

NHSBT OpenClinica User Guide

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1 Introduction to OpenClinica

OpenClinica is a clinical data management system used for electronic data capture and data management that is accessed via a web browser.

1.1 Key terminology

Study: the trial, i.e. SWiFT trial

Participants: Participants, in this context, refers to patients who are eligible for the trial and who go on to be randomised and take part in the study

Event or Study Event: these can be visit related data collection points such as Pre-Hospital 1 and 2, or ad hoc events, such as SAE and Concomitant medication. These have at least one data collection form associated with them.

Case Report Form (CRF): forms used to collect and contain data for a Study Event

Data items: the questions on the forms

Queries: enquiries or alerts about potential incorrect data.

Annotations: notes on a form that do not contain clinical data and are usually used for keeping track of workflow.

Reasons for Change: notes added by a user when modifying data on a form that has already been marked as Complete.

Roles: categories for users in OpenClinica that determine the tasks available to them in the system.

1.2 Icons glossary

Each Event and form will be allocated a status, Events may be given an attribute, data items will have a query/annotation status, and there will be a choice of actions for participants, Events, and forms. These are all illustrated using the following icons.

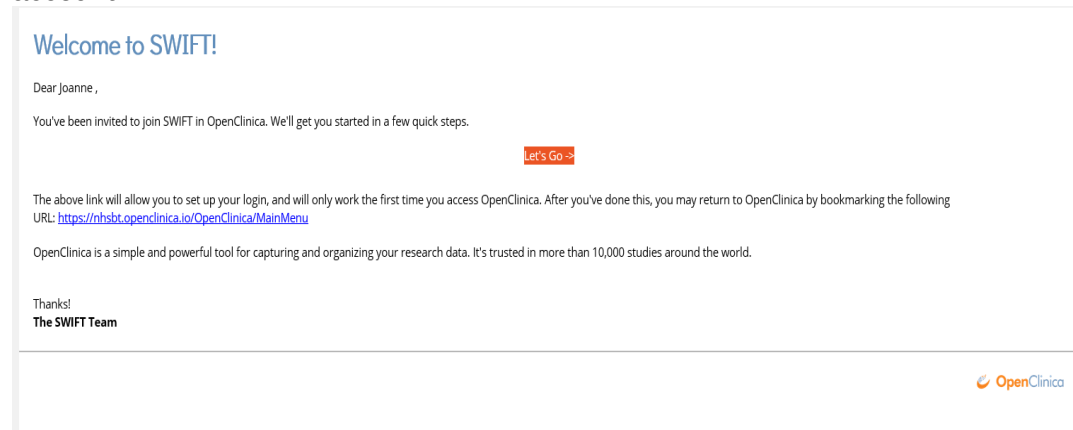
Icon	Status/Action	Description
Event and Form Statuses		
	Not Started	The Event the form is for has been scheduled, and data entry for the form has not started
	Not Scheduled	The Event has not been scheduled. Common Events such as Adverse Events remain in this status throughout the study.
	Scheduled	The Event has been scheduled, but no data has been entered.
	Data Entry Started	A user has started to enter data, but not all the Forms in the Event have a status of completed.
	Completed	For an Event, this icon means that a user has completed data entry for all Forms in the Event. For a Form, it means a user has completed the Form and therefore if further changes are needed in that Form, you are required to provide a reason for change.
	Skipped	The user has decided not to complete the Event. Any data that has been entered can still be viewed and/or exported. You can select this setting from the dropdown menu on the Update Event screen when the current status is scheduled.
	Stopped	The Participant has temporarily stopped participating in the study. You can select this status from the dropdown menu on the Update Event screen when the current status is data entry started.
	Removed	The Event has been removed. Users can still view Forms. This will supersede any of the other statuses.
Event Attributes		

	Signed	The Event has been signed. This icon appears in addition to the status. Note: If an Event is signed, changes to an item in a Form in that Event removes the signature. This also occurs if an Event status is changed from completed, stopped, skipped, or not scheduled after being signed. In addition, this changes the Participant Status from signed to available and the Event Status to completed. Archiving/unarchiving or removing a Form will unsign the Event. The exception is that when archiving/unarchiving, a Form with a status of Not Started will not be unsigned. Multiple users can sign an Event, so even if an Event has already been signed, the sign action will still be available. If there are multiple signatures, the most recent one appears on the Form, and the others appear in the Audit Log.
	Locked	A Data Manager locked the Event. No data can be added, and the Event cannot be removed. This icon appears in addition to the status.
Actions		
	View	View Participant Details, data about Event, data in a Form.
	Enter/Edit	Enter or edit data in the Form or Event.
	Clear Form	Clear all data in the Form. This resets the Form to Not Started and closes all associated queries, but audit history is retained.
	Sign	Sign-off on Event.
Statuses for Queries and Annotations		
	No Query	Click this bubble to create a query.
	New	A query has been added by either a site user (e.g., a comment/annotation), data manager, or monitor, or was auto-generated by OpenClinica based on built-in edit checks.
	Updated	Either a site user, data manager, or monitor has added information to the query.
	Closed	The query is considered resolved by the data manager or monitor.
	Closed Modified	Slightly paler than Closed, this means the data was changed after the query was closed.
	Multiple New Queries	You can select each query from the sidebar.
	Multiple Updated Queries	You can select each query from the sidebar.
	One or Multiple Annotations	You can select each annotation from the sidebar.

2 Accessing OpenClinica

2.1 Username and password

To access the data entry for the trial, please contact SWiFT@nhsbt.nhs.uk. You will then receive an email from donotreply@openclinica.io providing you with a link to set up your account.



Clicking 'Let's Go' in the email will open the following webpage.

A screenshot of the OpenClinica website's password setup page. The header features the OpenClinica logo. The main heading is "Enter a new password for *account@company.com*". There are two password input fields, each with a lock icon on the left. The first field is labeled "your new password" and the second is labeled "confirm your new password". At the bottom of the page is a large blue button with a white right-pointing arrow.

Your password must be at least 8 characters in length and contain at least one of each of the following types of characters:

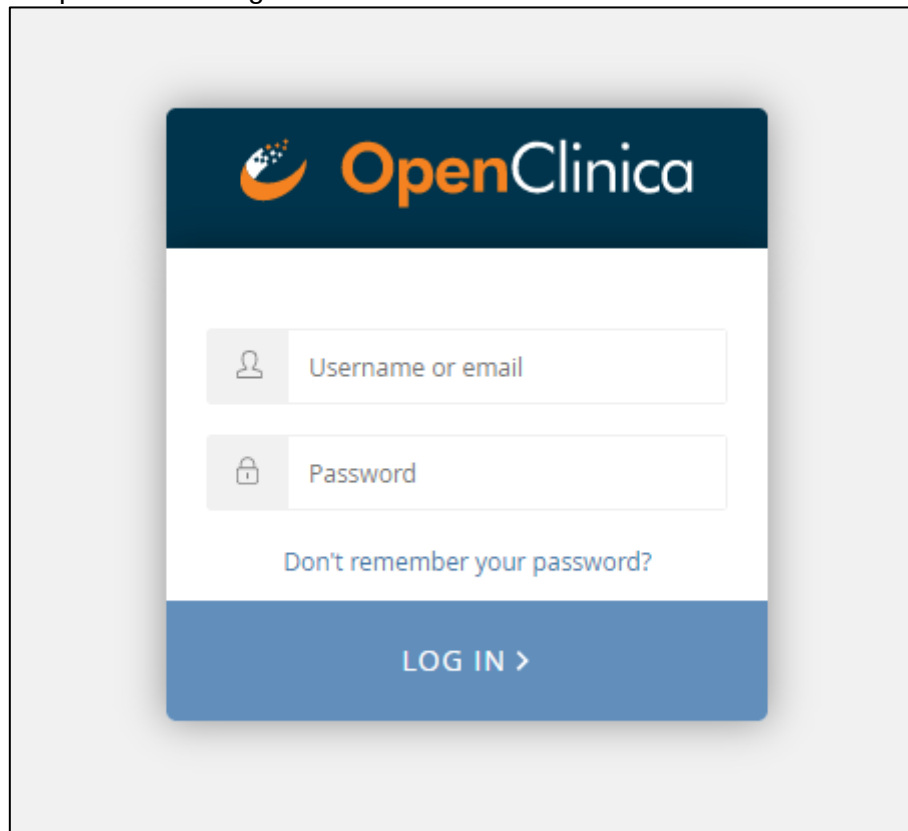
- Lower case letters (a-z)
- Upper case letters (A-Z)
- Numbers (0-9)
- Special characters (!@#\$%^&*)

Please also note:

- Passwords expire every 180 days, and users are automatically prompted to create a new password.
- User accounts are locked after ten failed login attempts from the same IP address.
- Users are automatically logged out of OpenClinica after one hour of inactivity.
- Invitations to studies expire in 14 days if they have not been accessed.

2.2 Logging in

Go to <https://nhsbt.openclinica.io/OpenClinica/MainMenu> and use your case-sensitive username and password to log in.



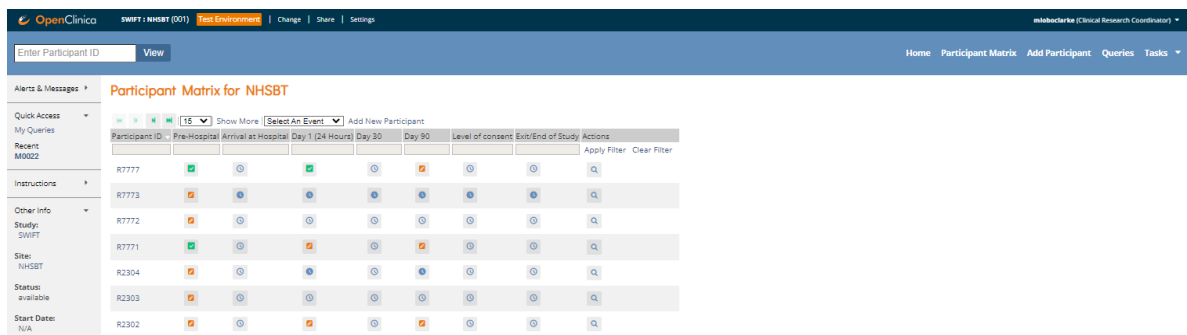
2.3 Password Reset

Please use the 'Don't remember your password?' option if you do forget your password.

3 Participant Matrix and adding a participant

3.1 Participant Matrix

Once logged in, you will see SWiFT study in the first row of the header along with your site name, e.g., Addenbrooke's Hospital on the left side and your username and role on the right side. Below this, in the second row of the header, you will find the navigation menu. Click 'Participant Matrix' in this navigation menu to get to the below page (your home page depends on your OpenClinica user role).

The screenshot shows the 'Participant Matrix for NHSBT' page in OpenClinica. The page has a dark blue header with the OpenClinica logo and navigation links. Below the header is a search bar for 'Enter Participant ID' and a 'View' button. The main content area displays a table of participants. The table has columns for 'Participant ID', 'Pre-Hospital', 'Arrival at Hospital', 'Day 1 (24 Hours)', 'Day 30', 'Day 90', 'Level of consent', 'Exit/End of Study', and 'Actions'. The table lists several participants with their IDs and corresponding status icons. On the left side of the page, there is a sidebar with 'Quick Access' and 'My Queries' sections. The 'Quick Access' section includes links to 'My Queries', 'Recent M0022', 'Instructions', and 'Other Info'. The 'My Queries' section includes links to 'Study: SWiFT', 'Site: NHSBT', 'Status: available', and 'Start Dates: N/A'.

The Participant Matrix is the table on this page. It contains all the participants who have been approached to assess eligibility at your site and each row represents a participant. The Participant Matrix can be used to

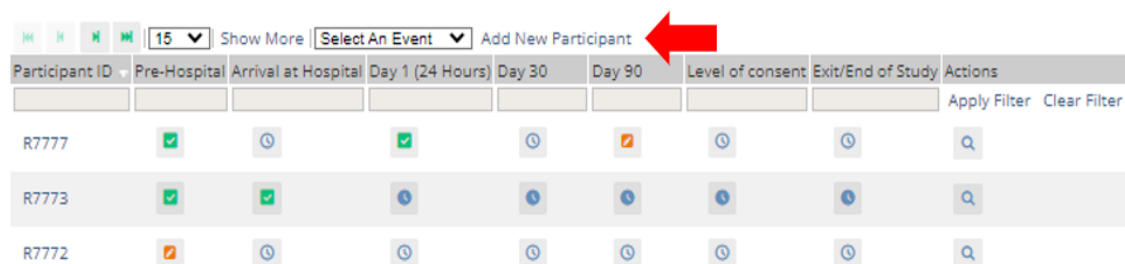
- Manage Participants:
 - Add a Participant
 - Edit Participant Data
 - Remove a Participant
 - Restore a Participant
 - Sign a Participant Record (Investigators Only)
- Schedule Events
- View Participant Details

The Participant Matrix lists Visit-Based Events across the top of the matrix and Participant IDs down the side. Each icon represents the status of the Participant/Event combination. A key for the icons is listed on the left side of the screen and in the **icons glossary**. Hover over the icons in the Participant Matrix to see more details about the Event.

3.2 Adding a participant

Click the text 'Add New Participant' found above the matrix.

Participant Matrix for NHSBT



Participant ID	Pre-Hospital	Arrival at Hospital	Day 1 (24 Hours)	Day 30	Day 90	Level of consent	Exit/End of Study	Actions
R7777								
R7773								
R7772								

Add New Participant

Participant ID *

Cancel

Add

Add the participant ID and click the blue 'Add' button.

Once you have lots of participants in your Participant Matrix, you can use the grey box below the table heading 'Participant ID' to filter for a chosen participant.

Participant Matrix for NHSBT

Participant Matrix for NHSBT

15 Show More Select An Event Add New Participant

Participant ID	Pre-Hospital	Arrival at Hospital	Day 1 (24 Hours)	Day 30	Day 90	Level of consent	Exit/End of Study	Actions
R7777								Apply Filter Clear Filter
R7777								

Results 1 - 1 of 1.

4 The Participant Details Screen

In the Participant Matrix, click on the Participant ID or the View button  for the participant whose record you want to see. This is the Participant Details screen for the chosen participant. It is divided into the following sections:

- General Information
- Visit-Based Events
- Common Repeating Events: Adverse Events, SAE
- Common Non-Repeating Events: End of Study

Participant R7777

R7777 Audit Log | Showing Active Records

Expand All Collapse All

General Information

Edit Invite View participant access code

Participant ID	R7777	Status	Available	First Name	John Jones	Mobile	
Study Name	SWIFT	Site Name	NHSBT	Participate Status	Active	Email	sara.last@nhsbt.nhs.uk

Visits

1 visit added

Sort by Date Search form or visit name Add New

Day 30	25-Nov-2022	Form 4 - Day 30	
Arrival at Hospital	25-Nov-2022	Form 2 - Arrival at Hospital	
Day 90	24-Nov-2022	Form 5 - Day 90	Form 6 - Quality of Life
			Form 7 - ModRUM (Health and Soc...)
Day 1 (24 Hours)	24-Nov-2022	Form 3 - Day 1 (24 Hours)	
Pre-Hospital	24-Nov-2022	Form 1 - Pre-Hospital	Form 1a - Pre-Hospital 2

SAE

Withdrawal

5 Study Events

An Event is a data collection point such as Pre-Hospital, Arrival and SAE. These have at least one data collection form associated with them. An Event might or might not be connected to a real-world visit.

5.1 Types of events

Event Type	Description	SWiFT Events
Visit-Based	An event that is associated with a visit date.	All Events except those listed below.
Common	An event that is not necessarily associated with a visit date, that	SAE and Withdrawal

	could happen at any point in the trial.	
Repeating	An event that repeats in the study, either a known or an unknown number of times.	SAE

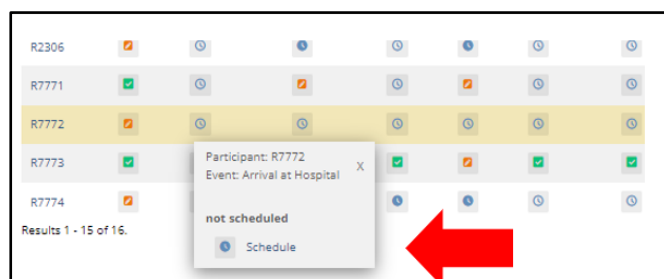
A scheduled event is indicated by this icon . Please find a key for the icons associated with events and forms (Statuses and Actions) in the sidebar and in the **icons glossary**.

5.2 Scheduling an Event

To input data into a form for a Visit-Based Event, you must first 'schedule' the Event. Please only schedule Events that you are ready to input data for.

To schedule a Visit-Based Event from the Participant Matrix:

1. Click on the Schedule button  for the participant and the Event that you want to schedule.
2. Select 'Schedule'.



3. Leave the start date as the current date and the time empty as they are by default.
4. Leave the end date and time empty.
5. Click the blue 'Proceed to Enter Data' button.

Schedule Study Event

Participant ID: **R7772**

Study Event Definition: **Arrival at Hospital (Non-repeating)** *

Start Date/Time: * : (DD-MMM-YYYY HH:MM)

End Date/Time: : (DD-MMM-YYYY HH:MM)

Leave blank if n/a.

▣ Schedule another event.

▣ Schedule another event.

▣ Schedule another event.

▣ Schedule another event.

Proceed to Enter Data **Cancel**



To schedule a Visit-Based Event from the **Participant Details** screen:

1. Click on the blue 'Add New' button in the Visits section of the page.

Visits

Sort by Date

Search form or visit name

Add New

Select the Event that you want to schedule from the Study Event Definition drop-down list.

Schedule Study Event

Participant ID: **R7772**

Study Event Definition: **Arrival at Hospital (Non-repeating)** *

Start Date/Time: : (DD-MMM-YYYY HH:MM)

End Date/Time: : (DD-MMM-YYYY HH:MM)

and follow steps 3-5 of the scheduling a Visit-Based Event from the Participant Matrix method above.

6 Entering data and completing a form

To start data entry on a form, navigate to the **Participant Details** screen. The way you open the form depends on the type of Event it is associated with.

- a. If the form is for a Visit-based Event, find the Event and CRF that you wish to complete within the Visits section next to the relevant Event and click the form.
- b. If the form is part of a Common Event, then go to the Event's section and click 'Add New' to open the form.

Sort by Date

Search form or visit name

Add New

Day 90 24-Nov-2022	Form 5 - Day 90	Form 6 - Quality of Life	Form 7 - ModRUM (Health and Soc...)
Day 1 (24 Hours) 24-Nov-2022	Form 3 - Day 1 (24 Hours)		
Pre-Hospital 24-Nov-2022	Form 1 - Pre-Hospital	Form 1a - Pre-Hospital 2	

AE

Form 10 - Serious Adverse Events

Add New

Search here

Actions Form Status Last Updated Updated By

Once the form is open, you will see the participant ID and the form name at the top of the screen – as below:

R9999: Pre-Hospital



Study of Whole blood in Frontline Trauma

Complete for all patients who receive blood products from a 'trial box'

ARRIVAL ON-SCENE

6.1 Types of questions

Number or text: Please type required data into box.

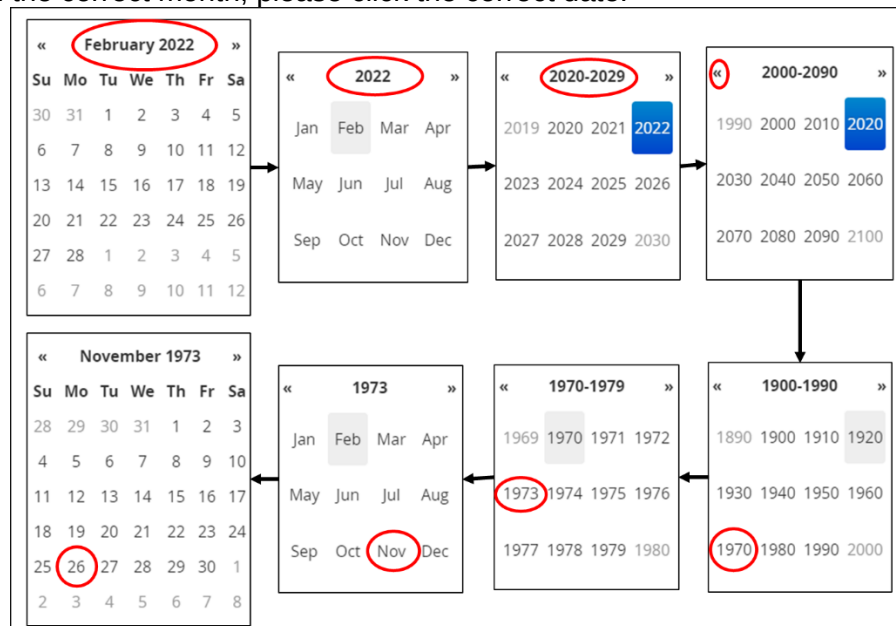
Select: For questions where only one option should be selected, the tick boxes are circles:

☐ option a
 ☐ option b
 ☐ option c

and for 'select all that apply' questions the tick boxes are squares:

☐ option a
 ☐ option b
 ☐ option c

Date: To enter a date, you can use the calendar widget that appears after clicking in the box to enter data. To zoom out to all months in the current year, click the month and year. If the date is outside this year, click the year to zoom out to all years in the decade. Once you have found the correct month, please click the correct date.

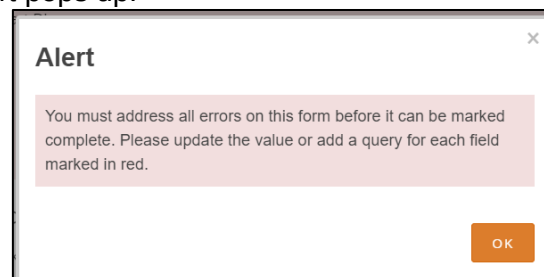


Instead of using the widget, you can enter the data yyyy-mm-dd e.g., 2022-02-01 for 1st of February 2022.

Time: Please enter time in the 24-hour format hh:mm, e.g., 09:34.

Once you have completed the form, click the orange 'Complete' button and then the orange 'CONFIRM' button.

You may find that an alert pops up.



To resolve the errors, click the orange 'OK' button. If values were entered incorrectly, then please correct them. However, if the value is correct then you will need to add a query. If you close the form without changing the data or adding a query to explain the data inputted, a query will automatically be generated for the question. This will need to be resolved as explained in **Section 8**.

6.2 Adding queries

This will only be available to certain user roles. Site staff will not usually create queries on data items. Click on the speech bubble next to the data item with the issue to open the query form.

Site Country

☒ UK

☐ Australia

☐ Canada

☐ New Zealand

☐ Other

Click the orange '+ New' button next to 'Queries'. Please explain why the value entered value is correct in the 'Add a new query' box. Then click the orange 'Add Query' button.

View All History

Queries **+ New**

Annotations **+ New**

Add a new query

Assign to: ☐ Email?

Add Query

AN Value changed from "" to "8"
2 minutes

☒ Show value changes

Once you have finished amending values and raising queries, click the orange 'Complete' button and then the orange 'CONFIRM' button.

6.3 Viewing and editing entered data

To view or edit completed forms, navigate to the **Participant Details screen**.

To view the form, locate the Event and the form of interest and click the View button .

If you need to amend the values after completing the form, you can click the Edit button , but now if you change a value you will be asked to provide a reason for the change. Please make all changes and then go to the end of the form, where you will find the boxes for the reasons for change. If the same reason applies for all changes, enter it into the first box and then tick the 'Apply to all' tick box.

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

Enter a reason for your changes ☐ Apply to all

Date of approach *

Enter a reason for changing this value

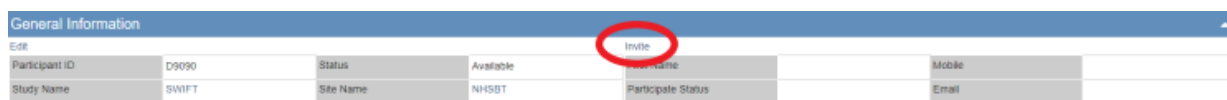
Click the orange 'Close' button when finished.

7 Participate forms

7.1 Inviting a participant to complete Participate forms

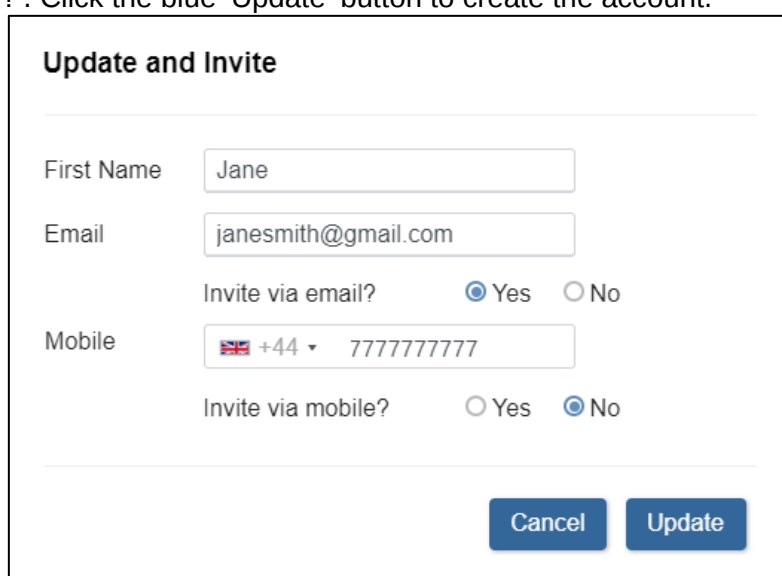
The QoL and ModRUM forms are to be completed by participants independently on their own electronic device via their email address (pc, tablet or mobile phone). To allow them to do so sites will need to 'invite' them to OpenClinica.

To do this navigate to the **Participant Details screen** for the chosen participant. In the 'General Information' section, click 'Invite'.



The screenshot shows the 'General Information' section of the Participant Details screen. It includes fields for Participant ID (D9090), Status (Available), First Name, Last Name, Study Name (SWIFT), Site Name (NHSBT), Participate Status, and Email. The 'Invite' button is circled in red.

Then, to create a Participant account enter their first name and email and select Yes on 'Invite via email?'. Click the blue 'Update' button to create the account.



The 'Update and Invite' form contains the following fields and options:

- First Name: Jane
- Email: janesmith@gmail.com
- Invite via email?: ☒ Yes ☐ No
- Mobile: (Country code dropdown shows +44)
- Invite via mobile?: ☐ Yes ☒ No
- Buttons: Cancel, Update

You can return to the **Participant Details screen** to send or resend an invitation at any time. Once the information has been updated, when you return to the **Participant Details screen**, the Participant's contact information appears. The Participant Status appears on the **Participant Details screen** and is defined as follows:

Status	Description
Created	The participant account was created, but the invitation has not yet been sent, and the participant has not yet accessed Participate. Both Invite via email and Invite via mobile were set to No.
Invited	The participant account was created. An invitation was sent via email and/or mobile, but the participant has not yet accepted the invitation.
Active	The participant has successfully accessed Participate and can complete forms. Once the participant has completed the form the status will remain as Active.
Inactive	The participant has been removed from the study. (Data Managers and Investigators can remove participants. Any data associated with removed participants can be viewed but cannot be edited or extracted from the database.)

The Participant status is also visible in the Participant Matrix. To view the Participant status, click Show More, above the matrix. This makes the Participate Status column appear.

Participants only have access to forms that are in Events with a status of Scheduled or Data Entry Started. Forms that have been identified as Participate Forms, i.e., Day 90 (QoL and ModRUM) form can be completed by Active Participants as well as CRCs and Investigators. When the Participant enters data into a Participate Form, that Form data is immediately available in OpenClinica for review.

Guidance on how participants should complete forms can be found here:
<https://docs.openclinica.com/oc4/participate/oc4-oc4-participate-participants-view/>

If a participant is not able to complete the participate forms electronically (for eg. If they do not have access to an email account) then it is possible to print the QoL and ModRUM forms by clicking on the printer icon on the electronic form. The paper form can be completed by the participant and the responses transcribed to the electronic forms by the site staff. The completed paper copy should be retained at site.



R7777: Form 6 - Quality of Life

SWIFT
Study of Whole blood
in Frontline Trauma

The form should be completed at 90 Days Post-Arrival at Hospital

Under each heading, please tick the ONE box that best describes your health TODAY

8 Viewing and responding to queries

To view all data queries for your site, click 'Queries' in the second row of the header. There is a summary table and the main queries table on this page. To see only the queries assigned to you, expanding the Quick Links header in the left-hand sidebar and click 'My Queries'.

8.1 The Queries Table

The queries table displays queries, annotations, and reasons for change. Details about each query, annotation, or reason for change are listed in the Detailed Notes column. You can

filter for queries only using the 'Type' column. Click the view within record icon  for the query you wish to view, update, or respond to.

Queries

Summary count by status (based on table filters)

New	1
Updated	--
Closed	--
Not Applicable	--
Closed Modified	--
Total	1

50 Show More

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
116	K0001	001	Query	New	1	1	Withdrawal	Form 11 - Withdrawal	withass_dt	2022-12-09	Automatic query for: The date should be after the study start date but NOT a future date. Please check	Maria Lobo-Clarke (mlboclarke)	Apply Filter Clear Filter

Results 1 - 1 of 1.

Respond using the 'Respond to query' box and click the orange 'Update' button.

If want to change the data, click on the cross in the top right of the query form and amend the data. If data is changed, you will be prompted to enter a reason for change. The click the orange 'close' button at the end of the form. You will still need to respond to the query to remove it from your open queries.

When using the query form, you can view the history for all queries and annotations on a single item by selecting View All History, or you can view the history of each query or annotation individually by selecting that query or annotation from the left panel. If you check the Show value changes tick box, each value change is included in the history.

9 Annotations

It is possible to add an 'annotation' to a data item. This is a comment that is visible by site and CTU staff. It can be used to record non-clinical information about the data item. For eg. If a start date or time is not available, adding this information into an annotation can alert the CTU that the information is not available and prevent a query from being raised.

To add an annotation, click on the speech bubble associated with that data item and then select '+ new' annotation

WB Donation 1 SXXXXXXXXXXXXX			Date donor (Donor 1)
G7756942685379			2022-10-2
WB Donation 2 SXXXXXXXXXXXXX (Please leave blank if NA)			Date donor (Donor 2)
G7532468798543			2022-10-2
Were additional Red Blood Cells transfused from outside the trial box?			

10 Signing forms/events

At the end of the study, all completed forms will need to be reviewed and signed by the PI.

This is done by clicking the Sign action icon  next to the chosen form or event.

Using the View button in the CRFs in this Study Event the PI can review the form. If happy, they will need to enter their username and Signature Code. This code can be requested by clicking the 'Send a new signature code to my email' text on this page. Then click the blue 'Submit' button to sign off on the form.

Once done, the form status will be completed with a signed icon.

Actions	Form Status 	Last Update 	Updated By 
   	completed 	15-Dec-2021	anewton
   	completed	16-Dec-2021	anewton

11 Conclusion

If you have any problems, please contact SWiFT@nhsbt.nhs.uk. Initially you will be given access to the training site and after a training period, you will be given access to the live system to enter real data. You can confirm you are accessing the live system by checking that the header does not contain .