

OpenClinica User guide



What's inside

The training covers the following in general

- OpenClinica introduction
- Logging into OpenClinica
- OpenClinica participant matrix
- Add a participant
- Schedule visits
- Data entry
- Saving data
- Missing data
- Data warnings
- Data queries
- Audit history
- SAE form
- Withdrawal form
- Points to remember
- What's next ?

OpenClinica

- Validated Data capture system for efficient clinical data management and automation.
- Electronic data entry with real time edit checks and auto save.
- Easy to use system allows users to quickly input, monitor and run reports on subject data to collect accurate and reliable data for analysis



Capture, clean, and manage
your clinical trial data.



Logging in to OpenClinica

- You will receive an email containing a link to allow you access to OpenClinica, once all training logs have been completed and received by Data Management.
- Enter the username given by Data Management on the log in screen and make up a password for the first time you log in.
- Usernames should be entered in all lower case.
- Once you log in you will be taken straight to the home page for the SWIFT study. This will show you the current enrolment for your site, along with the expected enrolment, and a percentage table.

Welcome to SWIFT!

Dear Nikki,

You've been invited to join SWIFT in OpenClinica. Please click the button below to access the study.

[Let's Go ->](#)

Access OpenClinica anytime by bookmarking this URL: <https://nhsbt.openclinica.io/OpenClinica/MainMenu>

OpenClinica is a simple and powerful tool for capturing and organizing your research data. It's trusted in more than 10,000 studies around the world.

Thanks!
The SWIFT Team



 ndallas



[Don't remember your password?](#)

LOG IN >

 SWIFT (SWIFT) | Change | Design | Share | Settings

ndallas (Data Manager) ▾

Enter Participant ID View

Home Participant Matrix Queries Study Audit Log Tasks ▾

Alerts & Messages ▾

Quick Access ▾
My Queries

Instructions ▾
If needed you may change the study/site

Welcome to SWIFT

My Queries

Participant Enrollment by Site

Site	Enrolled	Expected Enrollment	Percentage
------	----------	---------------------	------------

Participant Enrollment for Study

Study	Enrolled	Expected Enrollment	Percentage
-------	----------	---------------------	------------

OpenClinica Participant Matrix

All participants for your site are shown on the participant matrix, as well as the completion status of the forms.

My Queries will open all queries that have been assigned to you.

You can filter the matrix by form by clicking on the 'Select An Event' drop down menu.

An Icon Key is located down the left hand side of the screen to show what the form status' mean.

If you Click on 'Queries' on the tool bar it will open all queries for your site.

Participant Matrix for SWIFT

Participant ID	Pre-Hospital	Arrival at Hospital	Day 1 (24 Hours)	Day 30	Day 90	Level of consent	Exit/End of Study	Actions
0001								
001								
123456789123456789								
A0001								
C2222								
D9090								
G1234								
H0002								
H1111								
I0010								
K0001								
M0022								
M9090								
N0002								
N1987								



Adding a Participant in OpenClinica

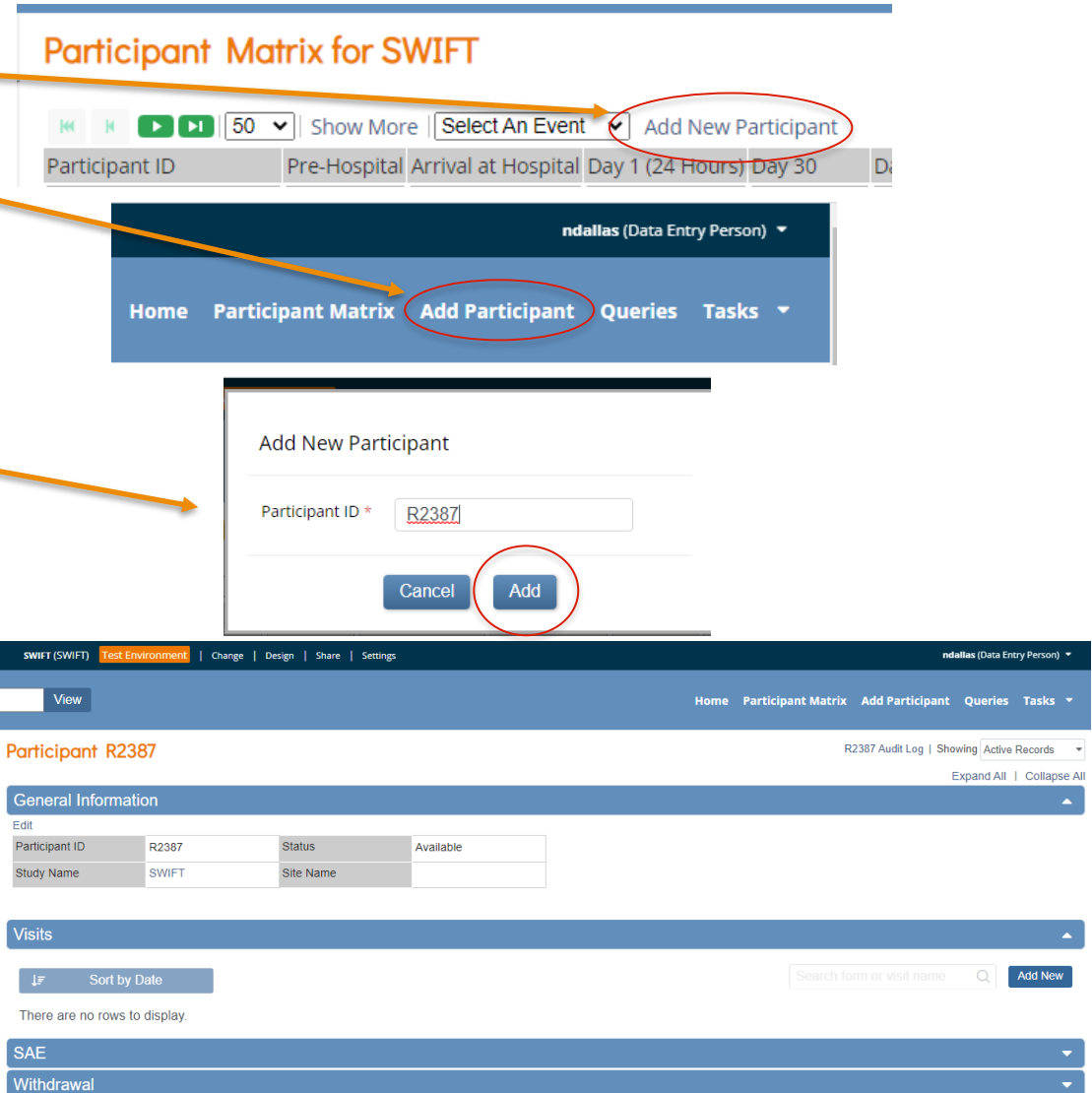
To add a participant you can click on 'Add New Participant' in the Participant matrix, or 'Add Participant' header on the right-hand side of the screen.

Once you have clicked on either of the add participant fields, a new window will appear for you to enter the new participant ID (randomisation no.) which needs to be entered in the correct format 'Rxxxx', and then click 'Add'

Once you click 'Add' your participant page will open up. The **General information** section will show the participant ID, study name, and site name auto-populated.

The **Visits** section is where you will schedule the forms to be entered.

SAE and **Withdrawal** forms are completed under their own headers and do not need to be scheduled.



Participant Matrix for SWIFT

ndallas (Data Entry Person)

Home Participant Matrix **Add Participant** Queries Tasks

Add New Participant

Participant ID * R2387

Cancel Add

SWIFT (SWIFT) Test Environment | Change | Design | Share | Settings

ndallas (Data Entry Person)

View Home Participant Matrix **Add Participant** Queries Tasks

Participant R2387 R2387 Audit Log | Showing Active Records | Expand All | Collapse All

General Information

Edit

Participant ID	R2387	Status	Available
Study Name	SWIFT	Site Name	

Visits

Sort by Date

Search form or visit name

Add New

There are no rows to display.

SAE

Withdrawal

Scheduling Visits

Visits to be scheduled:-

- Pre-hospital
- Arrival at hospital
- Day 1 (24 hours)
- 30 days
- 90 days
- Level of consent
- Exit/End of Study

Visits should only be scheduled when the forms are ready to be entered.

To schedule a visit, click on the 'Add New' icon under the 'Visits' header in the participant front page.

Select from the drop down menu the forms you need to enter data into.

The start date will be the date you are scheduling the forms.

If you need to schedule multiple visits at once then you can click the '+Add another visit'.

Click the 'Add Visits' icon. This will add the forms to the participant front page for editing.

Visits

Sort by Date

Search form or visit name

Add New

There are no rows to display.

Add Visits

Participant ID: R2387

* Visit Name

Pre-Hospital (Non-repeating)

* Start Date

19-Apr-2023

Show advanced options

+ Add another visit

Add visits

Visits

1 visit added

Sort by Date

Search form or visit name

Add New

Pre-Hospital	Form 1 - Pre-Hospital	Form 1a - Pre-Hospital 2
19-Apr-2023		

Entering Data

You can move between data fields by either mouse, or the tab key.

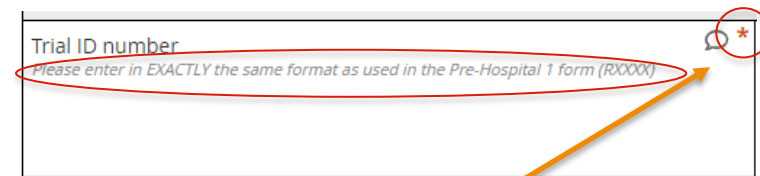
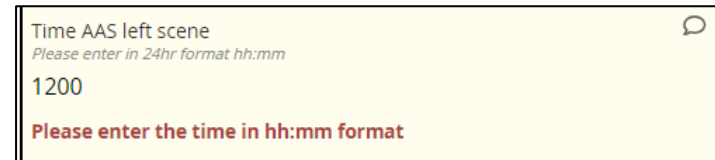
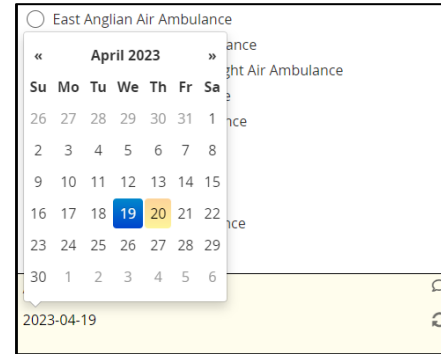
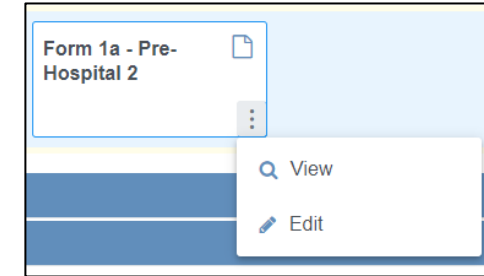
To edit a form click on the 3 vertical dots on the bottom left hand side of the form box.

The date fields will bring up a calendar for ease of entry. Once entered it will revert to the American format yyyy/mm/dd.

The time needs to be entered in the hh:mm format. A warning will fire if the date is entered in the wrong format, and this will stop you from being able to close out the form.

Data entry guidance notes are included in grey under the field name. These are to help make sure data is entered in the correct format to reduce data queries.

Mandatory data fields are shown with a red asterix in the right hand corner of the data fields box.



Saving the data

At the bottom of the forms there are 2 options for closing out the form :-

- **Close**

This will save any changes made to the form, the status of the form will show as 'Data Entry Started' on the Visits section of the participant page. If you need to come back to the form to complete data entry then you should select this option rather than complete.

- **Complete**

This will close out the form once all the data entry has been completed. Any changes made to the form once completed, a 'reason of change' notice will appear at the bottom of the page. This needs completing otherwise an automatic query will be raised.

Close

✓ Complete

Looks like you've made some updates. Please tell us why:

Enter a reason for your changes

☐ Apply to all

Heart Rate *
Enter a reason for changing this value

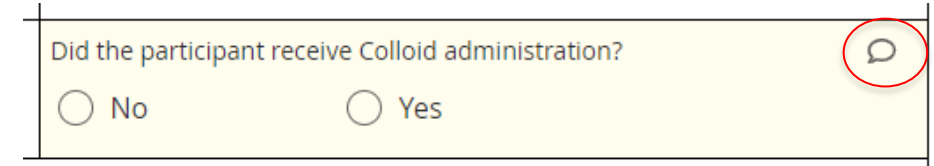
All changes saved.

Close

Missing Data

- If data is unavailable at the time of completing the form then the data field should be left blank, with an annotation left for data management explaining why the data field can't be completed.
- Once an annotation is added to a data field, the following icon  will appear in the top right hand corner.
- If an annotation is not added explaining why this data is missing, it will be queried by the trial team when the data is reviewed.

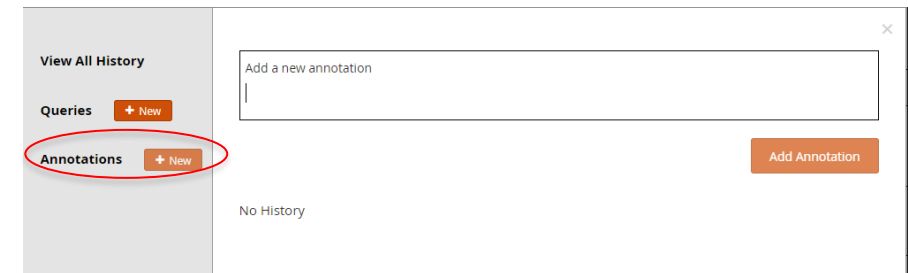
Adding an annotation to a data field:-



Did the participant receive Colloid administration?

☐ No ☐ Yes

A red circle highlights the annotation icon (a speech bubble with a question mark) in the top right corner of the form.



View All History

Queries [+ New](#)

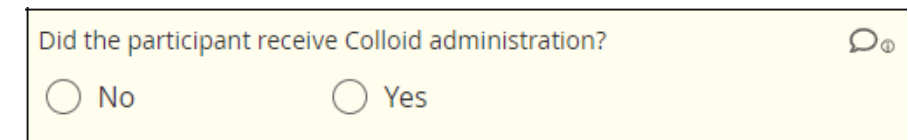
Annotations [+ New](#)

Add a new annotation

[Add Annotation](#)

No History

The modal window shows a sidebar with 'Annotations' selected and circled in red. The main area contains a text input field and an 'Add Annotation' button.



Did the participant receive Colloid administration?

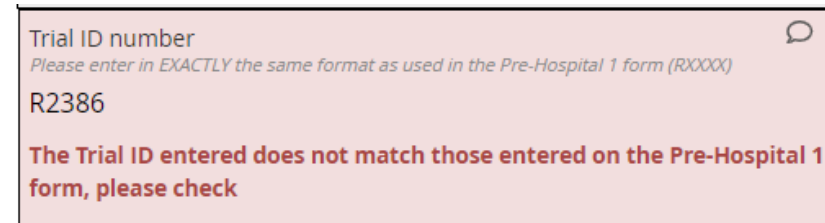
☐ No ☐ Yes

The annotation icon (a speech bubble with a question mark) is now visible in the top right corner of the form.

Data Warnings

- If data entered is inconsistent with a warning condition that has been built into the study design, then a warning note will appear as well as the data field turning red.

- A warning message will appear if you try to close out the form without addressing the warnings fired in the data field. An automatic query is generated if the warning is not addressed and the form closed.

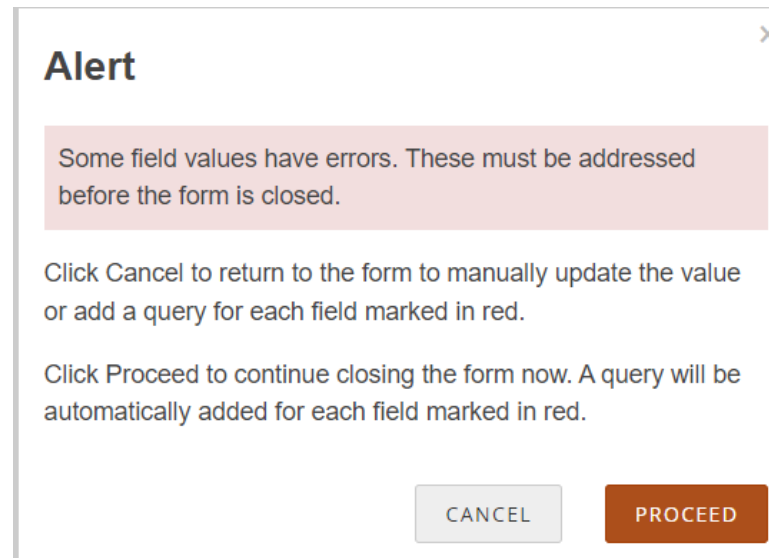


Trial ID number 

Please enter in EXACTLY the same format as used in the Pre-Hospital 1 form (RXXXX)

R2386

The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check



Alert 

Some field values have errors. These must be addressed before the form is closed.

Click Cancel to return to the form to manually update the value or add a query for each field marked in red.

Click Proceed to continue closing the form now. A query will be automatically added for each field marked in red.

Data Queries

A Data Query is either manually or automatically raised against an individual question if:

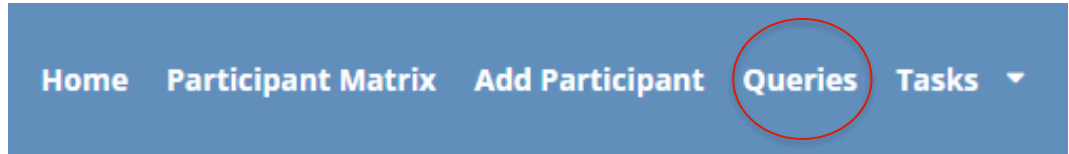
- I. There is concern over **accuracy, completeness or validity of data**
- II. Additional explanations are required regarding warnings or missing data flagged by the database.

Data queries will be raised by the trial team / data manager reviewing the data and the staff at site should regularly review these queries and respond to them as appropriate. **Sites are NOT to raise queries.**

An automatic query will be generated if a warning isn't addressed before closing out a form.

The query text should explain the issue fully and clearly.

All queries for your site can be found in the 'Queries' section in the top right hand corner banner.



Home Participant Matrix Add Participant **Queries** Tasks ▼

Data Queries - Continued

The list of queries is shown along with a summary of the resolution status for all queries raised at your site.

To view a query you can click on the following icons in the 'Actions' column:



Will open the data field for the query only.



Will open the form containing the data field that has been queried.

Alternatively you can click on the speech bubble in the top right hand corner of the data item when in a form.

Alerts & Messages

Quick Access

My Queries

Recent

R2387

Arriv > Form 2 - A

Instructions

Use the header bar to sort and filter listed queries.

Info

Queries

Summary count by status (based on table filters)

New

Updated

Closed

Not Applicable

Closed Modified

Total

445

5

3

--

12

465

50

Show More

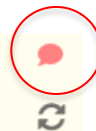
Apply Filter

Clear Filter

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
464	R2387	SWIFT	Query	New	0	0	Arrival at Hospital	Form 2 - Arrival at Hospital	arhos_tid	R2386	Automatic query for: The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check	Nikki Dallas (ndallas)	
465	R2387	SWIFT	Query	New	0	0	Arrival at Hospital	Form 2 - Arrival at Hospital	bldtest_dt	2023-05-18	Automatic query for: The date should be after the study start date but NOT a future date. Please check	Nikki Dallas (ndallas)	

Date Sample taken

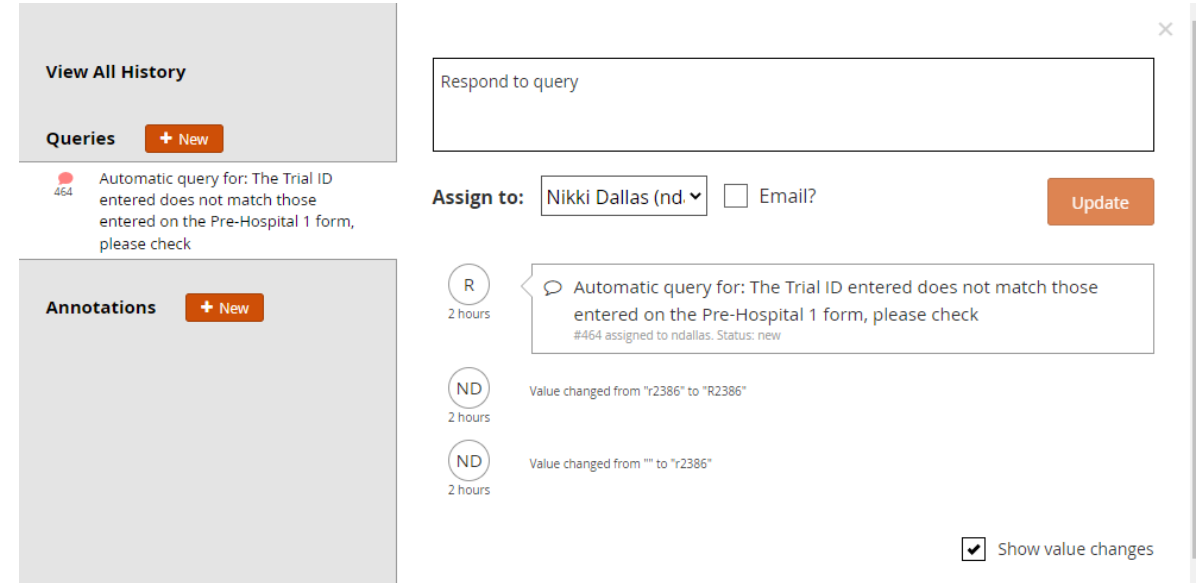
2023-05-18



Data Queries - Continued

To respond to an existing Query:

- To respond to a query, click on 
 - This will allow you to respond to the query and amend the data at the same time
- Enter response into the box that appears entitled 'Respond to Query' and click 'Update'. **Amend the data in the form. NHSBT data management are not allowed to amend data fields for your**
- Once you have responded to the query the colour of the speech bubble changes from **red** to **Orange**.
- The trial Data Manager will review all responses and check that the data has been amended as appropriate, if all is satisfactory, the query will be closed and the speech bubble will now appear **grey**.



The screenshot displays the NHSBT Data Manager interface. On the left, there are two panels: 'View All History' and 'Queries'. The 'Queries' panel shows a query for trial ID #464 with the message: 'Automatic query for: The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check'. Below this is an 'Annotations' panel with a '+ New' button. On the right, the 'Respond to query' workflow is shown. It includes a text input field for the response, an 'Assign to:' dropdown menu (currently set to 'Nikki Dallas (nd)'), an 'Email?' checkbox, and an 'Update' button. Below the input field, a list of annotations is shown, including the original query and two value changes: 'Value changed from "r2386" to "R2386"' and 'Value changed from "" to "r2386"'. A 'Show value changes' checkbox is at the bottom right.

* Data query responses can be assigned to a data manager, If the 'Email?' box is checked then the assigned person will receive and email notification that the query has been updated.*

Audit History

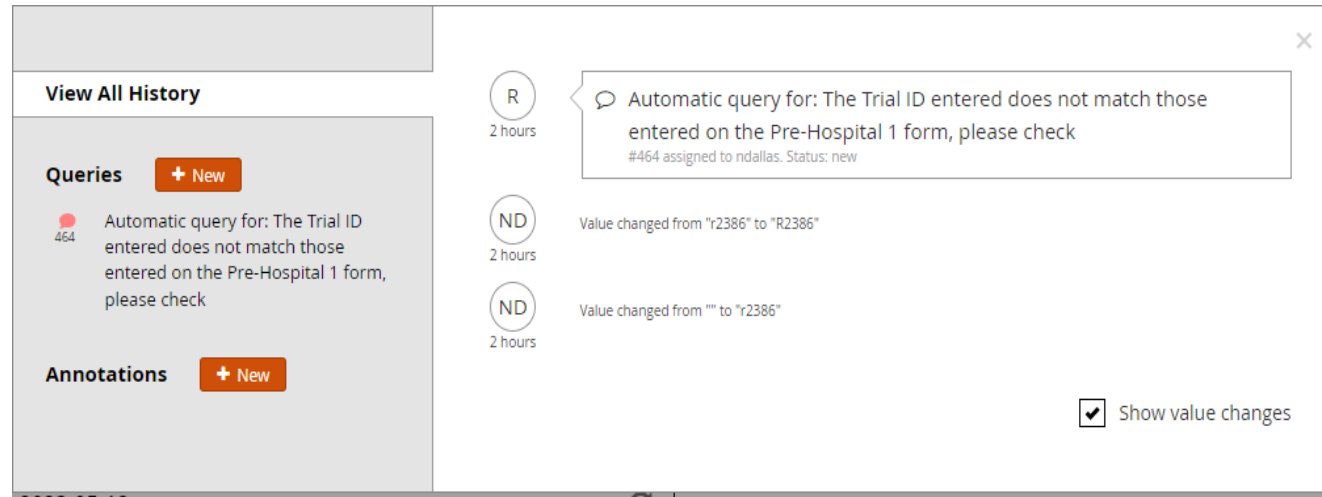
The Audit History is a chronological record of:

- Response value
- Any warning messages
- Any overrule reasons
- Any reasons for change
- Any attached comments and lock status

Whenever any of these items are changed, a record is kept of the date/time of the change and the name of the user who carried it out.

An audit trail is maintained so that changes or modifications to data can be viewed; the audit trail is necessary to comply with GCP

* The Audit history can be accessed by clicking on the speech bubble  in the top right hand corner of the data field. *



The screenshot displays the 'View All History' section of the system. It features two main categories: 'Queries' and 'Annotations', each with a '+ New' button. Under 'Queries', there is a red dot icon with the number '464' and a text entry: 'Automatic query for: The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check'. Under 'Annotations', there is a text entry: 'Automatic query for: The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check'. To the right, a list of audit events is shown, each with a circular icon (R or ND) and a timestamp of '2 hours'. The first event is a red circle with 'R' and a speech bubble icon, with the text: 'Automatic query for: The Trial ID entered does not match those entered on the Pre-Hospital 1 form, please check #464 assigned to ndallas. Status: new'. The second event is a blue circle with 'ND' and the text: 'Value changed from "r2386" to "R2386"'. The third event is a blue circle with 'ND' and the text: 'Value changed from "" to "r2386"'. At the bottom right, there is a checkbox labeled 'Show value changes' which is currently checked.

SAE forms

SAE forms are scheduled on the participant page, underneath the visits section.

To add an SAE – click ‘Add New’ and complete all information within the form. Ensure to exit the form using the “Complete” option (not “Close”).

To add follow-up information to an SAE, the initial report should be over-written with the follow up information

SAE’s need to be added to the database within 24 hours of awareness of the SAE. An automatic email is sent to the SAE mailbox at the CTU as soon as an SAE form is completed in the database. **Refer to the protocol for events that are excluded from reporting.**

PI signature is needed once the SAE form is completed. This needs to be done every time the form is updated.

To sign an SAE please ensure (1) The form is marked as 'COMPLETE' (2) The PI is signed into OpenClinica using their own account (3) The 'SIGN' icon is selected from the SAE action column of the relevant SAE.

SAE

Form 10 - Serious Adverse Events **Add New**

Search here

Actions	Form Status ↑↓	Last Updated ↑↓	Updated By ↑↓
⋮	completed	11-Aug-2023	

Result 1-1 of 1 Show 10 per page

Adverse Event

Adverse Event **Add New**

Actions	AE - Y/N ↑↓	Start Date ↑↓
⋮	Yes	11-Nov-2022
⋮	Yes	01-Nov-2022

Result 1-1 of 1 Show 10 per page

SAE

Form 10 - Serious Adverse Events **Add New**

Search here

Actions	Form Status ↑↓	Last Updated ↑↓	Updated By ↑↓
⋮	data entry started	09-May-2023	ndallas

Result 1-1 of 1 Show 10 per page

Adverse Event

Adverse Event **Add New**

Actions	AE - Y/N ↑↓	Start Date ↑↓
⋮	Yes	11-Nov-2022
⋮	Yes	01-Nov-2022

Result 1-1 of 1 Show 10 per page

Casebook

Withdrawal forms

Withdrawal forms are scheduled on the participant page, underneath the SAE section.

To add a withdrawal form – click ‘Add New’ and complete all information within the form.

The screenshot shows the OpenClinica interface for a participant named 'ndallas'. The sidebar on the left contains a list of status filters: Not Started, Not Scheduled, Scheduled, Data Entry Started, Stopped, Skipped, Completed, Signed, Locked, Archived, and Removed. Below these are 'Actions' with options: View, Edit, Clear, Remove, Restore, and Reassign. The main content area displays a grid of form cards for different time points: 'Arrival at Hospital' (04-May-2023) with 'Form 2 - Arrival at Hospital'; 'Day 90' (26-Apr-2023) with 'Form 5 - Day 90', 'Form 6 - Quality of Life', and 'Form 7 - ModRUM (Health and Soc...)'; and 'Pre-Hospital' (19-Apr-2023) with 'Form 1 - Pre-Hospital' and 'Form 1a - Pre-Hospital 2'. Below the forms is a section for 'SAE' (Serious Adverse Events) and 'Withdrawal'. Under 'Withdrawal', there is a card for 'Form 11 - Withdrawal' with an 'Add New' button circled in red. An orange arrow points from the text 'click ‘Add New’' in the left box to this button. Below the card is a search bar and a table with columns: Actions, Form Status, Last Updated, and Updated By. The table currently shows 'No data available in table'.

Points to Remember

- Complete all data fields on a form.
 - If a field can't be completed then leave an **Annotation** for Data Management.
- Check for warning messages within the data fields before completing a form, otherwise an automatic query will be generated.
- Died on scene patients:-
 - Pre-hospital 1, Pre-hospital 2, and Exit forms to be scheduled and entered only.
 - Initials to be entered as **ZZZ** on Exit form if unknown.
- Any updates to the Initial report of an Serious Adverse Event form should be overwritten on the SAE eForm. Follow-up information should be noted as it becomes available.
- Day 90 Health Questionnaire should be printed out and given/sent to the patient for completing. Once returned it can be entered into OpenClinica. **DO NOT** take patients email addresses.

Forms in Swift

- **Pre-Hospital 1**
CRF completed by AAS team and given to site within 24hrs of randomisation, for entry onto OpenClinica.
- **Pre-Hospital 2**
CRF completed by AAS team and given to site within 24hrs of randomisation, for entry onto OpenClinica
- **Arrival at Hospital**
- **Day 1 (24 hour)**
- **Day 30, Discharge, Death**
Completed at 30 days post-randomisation, day of discharge, or death, whichever comes first.
- **Day 90**
Completed when Pt reaches day 90 **post randomisation**. Health questionnaires completed at this time point.
- **Exit/End of Study**
Completed for all participants at either day 90, discharge, or death, whichever comes first.
- **Level of Consent**
- **SAE**
To be completed on the DB within 24hrs of knowledge of the SAE.
- **Withdrawal form**

WHAT'S NEXT ?

- Access granted for Training database to enter dummy patient data (for practice)
- Database training signature log needs to be signed off
- You will be given access to Live database
- Refresher training can be done using SWiFT database specific presentation before the start of the project, if required
- Any OpenClinica issues, please contact the Trial Data Managers:

Rupa Sharma (rupa.sharma@nhsbt.nhs.uk) Phone: 01223 588924

Nikki Dallas (nikki.dallas@nhsbt.nhs.uk) Phone: 01223 588151



Thanks a lot