



Guide for UKMidSS Reporters



Contents

Contents	1
1 What is UKMidSS?	2
1.1 Background.....	2
1.2 The UK Midwifery Study System (UKMidSS)	2
2 Where to go for more information	3
2.1 Your details.....	3
3 Monthly reporting.....	4
3.1 'Cases' and 'nil returns'	5
3.1.1 How to identify your cases.....	5
3.2 Reporting 'denominator data'	5
3.3 Case Identification numbers (IDs)	5
3.3.1 Keeping track of your cases	6
4 Identifying controls/comparison women.....	6
5 Entering data	7
5.1 Key points.....	7
5.2 How to enter data.....	8
5.2.1 Logging in	8
5.2.2 Your home page ('Subject Matrix').....	8
5.2.3 Entering data	10
5.2.4 Children in Low-income Families Score	10
5.2.5 Data issues (DIs)	11
5.2.6 Discrepancy Notes (DNs)	12
5.2.7 Completing the form	14
5.2.8 Editing a completed form	14
5.2.9 Entering data on controls	16

1 What is UKMidSS?

1.1 Background

Government policy on maternity care says that healthy women with straightforward pregnancies should have a choice about where to plan to have their baby, including care in a midwifery-led setting. National guidelines recommend that women may choose any birth setting, but that for healthy women with straightforward pregnancies midwifery units are “particularly suitable”.

Because care in midwifery-led settings is becoming increasingly important, we need more information to improve care and make it even safer and also to see if it may be safe for some women with more complicated pregnancies to plan birth in these settings. This information is not routinely available.

1.2 The UK Midwifery Study System (UKMidSS)

The UK Midwifery Study System (UKMidSS) is a national infrastructure to facilitate a programme of national studies of uncommon events and conditions affecting women planning birth in midwifery units. UKMidSS had focussed on alongside midwifery units (AMUs) because that is where most births in midwifery-led settings are planned and take place. However, now we also include freestanding midwifery units (FMUs), and may have the opportunity to also include planned home births in the future. UKMidSS uses similar methods to the successful UK Obstetric Surveillance System (UKOSS) which has run in hospital obstetric units since 2005. The first three studies carried out using UKMidSS investigated outcomes in (a) severely obese women starting labour care in an AMU, (b) women with a baby admitted to neonatal care after birth in an AMU and (c) multiparous women starting labour care in an AMU who had experienced a previous PPH.

The fourth UKMidSS study investigates outcomes in (d) women giving birth in an AMU or FMU and having a PPH requiring transfer to an obstetric unit or receiving care from an obstetrician for a PPH on the midwifery unit. This study (PPH Study) starts on 1st September 2018 and is used as an example in this guide.

UKMidSS is led from the National Perinatal Epidemiology Unit (NPEU) at the University of Oxford and was funded by a National Institute for Health Research (NIHR) Post-doctoral Fellowship (PDF-2014-07-006) from 1st January 2015 to 31st December 2018 and by the Policy Research Programme in the Department of Health (Policy Research Unit in Maternal Health and Care, Award 108/0001) and subsequently by a NIHR Research for Patient Benefit programme (PB-PG-0418-20005) and NIHR Policy Research Unit in Maternal & Neonatal Health and Care (PR-PRU-1217-21202).

2 Where to go for more information

There is more information about UKMidSS on our website <https://www.npeu.ox.ac.uk/ukmidss> and in the protocol in your UKMidSS folder. We will also send you a newsletter every three months to keep you up to date with news and progress. Finally, you can follow us on Twitter @NPEU_UKMidSS or get in touch with us directly using the contact details in your folder.

2.1 Your details

We will use email, and occasionally phone or post, to keep in touch with you. If your contact details change or if you want let us know that the UKMidSS reporters for your unit are changing, please call or email us as soon as possible.

3 Monthly reporting

At the beginning of every month each UKMidSS reporter will receive an email like this asking you to report for the previous calendar month:

Dear Jane,

As you know, you are a [UKMidSS](#) reporter for The Lakeside midwife led unit, Lakeside Hospital, Laketown.

Please provide your UKMidSS report for **September 2019** by following this link:
<https://ukmidss.npeu.ox.ac.uk/Report/19bdfb7533eb407b8934f9000c92e973>

Thank you,
Rachel and the UKMidSS team

By following the link in the email you will reach a screen like this:

The screenshot shows the UKMidSS reporting interface. At the top left is the UKMidSS logo. Below it, the user is greeted with 'Hello, Jane.' and asked to report on the following: 'Lakeside midwife led unit, Lakeside Hospital, Laketown — September 2019'. The first section is titled 'PPH' and asks for the 'Number of women who had a PPH requiring transfer to an obstetric unit, or received care from an obstetrician for a PPH without transfer to an obstetric unit, after giving birth in the midwifery unit in September 2019?'. There is a text input field and a link to 'check our FAQs'. The second section is titled 'General' and asks 'How many women, in total, gave birth in the midwifery unit in September 2019?' with a text input field. Below that is a field for 'Your email address:'. The final section asks 'Please detail any additional information you would like to provide:' with a large text area. A 'Submit' button is located in the bottom right corner.

3.1 'Cases' and 'nil returns'

For the PPH study for UKMidSS you are being asked to report on women who give birth in your unit in the given month and who had a PPH requiring transfer to an obstetric unit or received care from an obstetrician for a PPH without transfer to an obstetric unit.

These women are your CASES each month.

- **Enter the number of cases.**
- **If you have had no cases in your unit in any given month please remember to enter 0 and record a 'nil return' for that month in your case log.**

3.1.1 How to identify your cases

In each unit, UKMidSS reporters will need to find the best way to reliably identify cases for UKMidSS studies. Based on the experience of the UK Obstetric Surveillance System (UKOSS), possible methods include: putting a sticker against the woman's details in the unit admission book, regularly checking manual or electronic data systems, having an UKMidSS item on the agenda at a regular meeting, emailing colleagues or a simple list on a noticeboard. When you find the method which works for you, why not share it with the UKMidSS office so we can share it with others?

3.2 Reporting 'denominator data'

Every month we will also ask you **how many women gave birth in your midwifery unit**. We need these 'denominator data' so that we can calculate the proportion of women giving birth in midwifery units affected by the condition or event we are studying. **Remember we are asking for data for your midwifery unit only.**

- **Please enter the information requested and your email address and click Submit.**

3.3 Case Identification numbers (IDs)

When you click Submit you will see a confirmation screen and receive an email listing the information you have submitted, the case IDs for the cases you have reported and including a link to the data collection system. This confirmation will look like this:

Dear Jane,

Thank you for submitting a report for [midwifery unit, hospital, town] for September 2019. The numbers you reported are as follows:

Number of cases for 'PPH Study'	2
Total women giving birth in unit	25

If you wish to change your reported numbers, please [contact us](#) quoting UKMidSS report reference [xx].

The following cases have been created for you:

- PH_31525
- PH_31537

Please [click here](#) to enter data on these cases. You may need to enter your UKMidSS OpenClinica username and password.

Thank you,
Rachel & the UKMidSS team

In most units there will be more than one UKMidSS reporter. When one reporter completes the monthly report, other reporters in the same unit will also receive the confirmation email.

- **If you realise you have made a mistake, or if you want to change the numbers you have reported, please email ukmidss@npeu.ox.ac.uk**
- **When you are ready to enter data click the link in the email to take you to the data entry website.**

3.3.1 Keeping track of your cases

So that you can retrieve the correct woman's notes for data entry and to make sure that you do not report the same woman twice it is important to keep a record of each case ID along with the woman's identifying details. This will also help if we have to contact you with a query after data entry. **Please note that identifying information should never be sent to UKMidSS.**

- **Record the case IDs for each month in your paper case log (provided in your UKMidSS folder) and record the woman's identifying details alongside.**

4 Identifying controls/comparison women

For most UKMidSS studies you will be asked to identify and enter data on CONTROLS or comparison women as well as your CASES. Please follow this procedure for identifying controls:

1. **Identify the date and time of delivery for the CASE you have reported.**
2. **From the unit admission book/electronic records identify the woman who gave birth in the unit immediately BEFORE the CASE (and who was not herself a case). This woman will act as the CONTROL. Please remember that a case cannot also be a control.**
3. **Record identifying details for controls alongside the relevant cases in your paper case log.**
4. **Retrieve the hospital case notes for the controls and enter data on controls via the website (same way as for the cases).**

5 Entering data

5.1 Key points

1. In order to access the data entry system (called Openclinica) you will need a computer with a web browser: Mozilla Firefox or Internet Explorer (preferably version 9 or above), NOT Google Chrome.
2. All the information you will need to complete the data collection form should be in the woman's notes or on your maternity data system.
3. Please do not enter any personally identifying information (e.g. name, address or hospital number) on the form.
4. The form is in several sections; you can start entering data, save and return to complete the form at any time.
5. To enter dates in the form click on the calendar  icon and select the date, or enter using the format dd-Mon-yyyy. The calendar icon is the easiest method to use.
6. To enter times in the form use 24 hour clock and the format hh.mm
7. Throughout the form, where you see a  icon you can hover over with your mouse for question-specific guidance.

5.2 How to enter data

5.2.1 Logging in

You will enter data on your UKMidSS cases and controls using a secure website called OpenClinica®.

- To access the website click on the link in your monthly confirmation email.
- You can also access OpenClinica® directly at <https://openclinica.npeu.ox.ac.uk/OpenClinica>

This will take you to the OpenClinica® log-in screen:



You will have received your unique OpenClinica® username and password by email. The first time you log in you will have an opportunity to change your password to something more memorable.

- If you forget your password, please email UKMidSS@npeu.ox.ac.uk.

5.2.2 Your home page ('Subject Matrix')

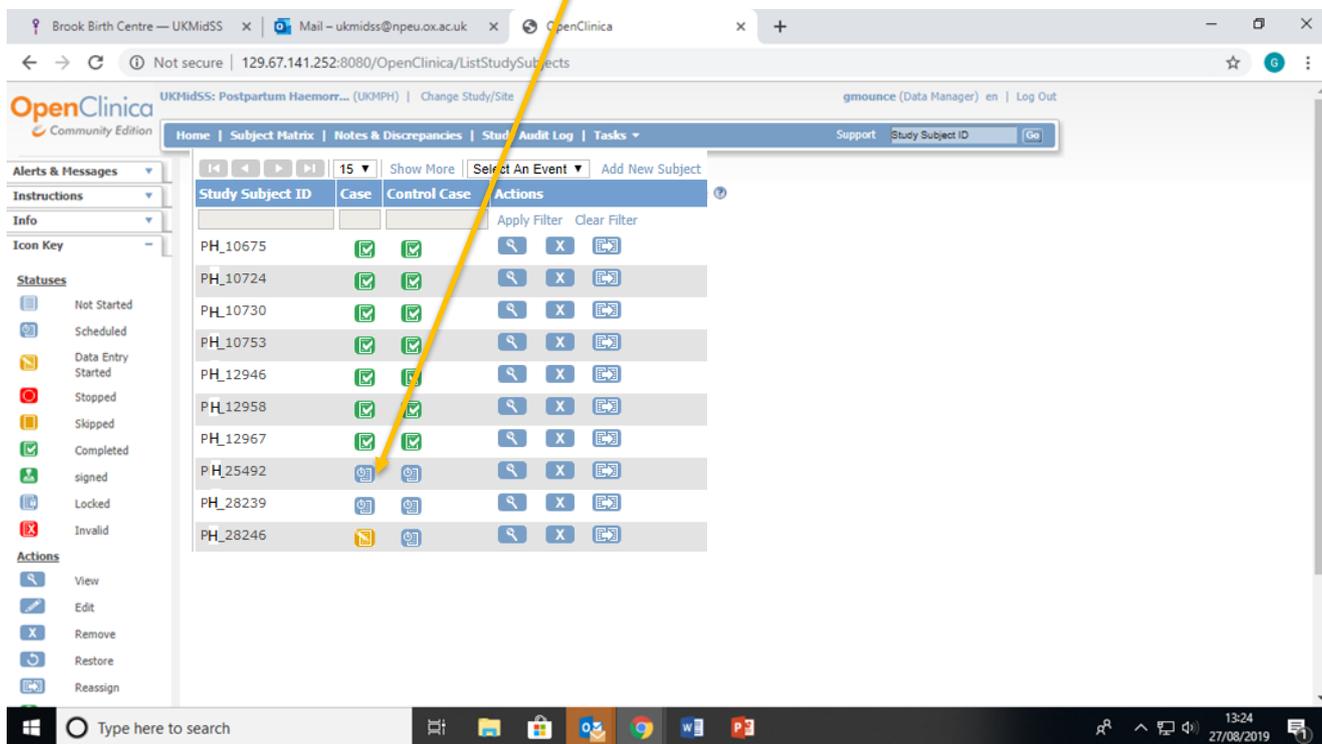
Once you have logged in you will see your individual home page or 'Subject Matrix' page. This will have your name in the top right and the name of the unit for which you are reporting at the top of the page.

- If you report for more than one unit check that the correct unit is listed at the top of the page.
- If you want to enter data for a woman from a different unit from the one shown click [Change Study/Site](#) at the top of the page and select the unit you require from the list.

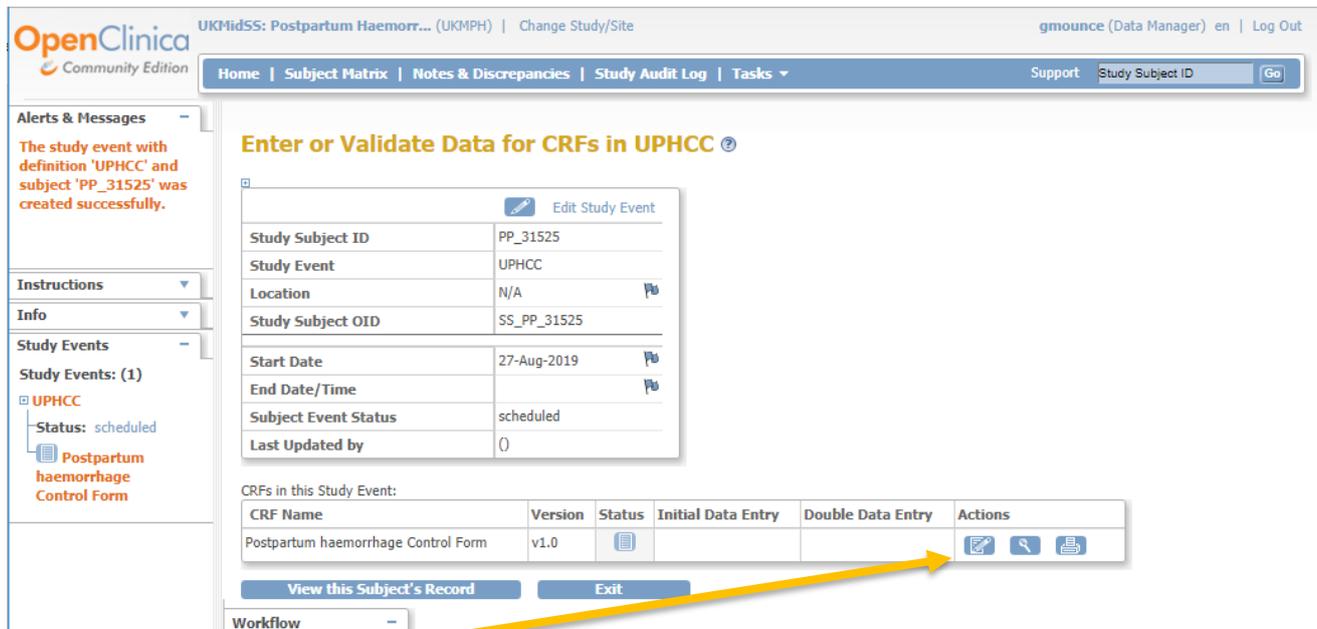
On the Subject Matrix page you will see the Study Subject IDs (Case IDs) for your Cases and the associated Controls.

For Cases and Controls 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.

To enter data on a Case click on the blue  icon alongside the Case ID in the Case column and click  View/Enter Data.



This will take you to a screen like this:



Click on the  Enter Data icon.

This will take you to the first data entry section, with the CASE ID at the top of the page.

5.2.3 Entering data

The screenshot shows a web browser window displaying the 'Postpartum haemorrhage v1.0' data entry form. The form is titled 'PP_31525' and is divided into sections. The current section is 'Section 1. Woman's details'. The form contains various input fields for BMI, age, ethnic group, employment status, CLIF score, height, and weight, along with checkboxes for 'Height not recorded' and 'Minimum weight not recorded'. A 'Save' button is visible at the bottom right.

Here you can enter data. The form is in six sections with a tab for each section.

- **Move from section to section by clicking on the blue arrow**  **or select different sections from the drop-down menu.**

Where there is a  icon you can hover over with your mouse for question-specific guidance.

- **Move from one question to the next using the Tab key.**
- **When you have finished entering data in each section click** 

5.2.4 Children in Low-income Families Score

Question 2.5 asks for the Children in Low-income Families Measure (CLIF) 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 the link next to question 2.5**

This will take you to a screen that looks like this:

The screenshot shows the UKMidSS postcode lookup screen. The screen displays the UKMidSS logo and a text input field with the label 'Please enter a postcode:'.

© 2016 - NPEU
[About this app](#)

- Enter the woman's postcode here and copy and paste the score for that postcode into the form at question 2.5

Please note, we are working on linking this system with OpenClinica® so that entering the postcode directly into the OpenClinica® form will return the CLIF score. Coming soon we hope!

5.2.5 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. If there are no DIs when you click  you will move to the next section.

If there are DIs these will be highlighted with a red exclamation mark and a box:



A list of DIs will appear at the top of the screen (in no particular order). There are two types of DI:

1. DIs where the data are invalid and **cannot** be saved, e.g.
The input you provided is not a valid data in dd-Mon-yyyy format
Enter time in format hh.mm (24 hour clock)
 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
 - **Check any DIs carefully.**
 - **Correct any errors in the data you have entered.**
 - **If the value you have entered is invalid, but you believe it to be correct you may click  and continue to the next section.**

When you save invalid data, the blue flag  next to the item will turn red  indicating a Discrepancy Note (DN), see section 5.2.6 below.

Note, the flag will only change colour if you refresh the page or move to another section and back again.

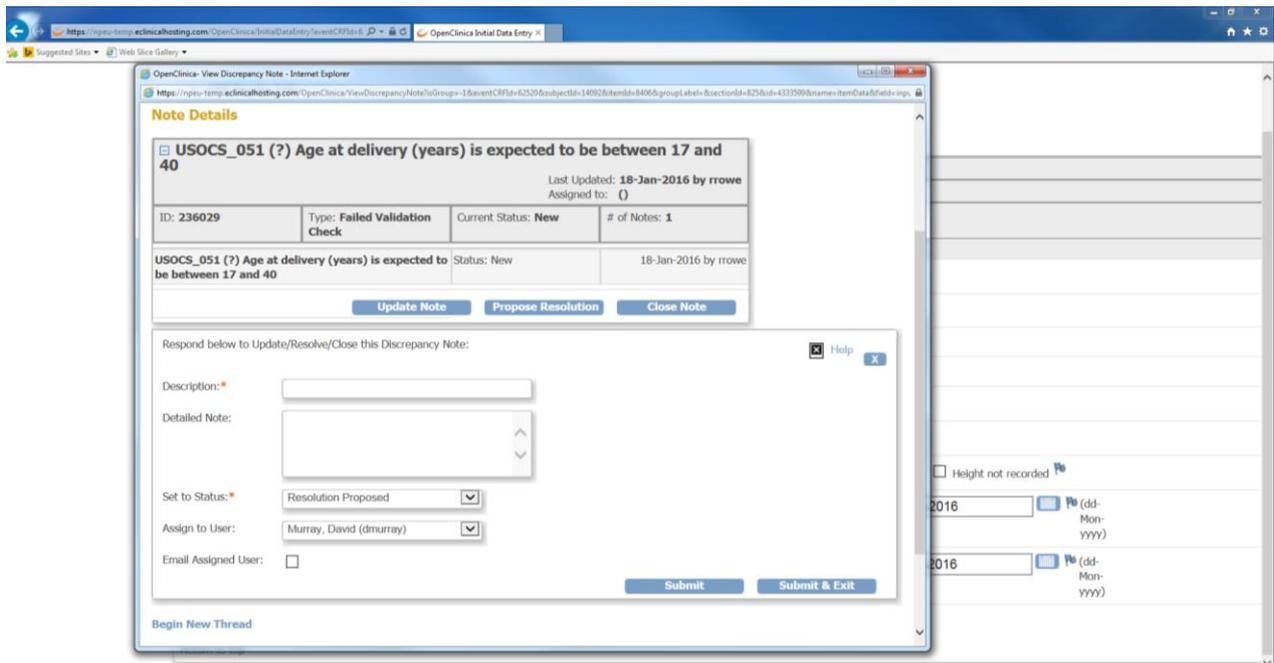
5.2.6 Discrepancy Notes (DNs)

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. If we have information explaining the DN we may not have to contact you to resolve it so this will save you work later!

You can enter this extra information in different ways:

1. While you are in the form entering data you can click on a red flag  to edit the DN. This will open a pop-up box like this:



- Click 

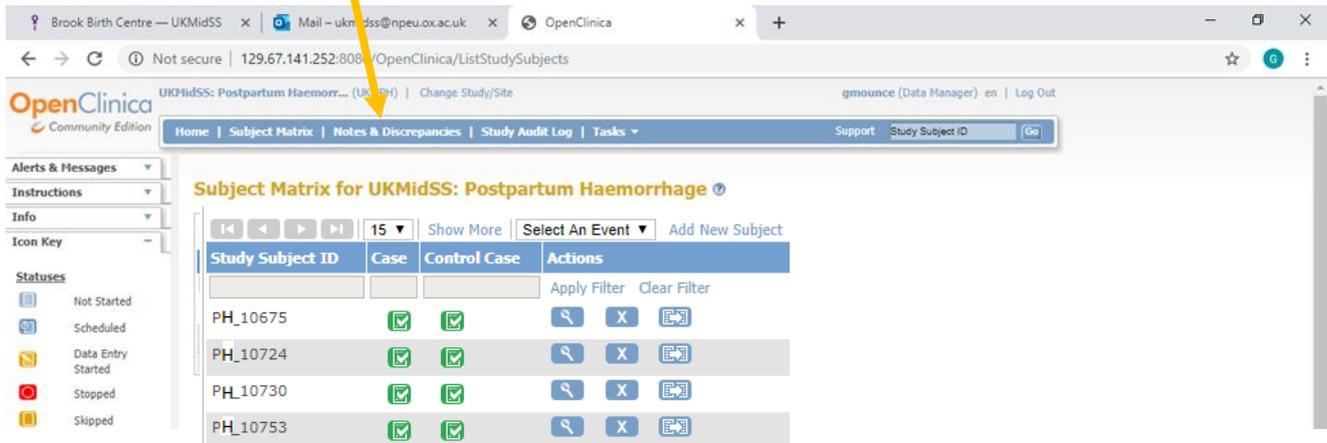
This will open a further box where you can enter information:

- 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 

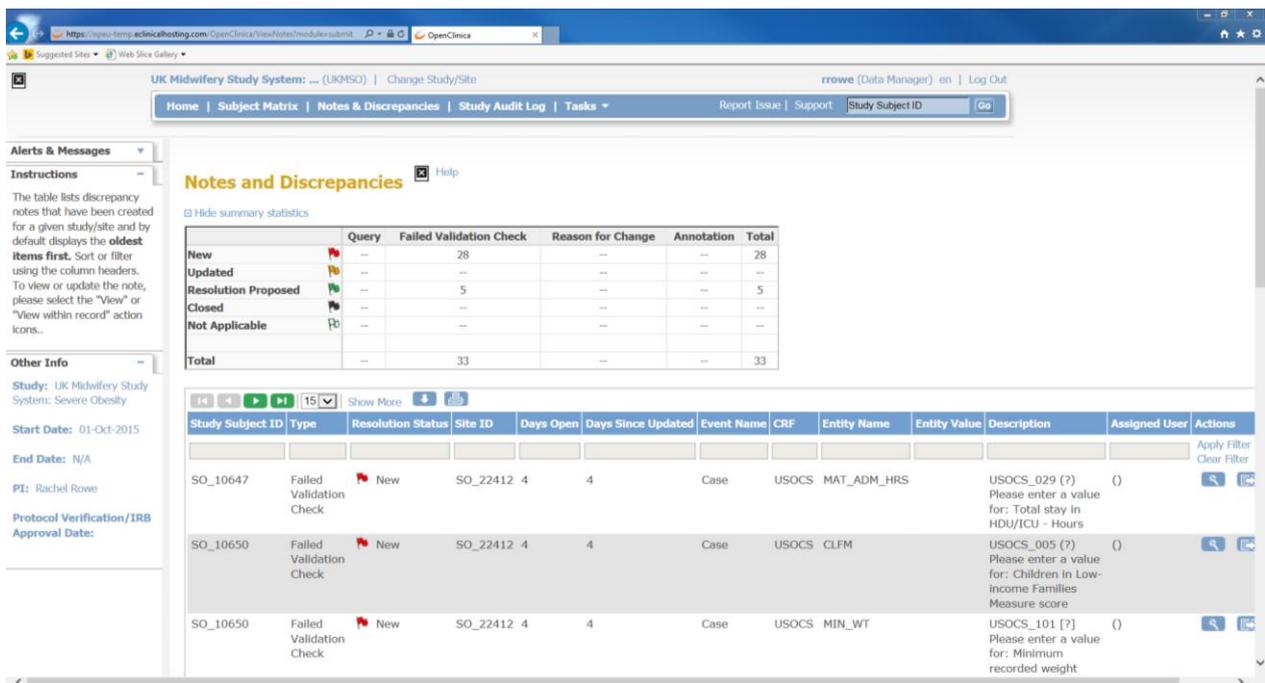
Now, if you return to that section, the flag next to that question will be green  indicating that you have proposed a resolution to the DN. If the flag does not immediately turn green, please refresh the page.

- You can also view all DNs, across all forms, from the Subject Matrix page by clicking on at the top of the page.

Notes & Discrepancies



Here you will be able to see and edit all DNs by Subject ID.



Click on the  icon at the end of the row to edit the DN and propose a resolution as described above. The flag will turn green .

5.2.7 Completing the form

Section 7 is the final section of the form, with just one question, giving you space to enter any other information you feel may be important. Remember please do not enter any personal details which might identify the woman, e.g. name, hospital number etc.

- At this point, if the form is complete check the 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

5.2.8 Editing a completed form

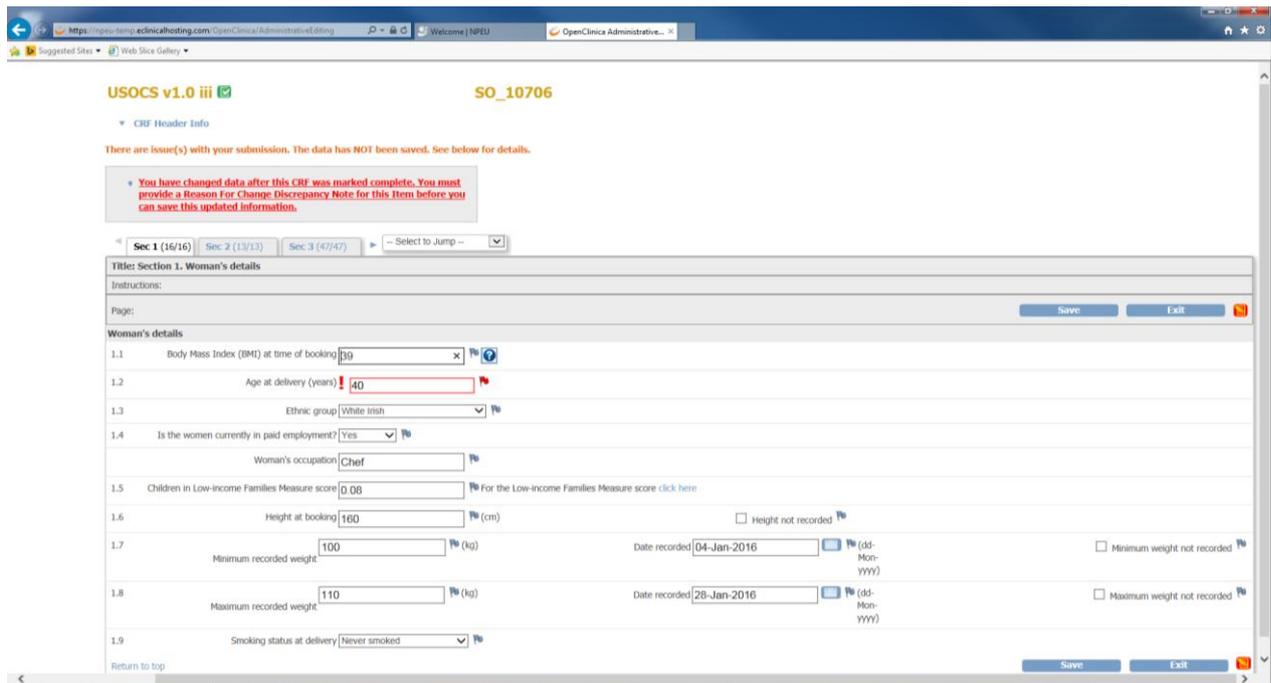
Once you have marked a form as complete you can still go back and edit the data you have entered (this is called Administrative Editing). For example you may have left an item blank the first time, and now have some data to enter or you may want to correct an incorrect value.

To change data once a form has been marked complete you must provide a reason for the change, otherwise the change will not be saved.

To edit data on a form which has been marked as complete:

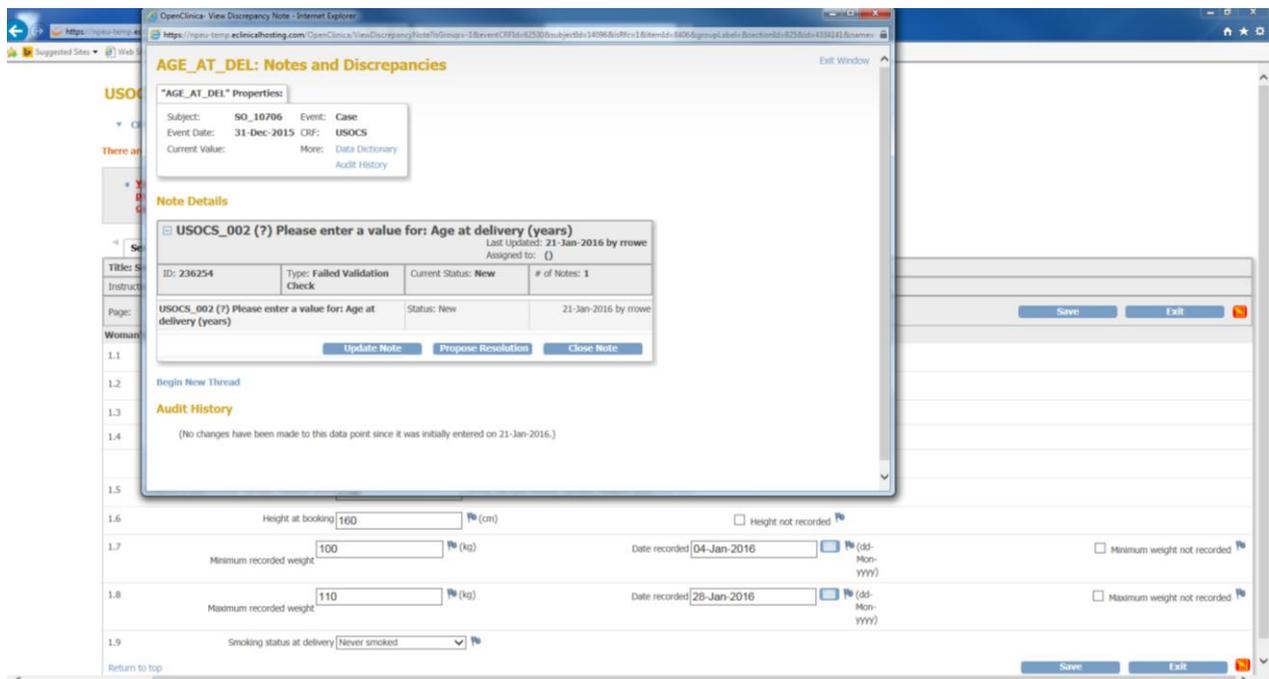
- From the Subject Matrix page, click on the green  icon alongside the Subject ID in the Case column and click  View/Enter Data
- Click on the  icon
- Find the data item you want to change, edit it and click

A message will appear in red at the top of the screen stating you must provide a reason for the change, before the data edit can be saved.



- Click on the flag icon next to the question

This will open a Notes and Discrepancies box:



- As described in section 5.2.6 above, Click **Propose Resolution**
- In the Description box give a reason why the data are being changed
- Click **Submit and Exit** and then click **Save**

The flag will now turn green and the new data and the extra information will be saved.

5.2.9 Entering data on controls

For each CASE you will also need to enter similar data for one CONTROL, identified as described above in Section 4.

- On the Subject Matrix page click on the  **View/Enter Data** icon in the Control column (next to each associated case).
- Enter data for the Control.
- Complete each form in the same way as for the Case.
- Don't forget to mark the form complete and save in Section 6.