



UKMidSS: Dealing with Data Queries



1 Introduction

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. This guide explains how to use OpenClinica to send us information to resolve these queries.

If you have problems or questions about this process please contact us: ukmidss@npeu.ox.ac.uk or 01865 289714.

2 Discrepancy notes

When data that are missing or unexpected are saved in OpenClinica a Discrepancy Note (DN), indicated by a red flag , is automatically created alongside the question. We may also create a DN if we want to query some other aspect of your data, e.g. where answers to different questions appear inconsistent with each other.

When you save a completed form which contains one or more DNs which we are unable to resolve we will notify you of these in your monthly UKMidSS Status Report, like this:

Month	Case ID		Question	Missing or invalid data
January 2016	SO_10372	Control 2	4.2	LMWH number of days is expected to be between 0 and 7 days
January 2016	SO_10383	Case	1.7	Please enter a value for: Minimum recorded weight
			1.7	Please enter a value for: Date minimum weight recorded
January 2016	SO_10398	Case	1.8	Please enter a value for: Maximum recorded weight
			1.8	Please enter a value for: Date maximum weight recorded
January 2016	SO_10398	Control 1	1.2	Age at delivery (years) is expected to be between 16 and 45
			3.5.4	Please enter a value for: Time of epidural or spinal?

2.1 How to resolve discrepancy notes

To send us information to resolve these queries please use the following process:

- Identify the Case ID associated with the query
- If the query is associated with a Control, check if it is Control 1 or 2
- From the Subject Matrix page, click on the green  icon alongside the Subject ID in the Case or Control column and click  View/Enter Data (for the Control, make sure you click on the correct Control Case)
- Click on the  icon
- Find the data item with the query – it will have a red flag  alongside

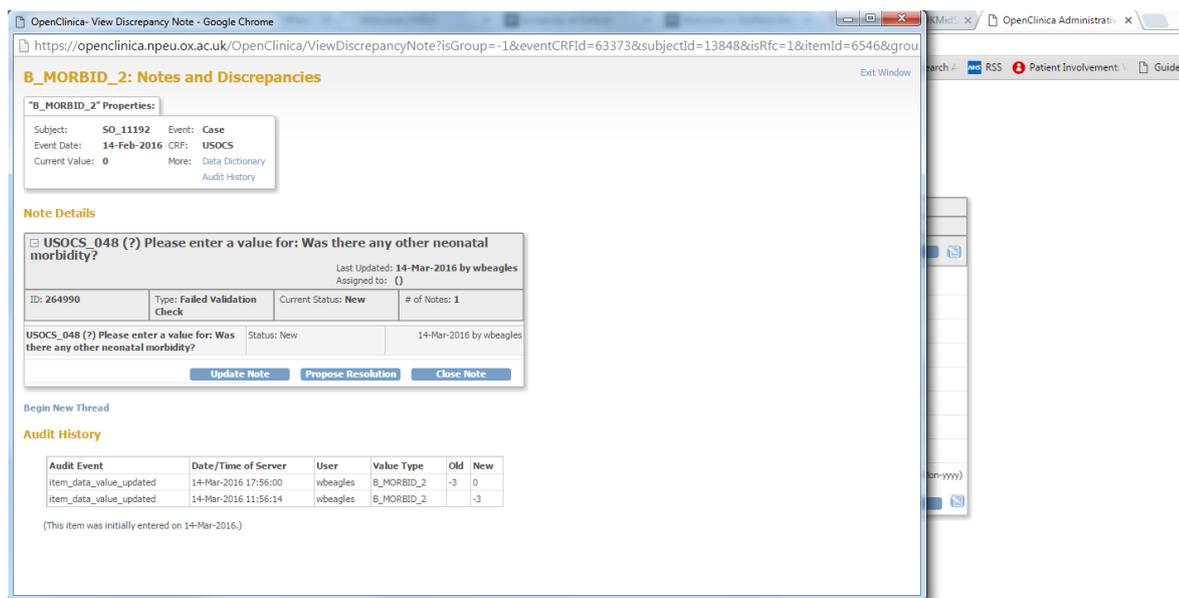
2.1.1 Missing data saved and entered later

You may have saved a section with incomplete data (e.g. if you were part way through a form) which you later finished entering, or you may have left an item blank and gone away and found the data to complete the form. In both cases, because at some point you saved missing data before completing the form, one or more DNs will have been created.

For us, this means that there is some uncertainty about the real value – is it missing or not? So that we can resolve this we need you to give us some information, using the following process:

- Click on the red flag 

This will open a pop-up box like this:



Although the data are no longer missing, because the section was saved with a missing value at some point, the DN asks for a value to be entered.

- Click 

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

- In the **Description box** enter information to explain, e.g. **Data originally missing, now entered and correct**
- In the **Set to Status box**, check that it says **Resolution Proposed**.
- Click 

2.1.2 Value outside expected range

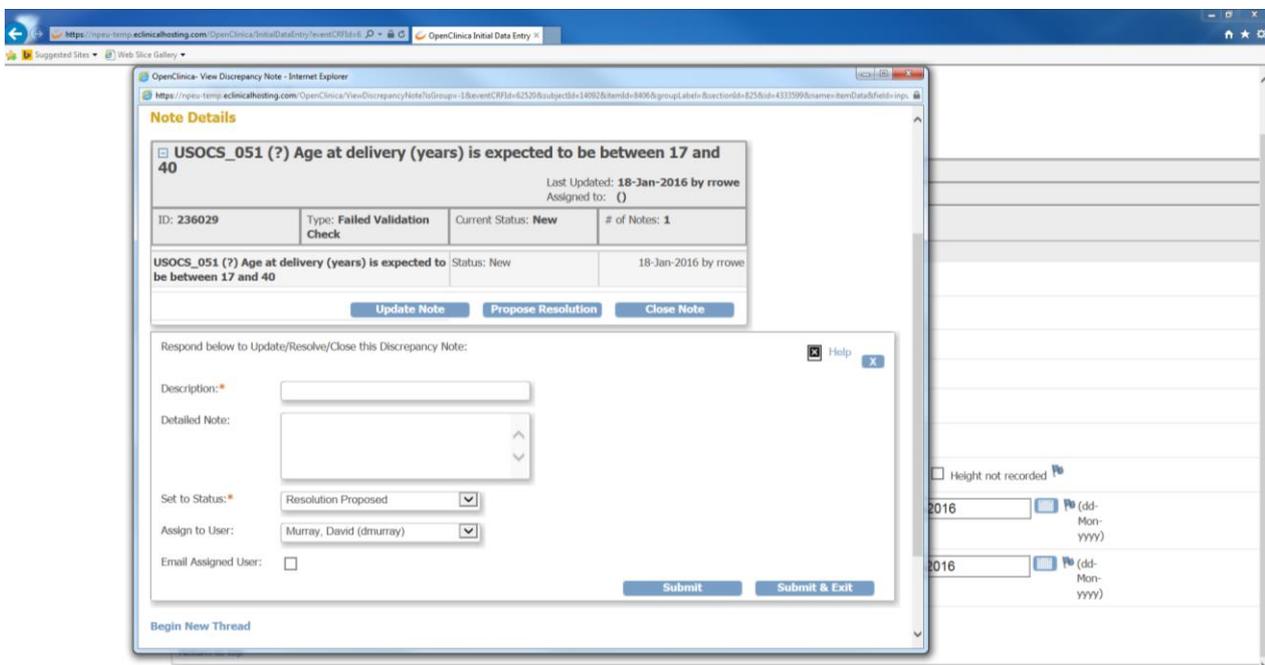
For some data items we have 'range checks' which check for values which are higher or lower than we would expect. If you have entered an unexpected value:

- **Check the notes – have you entered the correct value?**

If the value you have entered is correct:

- Click on the red flag 

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 explain, e.g. **Data confirmed**
- In the **Set to Status box**, check that it says **Resolution Proposed**.
- Click 

If the value you have entered is NOT correct and needs to be changed:

- Enter the correct value directly into the form and click

Save

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.

USOCS v1.0 iii SO_10706

CRF Header Info

There are issue(s) with your submission. The data has NOT been saved. See below for details.

You have changed data after this CRF was marked complete. You must provide a Reason For Change Discrepancy Note for this Item before you can save this updated information.

Sec 1 (16/16) Sec 2 (13/13) Sec 3 (47/47) - Select to Jump -

Title: Section 1. Woman's details

Instructions:

Page: Save Exit

Woman's details

1.1 Body Mass Index (BMI) at time of booking 39

1.2 Age at delivery (years) 40

1.3 Ethnic group White Irish

1.4 Is the women currently in paid employment? Yes

Woman's occupation Chef

1.5 Children in Low-income Families Measure score 0.08 For the Low-income Families Measure score click here

1.6 Height at booking 160 (cm) Height not recorded

1.7 Minimum recorded weight 100 (kg) Date recorded 04-Jan-2016 Minimum weight not recorded

1.8 Maximum recorded weight 110 (kg) Date recorded 28-Jan-2016 Maximum weight not recorded

1.9 Smoking status at delivery Never smoked

Return to top Save Exit

- Click on the flag icon next to the question
- Follow the process described above to Propose a Resolution to the DN
- In the Description box give a reason why the data are being changed
- Click and then click

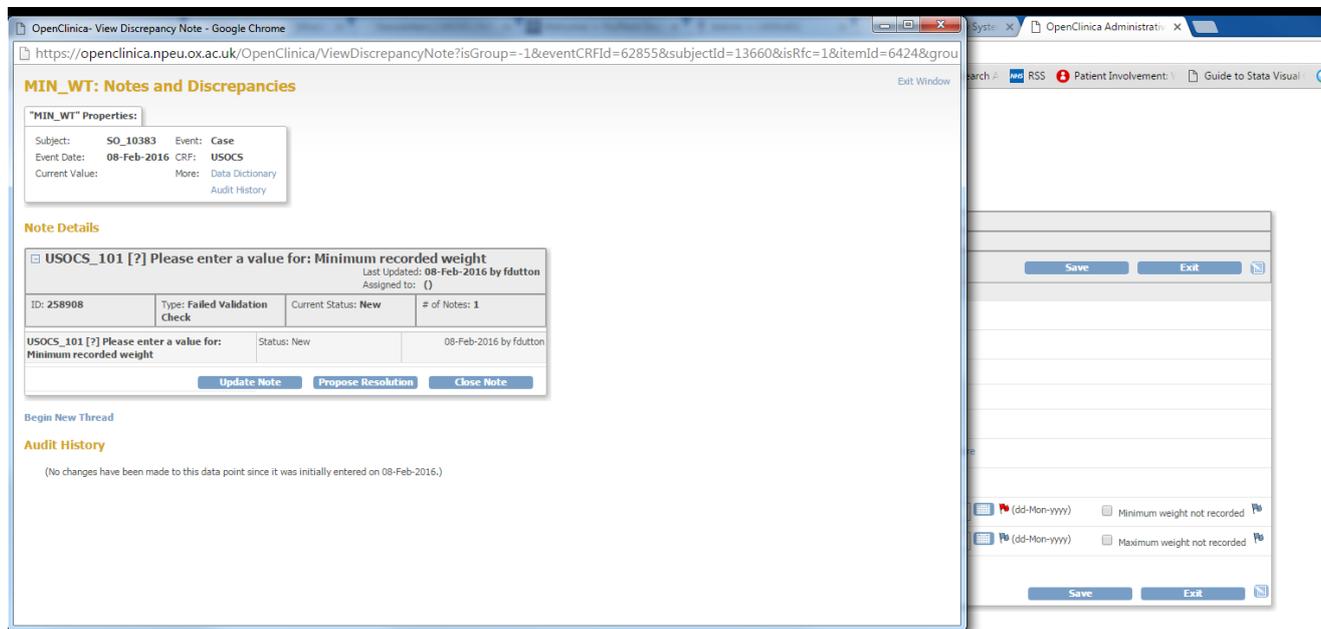
NOTE: If the new value you have entered results in supplementary questions opening you will need to enter these data and go through the process described above, providing a reason for the change.

2.1.3 Missing data

If the data are missing and will never be known:

- Click on the red flag 

This will open a pop-up box like this:



- Click 
- In the Description box enter information to explain, e.g. Weight measured only once or Data not available in notes
- In the Set to Status box, check that it says Resolution Proposed.
- Click 

If you have data available to complete the item:

Please follow the process for changing data as described on page 4.

2.2 Resolutions proposed

Whenever you Propose a Resolution to queries in this way the flag next to the data item will turn green . If the information you have provided is sufficient we will be able to close the query and won't have to contact you again. Thank you 