





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: <u>ukmidss@npeu.ox.ac.uk</u> 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 red, 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 Palongside

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:

OpenClinica- View Discrepancy	Note - Google Chrome	-			10.0		KMid	×	OpenClinica Administrati	• × /
https://openclinica.npeu	.ox.ac.uk/OpenC	linica/ViewDiscr	epancyNo	te?isGr	oup=-1	RFId=63373&subjectId=13848&isRfc=1&itemId=6546&gro	u			
B_MORBID_2: Note	s and Discrep	ancies				Exit Window	earch A	Mag RSS	8 Patient Involvemen	.t: V [
"B_MORBID_2" Properties:										
Subject: 50_11192 E	vent: Case]								
Event Date: 14-Feb-2016 C	RF: USOCS									
Current Value: 0 M	ore: Data Dictionary									
	Audit History									
Note Details										
								_		
USOCS_048 (?) Pleas morbidity?	se enter a value	for: Was there	any othe	r neon	atal		0	3		
inor brancy i		Last Up	dated: 14-Ma	r-2016 b	y wbeagle					
10. 064000 T	e di la bi la	Assign	ed to: ()							
ID: 264990 Type Chee	k	Current Status: New	/ # OT I	Notes: 1						
USOC5_048 (?) Please enter a v	alue for: Was Status	: New	14	+-Mar-201	5 by wbeag					
there any other neonatal morph	iity?									
	Update Note	Propose Res	olution	Close	Note					
na in Nava Thank I										
begin New Enread								-		
Audit History								_		
Audit Event	Date/Time of Ser	ver User	Value Type	Old	New			_		
item_data_value_updated	14-Mar-2016 17:56:	00 wbeagles	B_MORBID_2	-3	0		on-yyy	y)		
item_data_value_updated	14-Mar-2016 11:56:	14 wbeagles	B_MORBID_2		-3		6	3		
(This item was initially entered o	n 14-Mar-2016)						-	_		
					_					

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 Propose Resolutio

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
- Submit and Exit

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:

OpenClinica- View Discrepancy N	4ote - Internet Explorer				
https://npeu-temp.eclinicalhost	ing.com/OpenClinica/ViewDiscrepancyNote?isGro	up=-1&eventCRFld=62520&subjectId=1	14092&itemId=8406&groupLabel=&csectionId=8	258cid=43335998cname=itemData8cField=inpu	
Note Details					<u>^</u>
USOCS_051 40	(?) Age at delivery (yea	rs) is expected to I Last Up Assigne	be between 17 and dated: 18-Jan-2016 by rrowe d to: ()		
ID: 236029	Type: Failed Validation Check	Current Status: New	# of Notes: 1		
USOCS_051 (?) Age a be between 17 and 4	at delivery (years) is expected to 0	Status: New	18-Jan-2016 by rrowe		
	Update Note	Propose Resolut	ion Close Note		
Respond below to Upo	date/Resolve/Close this Discrepancy I	Note:		Help	
Description:*					L
Detailed Note:		^			
		~			Height not recorded
Set to Status:*	Resolution Proposed	v			2016
Assign to User:	Murray, David (dmurray)	~			Mon- yyyy)
Email Assigned User:					2016 10 (dd-
			Submit	Submit & Exit	yyyy)

Click

Propose Resolution

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.

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.

ttps://npeu-temp.eclinicalhosting.com/OpenClinica/AdministrativeEditing D =	i C 🔄 Welcome NPE3 🧳	OpenClinica Administrative ×	
- Summary			
USOCS v1.0 iii 🖾	SO_10706		
* CRF Header Info			
There are issue(s) with your submission. The data has NOT be	n saved. See below for details.		
 You have changed data after this CRF was marked com provide a Beason For Change Discrepancy Note for this can save this updated information. 	lete. You must Item before you		
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	~ 10		
1.4 Is the women currently in paid employment? Yes	1 10		
Woman's occupation Chef	P0		
1.5 Children in Low-income Families Measure score 0.08	Nor the Low-income	Families Measure score click here	
1.6 Height at booking 160	100 (cm)	Height not recorded	
1.7 Minimum recorded weight	1 (kg)	Date recorded 04-Jan-2016 Mon- Mon- yyyy)	Minimum weight not rec
1.8 Maximum recorded weight 110	🍋 (kg)	Date recorded 28-Jan-2016 Mon- VYYY)	Maximum weight not rec
1.9 Smoking status at delivery Never smok	ed 🗸		
Tables to be			Situa Evit

- 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 Submit and Exit 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:

OpenClinica- View Discrepancy Note - Google Chrome	and the second s	terror - Schutcher, A	Anno - sense - a		Syster ×	👌 🗅 OpenCli	nica Administrativ	×	
https://openclinica.npeu.ox.ac.uk/OpenClinica/ViewDiscrep	ancyNote?isGroup=-1&e	eventCRFId=62855⊂	jectId=13660&isRfc=1&ite	emId=6424&grou					
MIN_WT: Notes and Discrepancies	earch A 🛛 🧧	🔤 RSS 🔒 Pa	tient Involvement:	🗋 Guide to Stata Vis	ual 🤇 🤇				
"MIN_WT" Properties:									
Subject: SO_10383 Event: Case									
Event Date: 08-Feb-2016 CRF: USOCS Current Value: More: Data Dictionary									
Audit History									
Note Details					-				
USOCS_101 [?] Please enter a value for: Minimum re Last Up Assigne	corded weight dated: 08-Feb-2016 by fdutton d to: ()					Sav	e 📄 🗖	Exit	
ID: 258908 Type: Failed Validation Current Status: New Check	# of Notes: 1								
USOCS_101 [?] Please enter a value for: Status: New Minimum recorded weight									
Update Note Propose Resolu	tion Close Note				-				
Begin New Thread									
Audit History					re				
(No changes have been made to this data point since it was initially entered on 08	Feb-2016.)								
) •• (dd-Mon-yyyy)	Minimum we	ight not recorded 🏴	
] (11) (14)	dd-Mon-yyyy)	Maximum we	ight not recorded 🏴	
					L	Sav	ve)	Exit	

- Click Propose Resolution
- 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 Submit and Exit

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 The. 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