birth Centre, Macclesfield District General Hospital (Test) (Data Manager)
  - Midwife-led Unit, Countess of Chester Hospital (Test) (Data Manager)
  - St Mary's, Wythenshawe and the Manchester Birth Centre (Test) (Data Manager)
  - St Mary's Birth Centre, Salford Royal Hospital (Test) (Data Manager)
  - The Midwife Led Birth Suite, Royal Bolton Hospital (Test) (Data Manager)
  - Ingleside Birth Centre, Ingleside Birth & Community Centre (Test) (Data Manager)
  - Penrith Birthing Centre, Penrith Community Hospital (Test) (Data Manager)
  - Helme Chase Midwife Led Unit, Westmorland General Hospital, Kendal (Test) (Data Manager)
  - Acorn Birth Centre, Tameside General Hospital (Test) (Data Manager)
  - The Midwife Led Unit, St Mary's Hospital, Manchester (Test) (Data Manager)
  - The Midwife Led Birth Centre, The Royal Oldham Hospital (Test) (Data Manager)
  - Bluebell Birth Centre, North Manchester General Hospital (Test) (Data Manager)
  - Stockport Birth Centre, Stepping Hill Hospital, Stockport (Test) (Data Manager)
  - Midwife Led Unit, Warrington Hospital (Test) (Data Manager)
  - Fylde Coast Birth Centre, Victoria Hospital, Blackpool (Test) (Data Manager)
  - Preston Birth Centre, Royal Preston Hospital (Test) (Data Manager)
  - Chorley Birth Centre, Chorley and South Ribble Hospital (Test) (Data Manager)
  - Burnley Birth Centre, Burnley General Hospital (Test) (Data Manager)

At the bottom of the dialog box, there are two buttons: 'Change' and 'Cancel'.

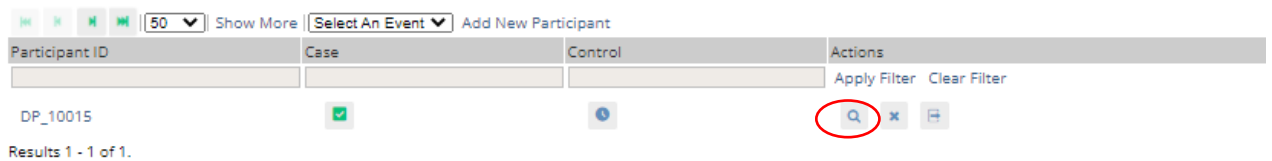
- 5- In order to identify the case/ control you wish to do the data entry for, you need to click on **“Participant Matrix”** on the right side of the screen.



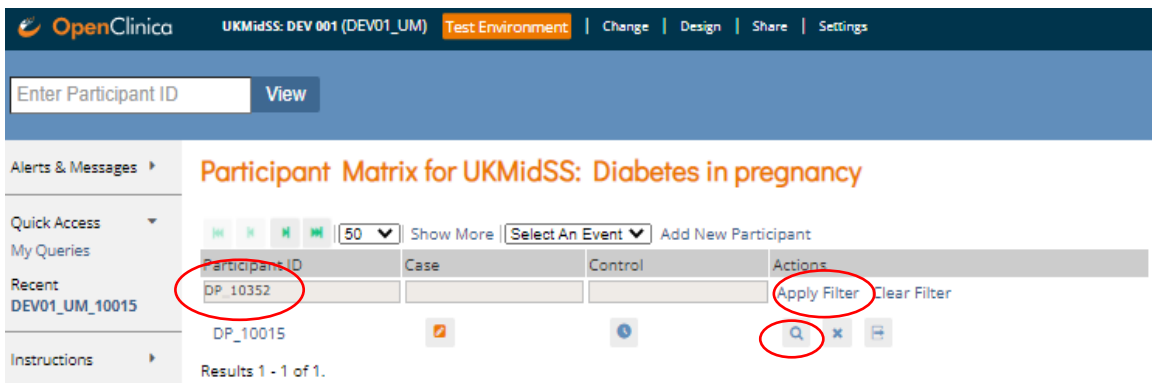
On the Participant Matrix page you will see the study “Participant IDs” for your cases and the associated controls. Each line represents a case, with its associated control. For cases and controls where no data have been entered you will see a blue icon  alongside the Participant ID. Where a form has 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 (**DP\_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 DP\_1009

General Information


Edit

Participant ID	DP_1009	Status	Available
Study Name	UKMidSS: Diabetes in Pregnancy	Site Name	Welshpool Birth Centre, Victoria War Memorial Hospital, Welshpool

Visits

Sort by Date

Control	01-Nov-2021	Control
Case	01-Nov-2021	Case

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 DP\_1009

General Information

Edit

Participant ID	DP_1009	Status	Available
Study Name	UKMidSS: Diabetes in Pregnancy	Site Name	Welshpool Birth Centre, Victoria War Memorial Hospital, Welshpool

Visits

Sort by Date

Control	01-Nov-2021	Control
Case	01-Nov-2021	Case

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

The screenshot shows the top of the form with the following elements:

- Participant ID:** DP\_1009
- Study name:** UKMidSS: Diabetes in Pregnancy
- Event type:** CASE

**Section 1: Case definition**

**Case Definition:**  
Any woman with a diagnosis of diabetes in pregnancy (gestational diabetes or pre-existing diabetes) and admitted for labour care in the 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 Was this woman admitted for labour care to the midwifery unit/birth centre? \*

Yes  
 No

Buttons: Close, Next →

- 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” .

The screenshot shows the form with the following elements:

- DP\_1009: UKMidSS: Diabetes in Pregnancy - CASE**
- Section 1: Case definition**
- Case Definition:**  
Any woman with a diagnosis of diabetes in pregnancy (gestational diabetes or pre-existing diabetes) and admitted for labour care in the 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 Was this woman admitted for labour care to the midwifery unit/birth centre? \*
- Yes  
 No

Buttons: Close, Next →

Footer: 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.

The screenshot shows a form titled "2.2 What was the woman's ethnic group?" with a list of radio button options including "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", and "Not recorded". Below the list is the instruction "Please select woman's ethnicity".

Overlaid on the form is a "View All History" window. It has a "Queries" section with a "+ New" button circled in red. A text input field contains "missing data, unable to retrieve" and is also circled in red. Below the input field is an "Assign to:" dropdown menu with "Alessandra Mor" selected, and an "Email?" checkbox. An "Add Query" button is to the right. A red arrow points from the "Assign to:" dropdown to the "missing data, unable to retrieve" text. There is also a "No History" link at the bottom of the window.

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.

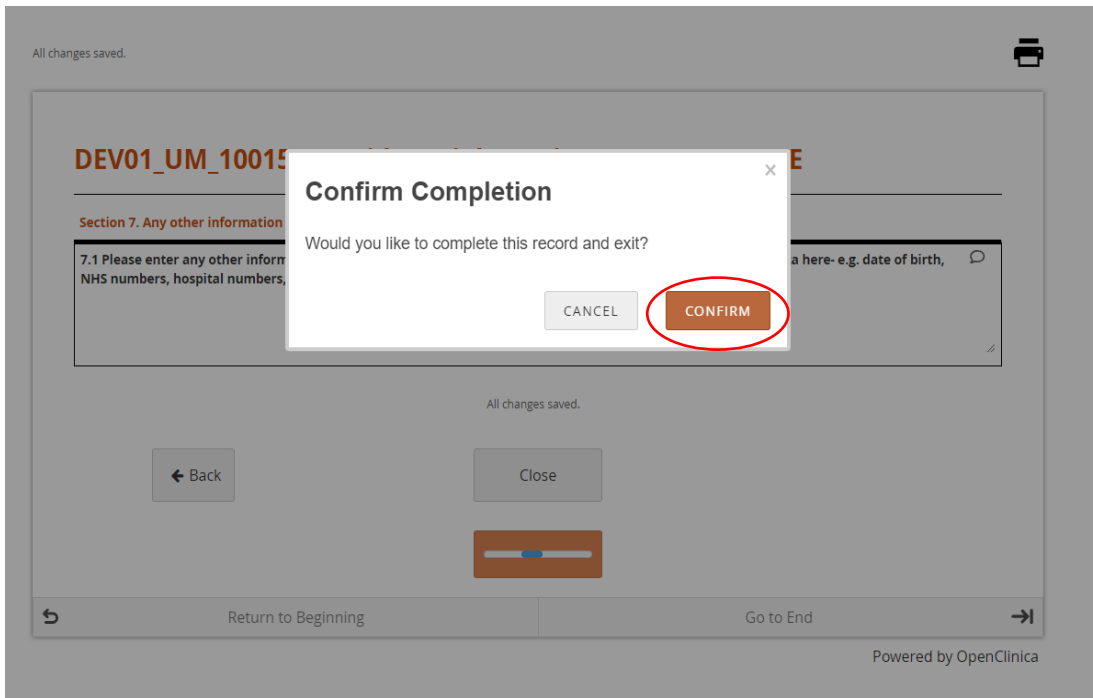
The screenshot shows a form titled "DPT\_10015: UKMidSS: Diabetes in Pregnancy - CASE". Below the title is "Section 7. Any other information".

Section 7.1 contains the text: "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. )".

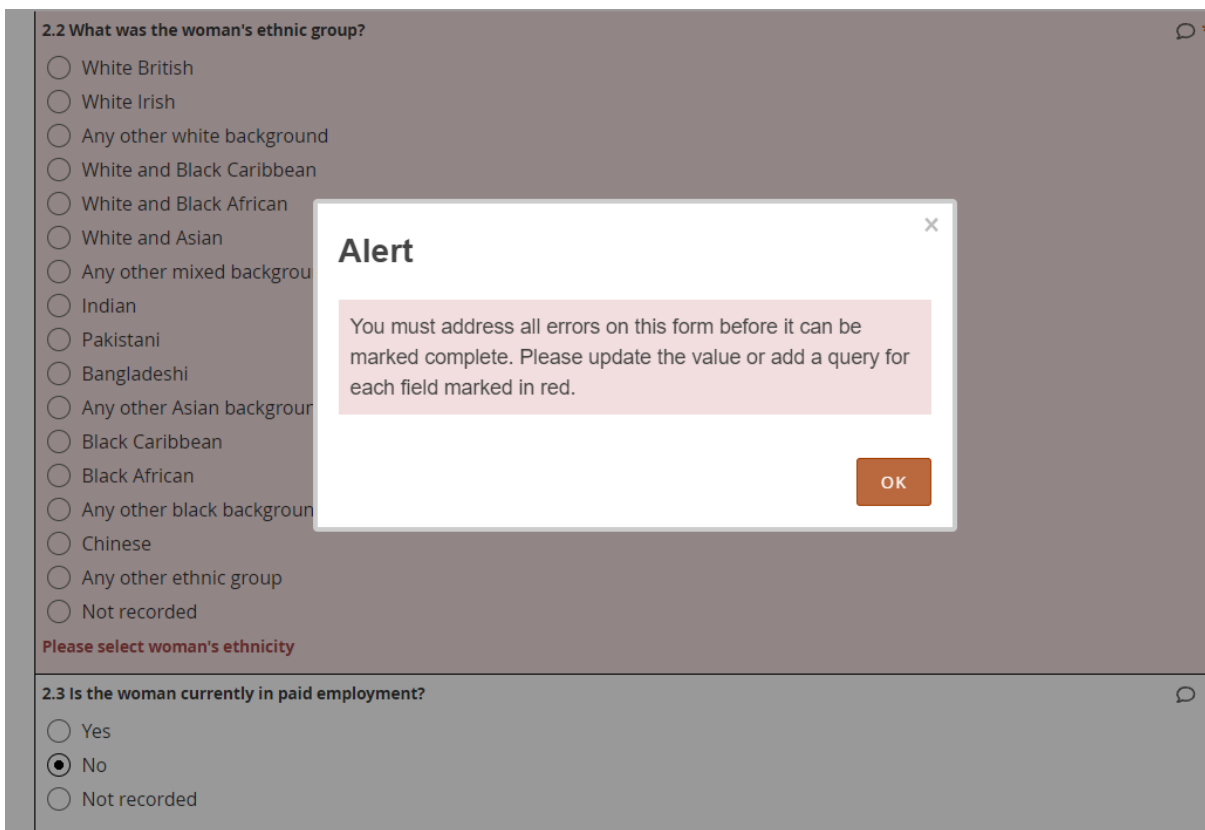
At the bottom of the form are three buttons: "Back", "Close", and "Complete". The "Complete" button is highlighted with a red circle.

At the very bottom of the page are navigation buttons: "Return to Beginning" and "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 DP\_1293

**General Information**

Edit

Participant ID	DP_1293	Status	Available
Study Name	UKMidSS: Diabetes in Pregnancy	Site Name	The Midwife Led Unit, Newham Hospital

**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: Diabetes in Pregnancy

50 Show More Select An Event Add New Participant

Participant ID	Case	Control	Actions
DP_1009	⚠	⚠	🔍 ✕ 🔄
DP_1017	✓	✓	🔍 ✕ 🔄
DP_1026	✓	✓	🔍 ✕ 🔄

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/m<sup>2</sup>
- 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.

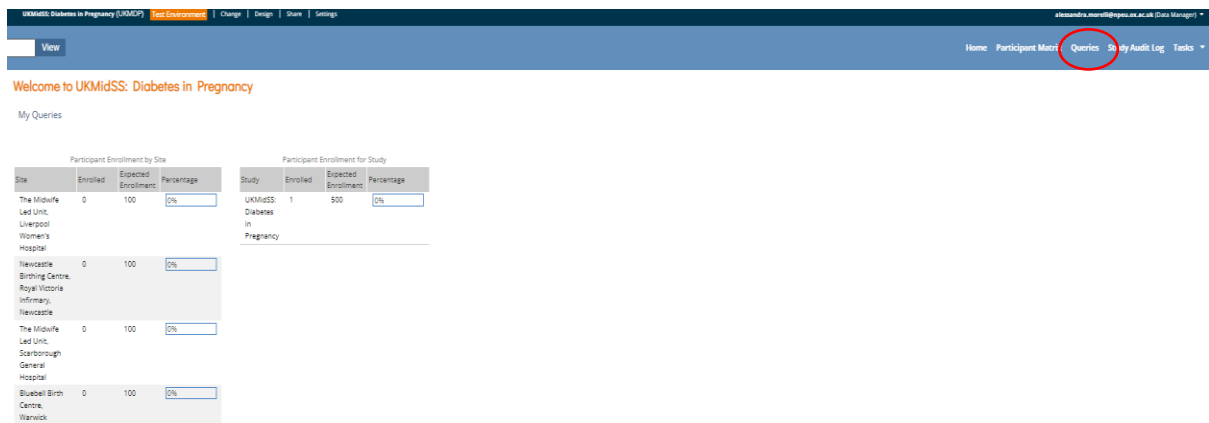
## 2- How to deal with data queries

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

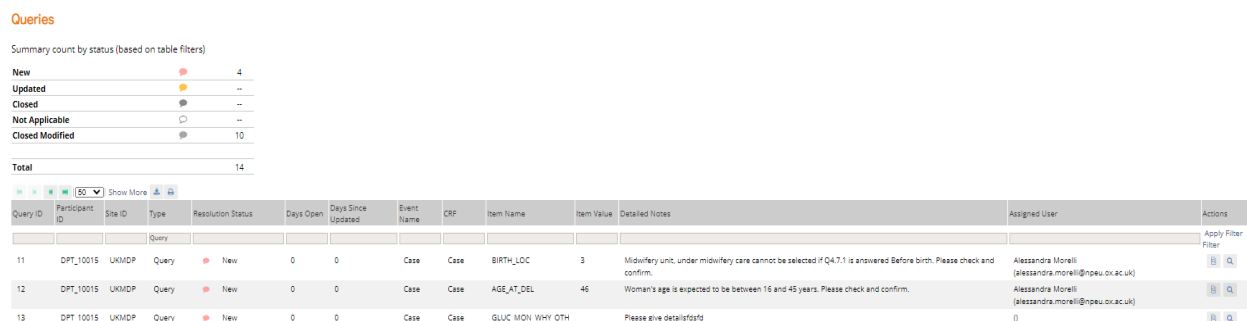


The screenshot shows the UKMidSS Diabetes in Pregnancy (UKMDP) interface. The top navigation bar includes 'Home', 'Participant Mgmt', 'Queries', 'Study Audit Log', and 'Tasks'. The 'Queries' menu item is circled in red. Below the navigation bar, there are two tables: 'Participant Enrollment by Site' and 'Participant Enrollment for Study'.

Site	Enrolled	Expected Enrollment	Percentage
The Midwife Led Unit, Liverpool Women's Hospital	0	100	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%

Study	Enrolled	Expected Enrollment	Percentage
UKMidSS Diabetes in Pregnancy	1	500	0%






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









The screenshot shows the 'Queries' page with a summary of query counts by status and a table of query details.

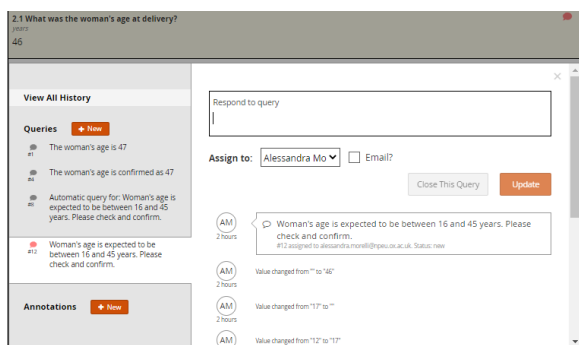
**Queries**


Summary counts by status (based on table filters)

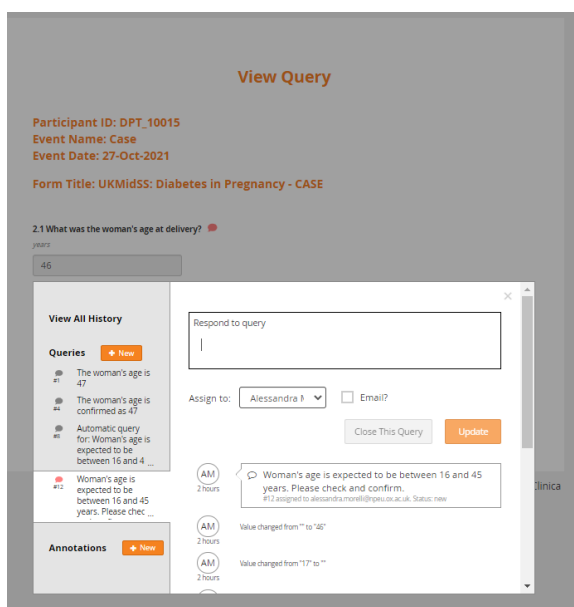
<b>New</b>		4
<b>Updated</b>		..
<b>Closed</b>		..
<b>Not Applicable</b>		..
<b>Closed Modified</b>		10
<b>Total</b>		14

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...		 

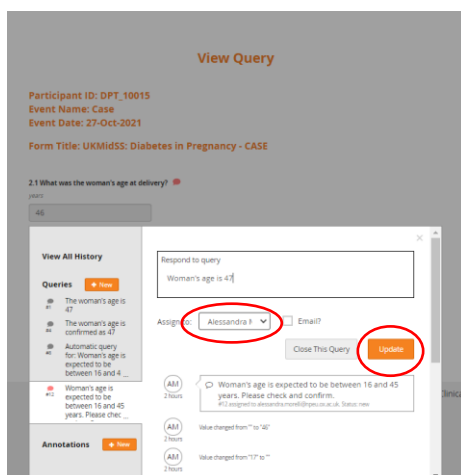
3- Click on the  icon to view the query within the actual record.






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

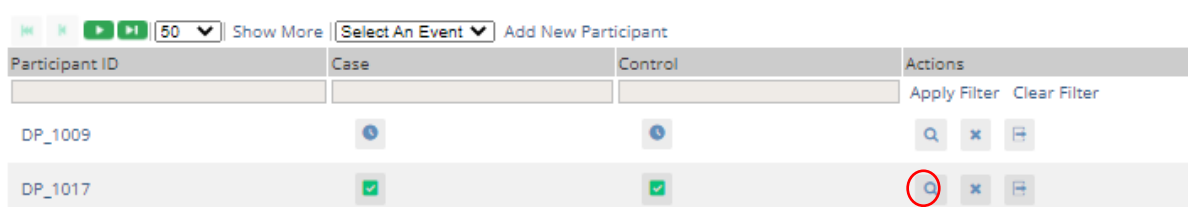
Discrepancy notes have been removed and integrated into the data entry form itself. When data that are missing or unexpected are saved in OpenClinica, now you will just treat it as a data query . Flags  will no longer appear on OpenClinica.

### 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.

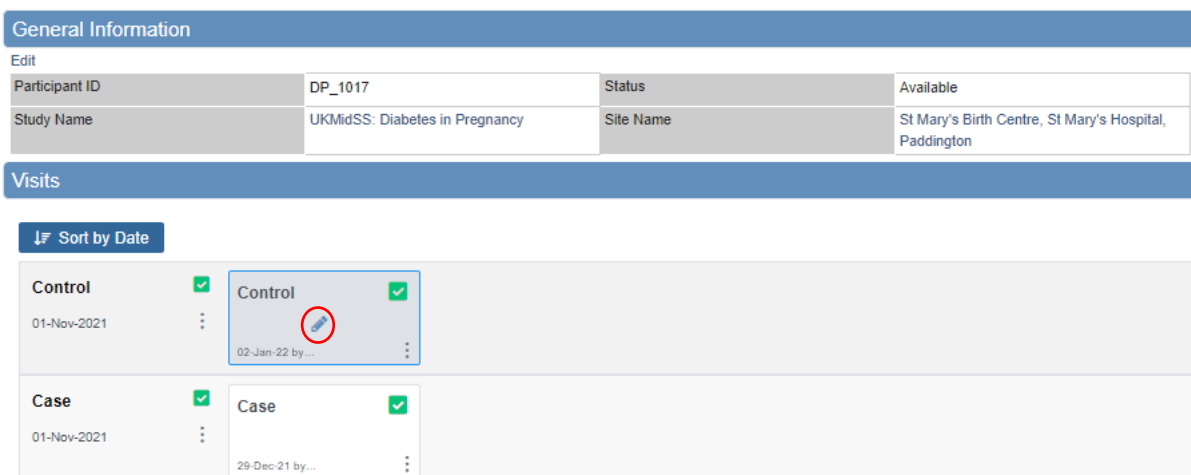
Go to **"Participant Matrix"**, click on the on the left, then **click** on the  magnifying glass icon.  
**Participant Matrix for UKMidSS: Diabetes in Pregnancy**



Participant ID	Case	Control	Actions
DP_1009			
DP_1017			

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

#### Participant DP\_1017



**General Information**

Edit

Participant ID	DP_1017	Status	Available
Study Name	UKMidSS: Diabetes in Pregnancy	Site Name	St Mary's Birth Centre, St Mary's Hospital, Paddington

**Visits**

Sort by Date

Visit Type	Date	Status	Actions
Control	01-Nov-2021		
Case	01-Nov-2021		

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? 🗨

Yes  
 No

3.11 During pregnancy, before admission in labour, was the woman admitted to hospital for glycaemic control not related to steroids? 🗨

Yes  
 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  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 →

## 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.

### DEV01\_UM\_10015: UKMidSS: Diabetes in Pregnancy - 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

Assign to: Alessandra Mor  Email?

Add a new query  
I confirm the age of 15 is correct

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](#)