Royal Papworth Hospital
NHS Foundation Trust

OpenClinica User Guide for Monitors (OC3)

Royal Papworth Hospital NHS Foundation Trust

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Accessing OpenClinica

1. You will receive an email from the Data Management team providing you with a link to the OpenClinica Test site and/or live site, your individual username and password. Please note this password will expire on 1st use and you will need to create your own.

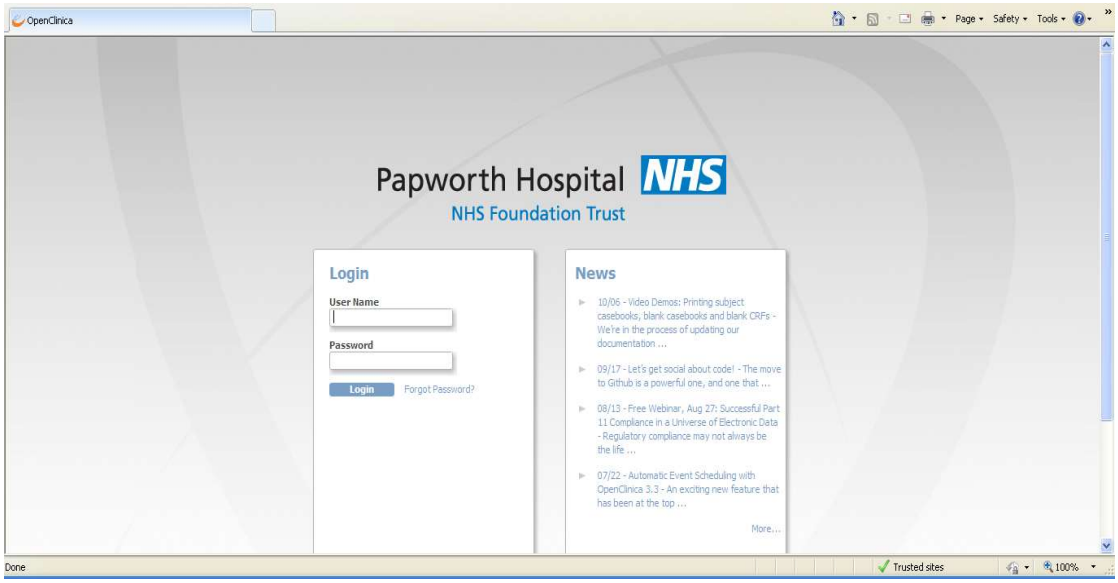
The Test Site can be accessed by clicking on the following link:

https://papworth-test.eclinicalhosting.com/OpenClinica/

The live site can be accessed by clicking on the following link:

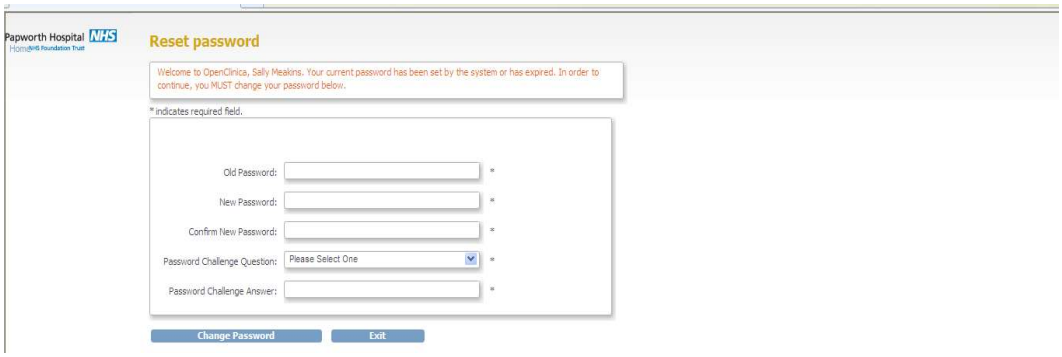
https://papworth.eclinicalhosting.com/OpenClinica/pages/login/login

As the URLs are case sensitive, please add these pages to your favourite sites for later use. An example of the log-on page can be seen below:



Changing your password on first time log in

1. Enter your username and password and login. Please note that the username and password fields are case sensitive.
2. You will then be asked to reset your password and select and answer a password challenge question. Passwords need to have at least 8 characters and contain both upper case letters and digits. An example of the Reset Password page can be seen below:

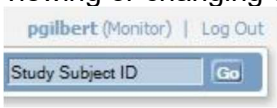


Please Note: If you enter your login details incorrectly OpenClinica will allow you a maximum of 3 attempts to enter them correctly before locking you out. If you are locked out please contact the Data Management team, who can reset passwords and send username reminders. There is also a 'Forgot Password?' facility on the log-on page.

If you experience any problems accessing OpenClinica please contact the data management/study team, contact details can be found at the end of this User Guide.

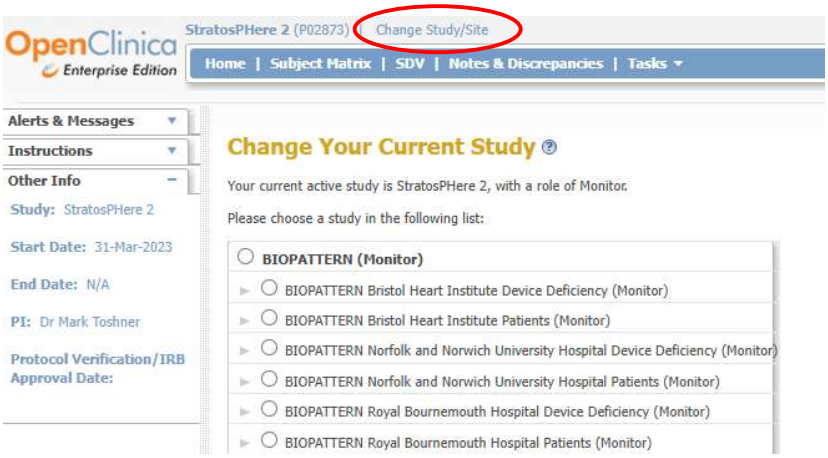
Logging out

When you're finished with OpenClinica you must log out. This prevents unauthorised persons viewing or changing data. Log out by clicking Log Out in the upper right corner of the screen.



Change Study/Site

When you log into OpenClinica, your active study will be the last study you worked on. If you are assigned to monitor more than one study or a site within a study, you can change this by using the Change Study/Site (function/page)



If within a study you have more than one active site to monitor, click the radio button for the site you want to enter, then at the bottom of the page click on Change Study button. A message will come up asking you to Confirm Changing study, please confirm this by clicking on the Confirm button.

Your "Home" in OpenClinica

After you've logged in, your "Home" screen opens. Underneath the welcome message there is a link to Notes & Discrepancies Assigned to Me: 0, this displays how many open notes are assigned to you, clicking on this will take you to these Notes & Discrepancies. You can

always return to the home screen by clicking the Home in the menu bar at the top of the screen.

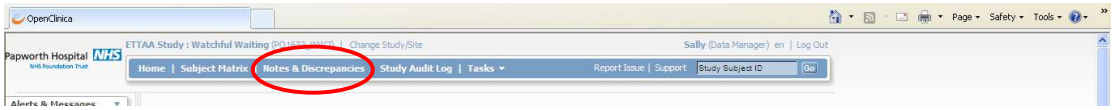
Your main activity in OpenClinica will be Notes and Discrepancy management and Source Data Verification (SDV). You can also view all data entered by clicking on the Subject Matrix icon in the blue banner at the top of the page. As a monitor it is not possible for you to enter Study Data, only to review data and answer queries on it.

By clicking on the Notes and Discrepancies Assigned to Me you will be provided with a summary and description of how many new queries/queries not yet addressed are assigned to you. Each row is a separate query i.e. there may be multiple queries on 1 CRF but each will be shown as a separate query(see diagram further down).

Notes & Discrepancies

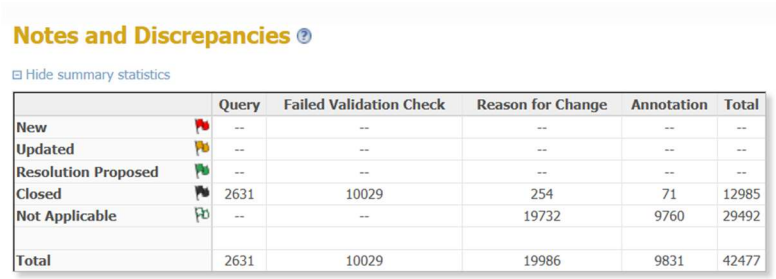
All assigned Notes and Discrepancies can be accessed by clicking on the Notes and Discrepancies in the blue menu bar at the top of the screen. In the screen that opens all discrepancies are listed and a summary of this list is given at the top of the screen in the box.

- **As a monitor it is your responsibility to address ALL notes and discrepancies even if the discrepancy note is for one of the patients you've NOT been allocated to monitor**.
- **If you notice large numbers of Notes and Discrepancies building up there may be a reason e.g. data outside of reference ranges, please speak with data management as this can be dealt with before they become unmanageable.**



The summary statistics table displays all flags, queries, failed validation checks, reasons for change, annotations, and total queries. It can also be used to view the breakdown and total count of queries before and after applying a filter condition

Before filtering:

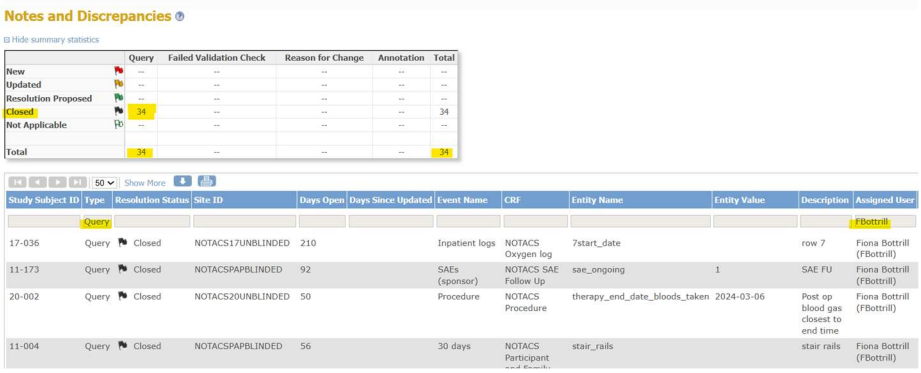


Notes and Discrepancies

Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	--	--	--	--	--
Resolution Proposed	--	--	--	--	--
Closed	2631	10029	254	71	12985
Not Applicable	--	--	19732	9760	29492
Total	2631	10029	19986	9831	42477

After filtering:



Notes and Discrepancies

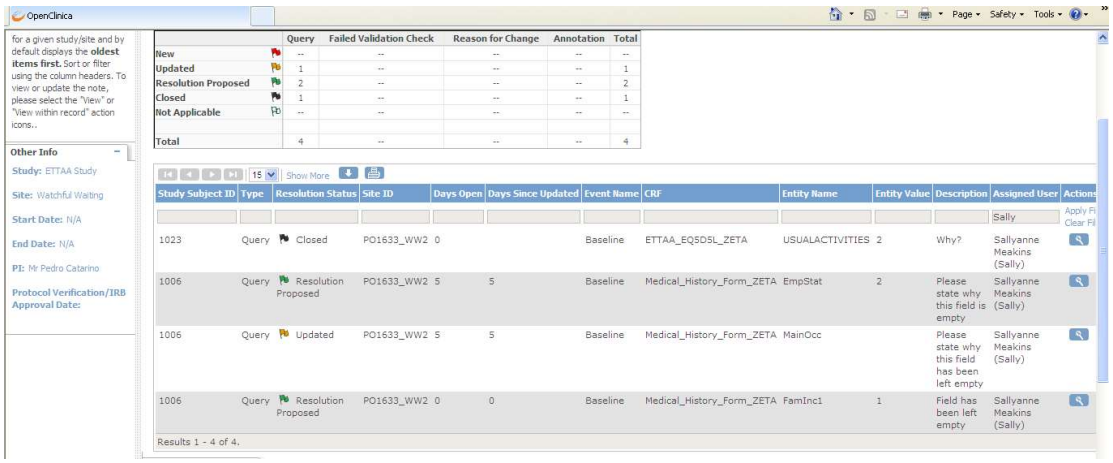
Hide summary statistics

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	--	--	--	--	--
Resolution Proposed	--	--	--	--	--
Closed	34	--	--	--	34
Not Applicable	--	--	--	--	--
Total	34	--	--	--	34

50 Show More

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User
	Query										FBottrill
17-036	Query	Closed	NOTACS17UNBLINDED	210		Inpatient logs	NOTACS Oxygen log	7start_date		row 7	Fiona Bottrill (FBottrill)
11-173	Query	Closed	NOTACSPAPBLINDED	92		SAEs (sponsor)	NOTACS SAE Follow Up	sae_ongoing	1	SAE FU	Fiona Bottrill (FBottrill)
20-002	Query	Closed	NOTACS20UNBLINDED	50		Procedure	NOTACS Procedure	therapy_end_date_bloods_taken	2024-03-06	Post op blood gas closest to end time	Fiona Bottrill (FBottrill)
11-004	Query	Closed	NOTACSPAPBLINDED	56		30 days	NOTACS Participant	stair_rails		stair rails	Fiona Bottrill (FBottrill)

Description of the Notes and Discrepancies page



OpenClinica

for a given study/site and by default displays the **oldest items first.** Sort or filter using the column headers. To view or update the note, please select the "View" or "View within record" action icons..

Other Info

Study: ETTAA Study

Site: Watchful Waiting

Start Date: N/A

End Date: N/A

PI: Mr Pedro Catarino

Protocol Verification/IRB Approval Date:

	Query	Failed Validation Check	Reason for Change	Annotation	Total
New	--	--	--	--	--
Updated	1	--	--	--	1
Resolution Proposed	2	--	--	--	2
Closed	1	--	--	--	1
Not Applicable	--	--	--	--	--
Total	4	--	--	--	4

15 Show More

Study Subject ID	Type	Resolution Status	Site ID	Days Open	Days Since Updated	Event Name	CRF	Entity Name	Entity Value	Description	Assigned User	Actions
											Sally	Apply Fi Clear Fi
1023	Query	Closed	PO1633_WW2	0		Baseline	ETTAA_EQ5DSL_ZETA	USUALACTIVITIES	2	Why?	Sallyanne Meakins (Sally)	
1006	Query	Resolution Proposed	PO1633_WW2	5	5	Baseline	Medical_History_Form_ZETA	EmpStat	2	Please state why this field is empty	Sallyanne Meakins (Sally)	
1006	Query	Updated	PO1633_WW2	5	5	Baseline	Medical_History_Form_ZETA	MainOcc		Please state why this field has been left empty	Sallyanne Meakins (Sally)	
1006	Query	Resolution Proposed	PO1633_WW2	0	0	Baseline	Medical_History_Form_ZETA	FamInc1	1	Field has been left empty	Sallyanne Meakins (Sally)	

Results 1 - 4 of 4.

In OpenClinica four types of discrepancy notes exist: “Query”, “Failed validation check”, “Annotation” and “Reason for change”.

The first type, “Query”, are created by Monitor’s particularly during the process of checking the data: if data entered in OpenClinica is looking unusual or incorrect, the monitor can create a Query to ask the person responsible for data-entry, to check or correct the item.

The second type, “Failed Validation Check”, is raised if a value entered exceeds a certain range, or if a Validation check is violated, for example a value that is unexpected and / or out of range such as a weight of more than 150 kg.

The third type, “Annotation” occurs when someone performing data entry needs to provide additional data to an input field.

The fourth type, “Reason for Change” is created automatically when data is changed in a CRF that was already marked as “Complete”.

A Discrepancy has a Resolution Status, which is indicated by the colour of the flag (see table below for colours): “New”, “Updated”, “Resolution Proposed”, “Closed” or “Not applicable”.

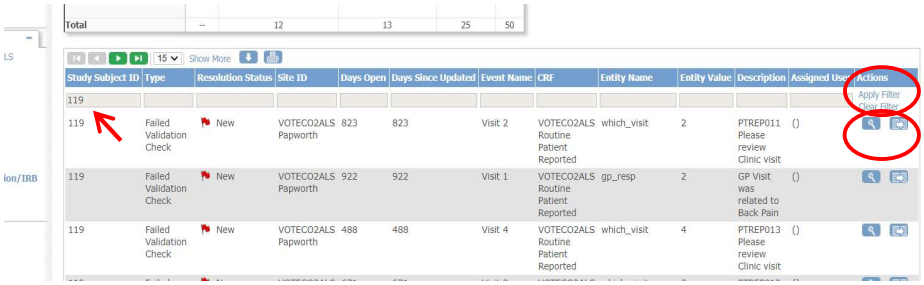
Flag Colours

Flag Colour	Description
Blue Flag	**Blank:** Flag un-used.
Black Flag	**Closed:** Once a resolution has been proposed and accepted by the study team the query will be closed and turn black.
Red Flag	**Query:** A query has been raised and requires attention.
White Flag	**Annotation:** A comment has been made about this field.
Green Flag	**Resolution Proposed:** A response/resolution to the query has been provided with the expectation that the issue can now be resolved.
Orange Flag	**Updated:** A flag can turn orange if ‘Update’ is selected instead of ‘Resolution Proposed’ when responding to a query. An ‘Update’ can be used for any correspondence regarding the query that is not proposing a resolution i.e. requesting clarification on the query raised, or explaining that you are waiting on information and will answer the query when possible

A CRF item can have one or more Discrepancies, and a Discrepancy can have a thread of one or more Notes. Each Discrepancy will have a row in this screen, but if an item has more than one Discrepancy, there will still be just one flag in the CRF.

A Discrepancy Note cannot be deleted: only the status can be changed to “Closed”.

Please Note: It is possible to manipulate the notes and discrepancies matrix using the filter. In the example below; the results have been filtered to only display the notes and discrepancies for ‘Subject 119’.



To filter by a column heading, click on the blank box below it (marked by the arrow), type in the criteria you want to filter by (in this case the Study Subject ID '119 ') and select 'Apply Filter' (circled on the screenshot). You can remove the filter by selecting 'Clear Filter'.

To view or update a Discrepancy, click one of the two icons in the right column, "View" or "View within record", the magnifier-icon or the right-arrow-icon (circled above).

If you click "View", a separate window will open with the details of the Discrepancy.

If you click "View within record", the CRF is opened in your current browser-window, plus a new window opens with the Discrepancy (please note that if the CRF has multiple pages then it may not show you the page where the discrepancy note is, if you need to look at the page containing the discrepancy note you will need to look through the CRF pages to locate it, using the Notes and Discrepancies flag on the affected field(s)).

Another convenient way to open the CRF plus the Discrepancy is by right-clicking on "View within record" and then choosing "Open link in new window".

In the next four sections we will discuss how each type of Discrepancy is generated, by whom and what statuses this type of Discrepancy can have and what is expected of you as a monitor.

Source Data Verification

The monitoring plan will guide you with how much source data verification is required.

Source data verification (SDV), a verification of the conformity of the data presented in case report forms/OpenClinica with source data, is conducted to ensure that the data collected are reliable and allow reconstruction and evaluation of the trial and therefore, seemingly, fulfils ICH E6's requirements of accuracy, completeness and verifiability from source documents.

For each patient you are allocated to monitor; you must look at every data point within the Case Report Form (CRF) in OpenClinica; being aware that each CRF may have multiple pages. If you don't agree with the data please see **How to add a discrepancy note**.

Once all notes and discrepancies have been dealt with and all of the data in OpenClinica for a particular event is correct, then you may SDV the CRF for that event. This is completed by clicking the SDV button at the end of the line for the CRF page you wish to verify (see diagram below).

If you inadvertently SDV a CRF in OpenClinica prior to checking all the source data, it is possible to undo this. It is preferable that this is not done but this can be undone by unclicking the box SDV Status for the line you wish to undo (once SDV'ed, the box is green with two white ticks; un-SDV'ed CRFs have blank white boxes).

As the study monitor it is expected that ALL CRF's for all of the patients you monitor should be followed up for SDV till the end of study (EOS) (unless otherwise stated in the monitoring plan).

Any changes to the CRF after SDV has been completed will reset the SDV status. When this occurs, the monitor can use the audit log to check what has been changed since SDV was marked as complete and will, therefore, not have to re-SDV the whole form. See **Study Audit log** below for guidance on accessing the audit log.

In the screen shot of the audit log below, the SDV status was set to false when the visit date was changed, the monitor would only need to review this visit date before remarking as SDV complete.

Study Event data entry started	23-Sep-2011 14:45:13	sberding	Status	scheduled	data_entry_started
Study Event completed	23-Sep-2011 14:47:02	sberding	Status	data_entry_started	completed

Name	Version	Date Interviewed	Interviewer Name	Owner
Screening	v.04			sberding

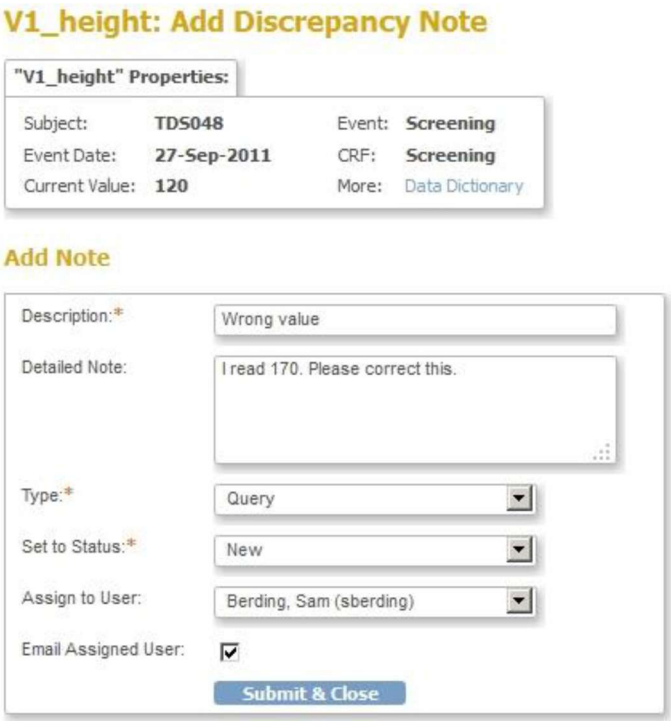
Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	27-Sep-2011 17:11:48	sberding	V1_visit_date (1)	24-Jul-2011	22-Jul-2011
EventCRF SDV Status	27-Sep-2011 17:11:48	sberding	EventCRF SDV Status (0)	true	false
EventCRF SDV Status	27-Sep-2011 11:28:22	pgilbert	EventCRF SDV Status (0)	false	true
Item data value updated	25-Sep-2011 15:09:06	root	V1_height (1)		170
Event CRF marked complete	23-Sep-2011 14:45:57	sberding	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Eligibility	v.01			sberding

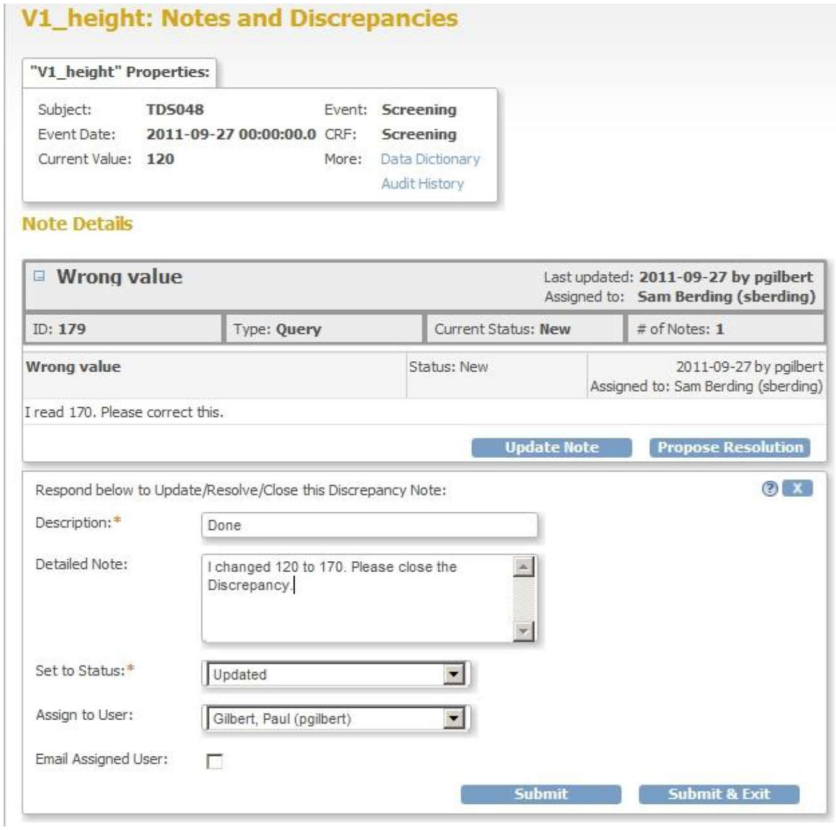
How to add a Discrepancy Note

If you disagree with the data entered or you wish the data to be re-checked you will need to create a discrepancy note. To do this you must click on the blue flag for the data point in question.

A new window will open allowing you to add a discrepancy note. You must provide a heading for the query. In the detailed note section please leave a description of what was found and what action should be taken. The Type of discrepancy note is “Query” and cannot be changed. The set to status can be chosen to either “New”, “Updated” or “Closed”. Please then assign to the user you wish to amend the query. By ticking the “Email Assigned User” the person needing to complete the query will automatically receive an email informing them that they have been assigned a query. Once you have completed all sections of the query click the Submit and Close button.

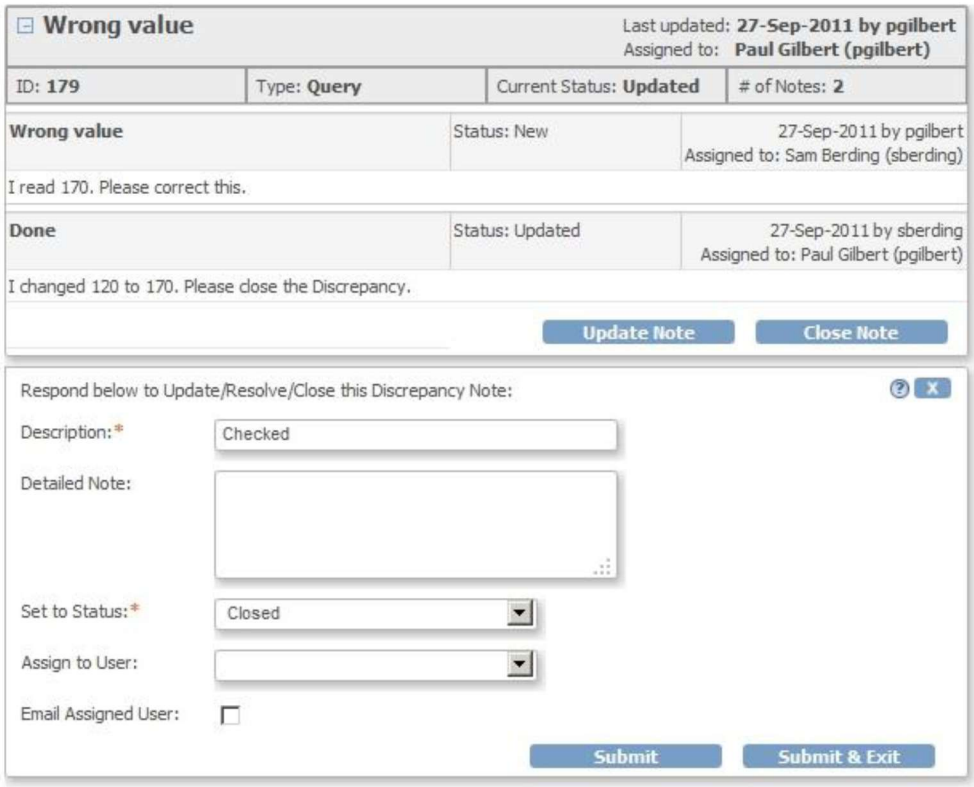


The user will see this Discrepancy in the list “Notes & Discrepancies Assigned to Me”. They can change the value for height (as shown in the screenshot above) and after that, update the Discrepancy, indicating the correction and setting the Status of the Discrepancy to “Updated” or “Resolution Proposed”. By default, the assigned user is the one who created the Query, so this is left unchanged and again it is possible to send an e-mail.



After the correction, if the monitor clicks the Notes and Discrepancies Assigned to me: the query will be in the list.

The monitor opens the CRF by clicking on the “view” or “view within record” icon (circled above) to verify the change. To complete this, the monitor clicks the Close Note button. A box will appear which must be completed in the same way as generating a query. A description header must be completed. Then a comment e.g. “Data amended. Query closed”. The “set to status” should be set to closed. The “Assign to User” can be left blank. Then click Submit & Exit to close the query.

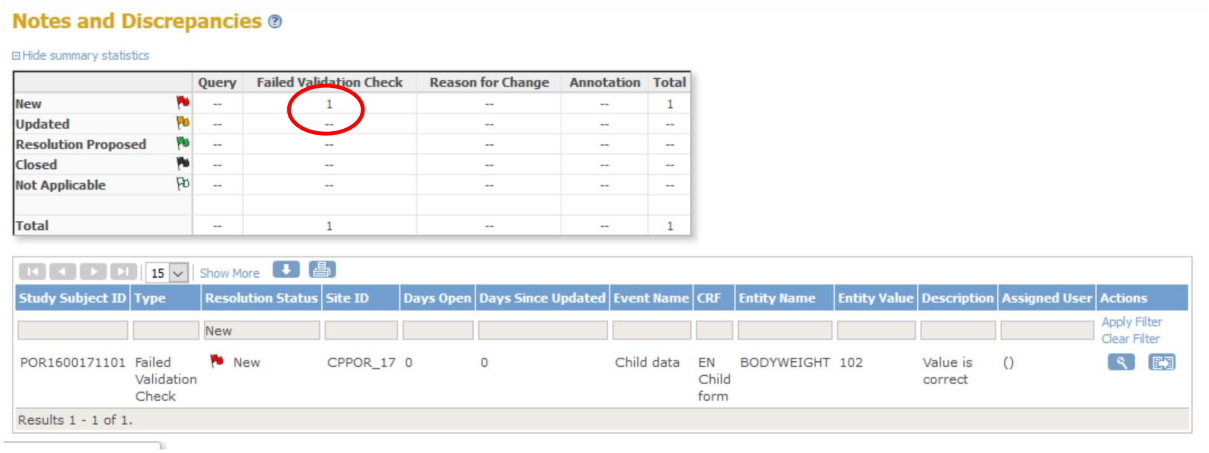


There might be an occasion where you disagree with the reply, you can click on Update note. Complete the response in the same way as detailed above and use the detailed note section to explain why you don't agree, "set the status" to "updated", assign the user and click the "email assigned user" so they know there is a further query on this data point.

There also might be more than one query to respond to. If this is the case once you've completed one of the queries click the Submit button, this will keep the page open and allow you to answer further queries. Once you've replied to all the queries click the Submit and Exit button and the page will close.

Failed Validation Check

A Failed Validation Check is a Discrepancy that is automatically flagged by OpenClinica based on rules defined during the database design stage.
For example, on a field where the weight is a required field, an upper range is defined of 99. If the user enters 102, this results in a message "[Please enter a weight between 0 and 99]". If 102 is indeed the weight, the user must enter this. In order to save the data they must first fill in the details of the failed validation check Discrepancy.
When you log in as the Monitor, the failed validation check will be listed in the Notes & Discrepancies.



Once the source data has been checked; the value can be accepted by the Monitor. You need to click Close Note and for the Description you can use “Accepted” and leave the Detailed Note section blank. For “Set to Status” choose “Closed”. You don’t need to assign a user, then press Submit & Exit. This will close the validation check.

Annotation

Annotations are discrepancies that can only be made by those entering data and there is no follow-up for them. The resolution status will show as “Not applicable” meaning there will be nothing to close. The monitor should however review these. There might be a particular variable being missed a lot, or data that is being collected at a later date – raising a query here will help the study team remember that the missing data still needs to be entered.

Reasons for change

After a CRF has been marked complete, all changes to the data have to be accounted for. This means that a reason for change must be given when data in this completed CRF is amended or added. If this is done manually by the user before pressing save, it will be a white (Not Applicable) flag, otherwise, OpenClinica will make the user enter a reason, and this will be a red (New) flag. Often the user will only use the description to explain the reason, and not the detail. In the example below the user manually added the note, but only put “Correction” as the reason, OpenClinica put the default error as “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.” When the Monitor opens this Discrepancy, not only is the normal information available, but also the Audit History. Here both the old and the new values are shown.

Note Details

Correction			Last updated: 27-Sep-2011 by sberding Assigned to: ()
ID: 186	Type: Reason for Change	Current Status: Not Applicable	# of Notes: 1
Correction		Status: Not Applicable	27-Sep-2011 by sberding
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.			

Begin New Thread

Audit History

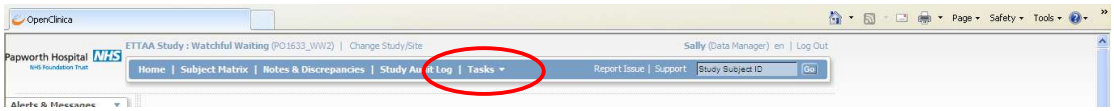
Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	27-Sep-2011 17:11:48	sberding	V1_visit_date	24-Jul-2011	22-Jul-2011

(This item was initially entered on 23-Sep-2011.)

The Monitor will see the Discrepancy in the CRF at the time of Source Data Verification. If the CRF was already marked as SDV'd, the status will change to Not-SDV'd (as the data within the CRF has been changed) The Monitor must complete the Source Data Verification again for this CRF.

Study Audit log

In the Study Audit Log all entries and changes are recorded. You can access the Study Audit Log by clicking on the Tasks in the blue menu bar at the top of the screen.



And then clicking on Study Audit Log

View Study Log for Bremen

Study Subject ID	Secondary Subject ID	Study Subject OID	Date of Birth	Person ID	Created By	Status	Actions
							Apply Filter Clear Filter
TDS015		SS_15			sberding	signed	
TDS016		SS_16			sberding	signed	
TDS017		SS_17			sberding	available	
TDS018		SS_18			sberding	available	
TDS019		SS_19			sberding	available	
TDS020		SS_20			sberding	available	

The screen opens up to show all patients.
Each patient has their own study audit log.
You can view the audit log for a particular patient by clicking on the magnifying glass icon at the end of the row of the patient you wish to view.
Every single data point for every CRF will be available to view.
You can see when the data was entered, by whom and if there has been any amendments to any data point.

Study Event data entry started	23-Sep-2011 14:45:13	sberding	Status	scheduled	data_entry_started
Study Event completed	23-Sep-2011 14:47:02	sberding	Status	data_entry_started	completed

Name	Version	Date Interviewed	Interviewer Name	Owner
Screening	v.04			sberding

Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	27-Sep-2011 17:11:48	sberding	V1_visit_date (1)	24-Jul-2011	22-Jul-2011
EventCRF SDV Status	27-Sep-2011 17:11:48	sberding	EventCRF SDV Status (0)	true	false
EventCRF SDV Status	27-Sep-2011 11:28:22	pgilbert	EventCRF SDV Status (0)	false	true
Item data value updated	25-Sep-2011 15:09:06	root	V1_height (1)		170
Event CRF marked complete	23-Sep-2011 14:45:57	sberding	Status (0)	available	unavailable

Name	Version	Date Interviewed	Interviewer Name	Owner
Eligibility	v.01			sberding

Please check the audit trail to see if there have been multiple amendments or changes to a data point and by whom.
Most importantly please use the audit trail to check who has completed the data submitted for AE and SAE reporting:

AE –
Please use the audit trail to check that the PI or affiliated investigator has completed the severity and the causality of an AE.

***It is important that the AE form is left open till the end of the study. Please only close when the period of collecting AE events has finished and all AE's have been resolved.**

SAE -
Please use the audit trail to check that the PI or affiliated co-investigator has completed the sections of the SAE report only they are designated to complete.

- SAE Medical assessment
- PI assessment

Check the Sponsor Assessment has been completed by the R&D director or other affiliated representative if the R&D director is the PI for the study.

This is the end of the user guide. Should you have any questions on monitoring in OpenClinica please contact papworth.randdqa@nhs.net or the Data Monitoring Team at Royal Papworth who will be happy to assist.

You can also email papworth.openclinica@nhs.net for any OpenClinica issues.