

IMPERIAL

OpenClinica eCRF Completion Guidelines for the COLLABORATE Study

Version: **V1.0**Date: **05/02/2026**

Prepared by: Name:	Role	Signature and Date
Rosie Way	ICTU Trial Manager	
Reviewed by: Name:	Role	Signature and Date
Rahi Jahan	ICTU Trial Operations Manager	

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1. OpenClinica Support

Contact Clinical Data Systems (CDS) Production Support for any OpenClinica related queries.

By e-mail: cds_support@imperial.ac.uk

By phone: +44 (0)207 5942614

Links to the OpenClinica training modules can also be found on the Website:

<https://www.imperial.ac.uk/clinical-trials-unit/clinical-data-systems/cds-openclinica/training-openclinica-40/>

2. Study Database Access

Upon successful completion of the OpenClinica role(s) based training, a user can request an OpenClinica account by completing the OpenClinica User Activation Form (UAF) accompanied by the relevant training certificate to CDS Production Support.

The form requires approval by either the Study Manager or Chief Investigator (CI). Once the form has been completed and sent to CDS Production Support, the requested role will be created in OpenClinica.

You will receive a time sensitive email from OpenClinica inviting you to the study, which includes details of the URL and a link to setup your password. You will have 14 days to click on the link to activate your account. If the time passes and the link becomes inactive, contact the CDS Production Support team and they will send you the invitation again. Please try to complete process in a timely manner.

URL: <https://imperial.openclinica.io/OpenClinica>

OpenClinica is a cloud based system which is accessible via one URL to access all studies you are assigned to.

Once your account has been activated, enter the unique username and password to gain access to OpenClinica.

Username and password are personal and must not be shared or transferred to other persons.

2.1 Password Management

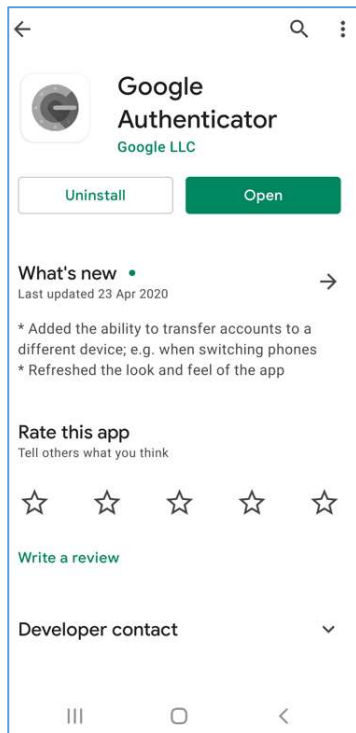
If you forget or enter an incorrect password more than twice you need to click on the “Don’t remember your password?” link on the login page and answer the questions provided, the answers are based on those set up when you first logged in.

OpenClinica will send an automatic email to the registered email address (provided on the UAF) with a link to reset the password. This does not affect the QR code or the MFA login details.

OpenClinica Login page details please contact the CDS Production Support who will be able to resend you the invitation.

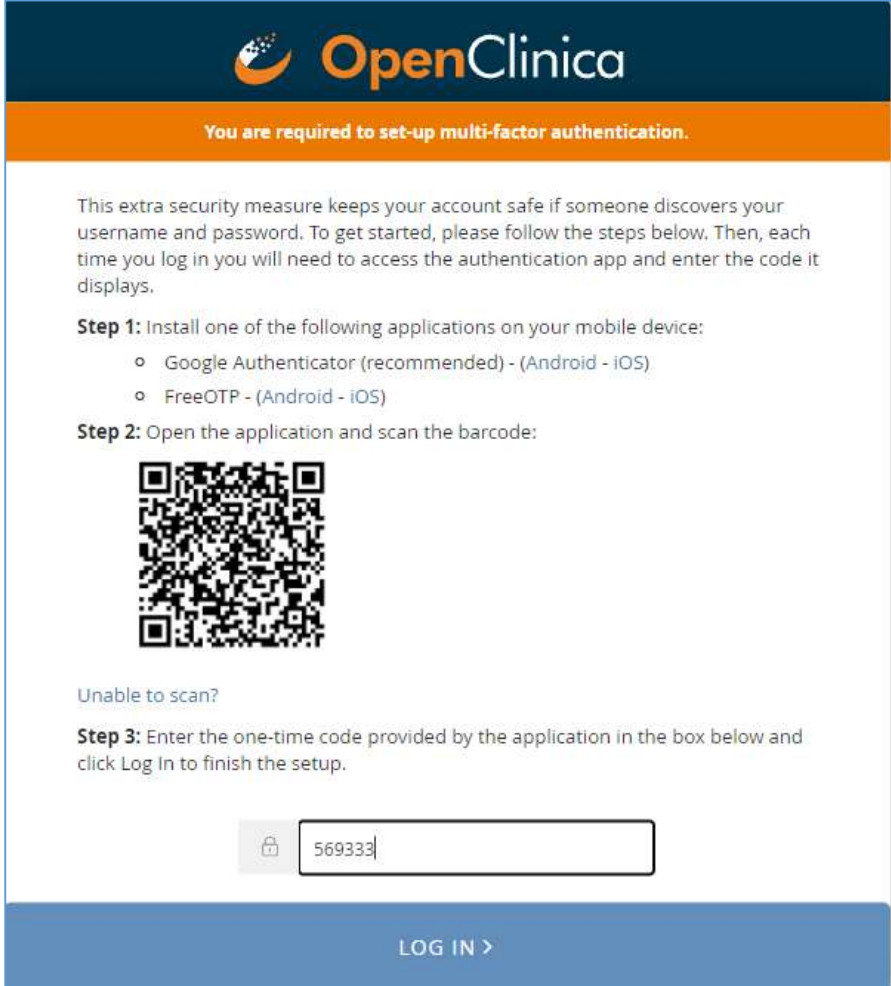
3. Using Multi Factor Authentication (MFA) to log into OpenClinica

1. Firstly, install **Google Authenticator** on your mobile device. You will be required to use this app each time you sign in to OpenClinica.



2. Open OpenClinica webpage (<https://imperial.openclinica.io/OpenClinica/MainMenu>) on your computer and login to your account with your existing username and password. Open the **Google Authenticator** on your mobile phone and scan the QR code displayed on the next page.

3. You will be provided with a 6-digit code on your mobile device after scanning the QR code on the computer screen.
4. Enter the 6-digit code into the field on the OpenClinica login page and click on "Log in".



OpenClinica

You are required to set-up multi-factor authentication.

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

Step 1: Install one of the following applications on your mobile device:

- Google Authenticator (recommended) - (Android - iOS)
- FreeOTP - (Android - iOS)

Step 2: Open the application and scan the barcode:



[Unable to scan?](#)

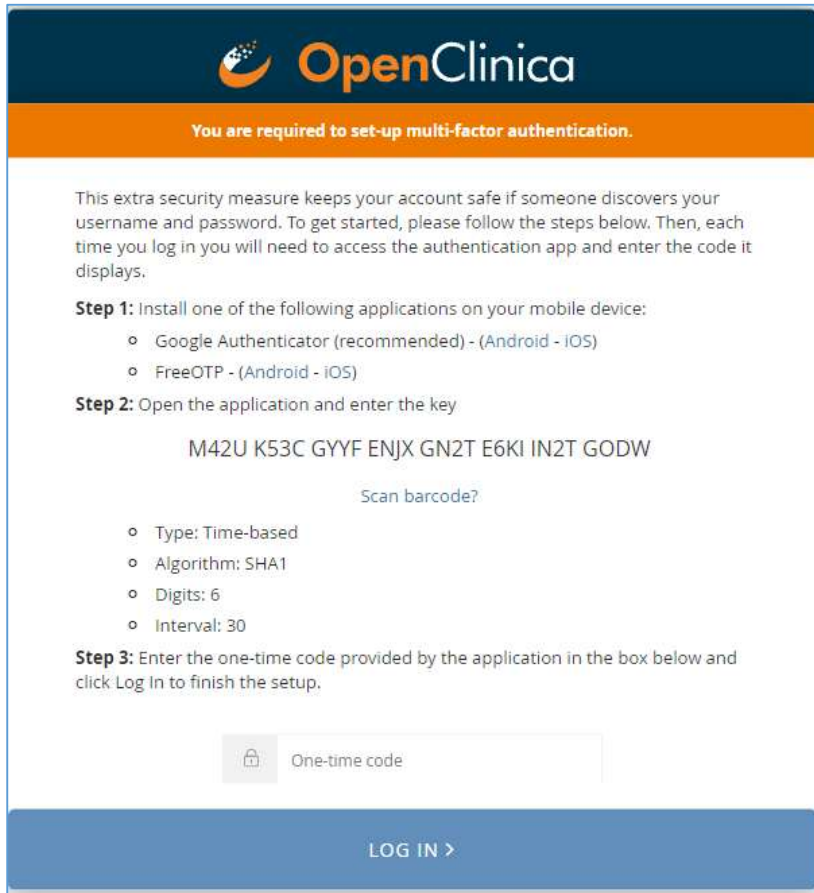
Step 3: Enter the one-time code provided by the application in the box below and click Log In to finish the setup.

LOG IN >

If you are unable to scan a QR Code

5. For users that are unable to scan the QR code, click on "**Unable to scan**" link on OpenClinica webpage after entering your username and password. This will provide 32-key code.
6. On the mobile app (**Google Authenticator**), select "**Enter a setup key**" and enter the 32-key code provided in the step above. This will generate a 6-digit code that will need to be entered into the field on the OpenClinica login page and click on "Log in".

7. The scanning of the QR code (or entering the 32-digit key code) is a one-time step.



OpenClinica

You are required to set-up multi-factor authentication.

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

Step 1: Install one of the following applications on your mobile device:

- Google Authenticator (recommended) - (Android - IOS)
- FreeOTP - (Android - IOS)

Step 2: Open the application and enter the key

M42U K53C GYYF ENJX GN2T E6KI IN2T GODW

Scan barcode?

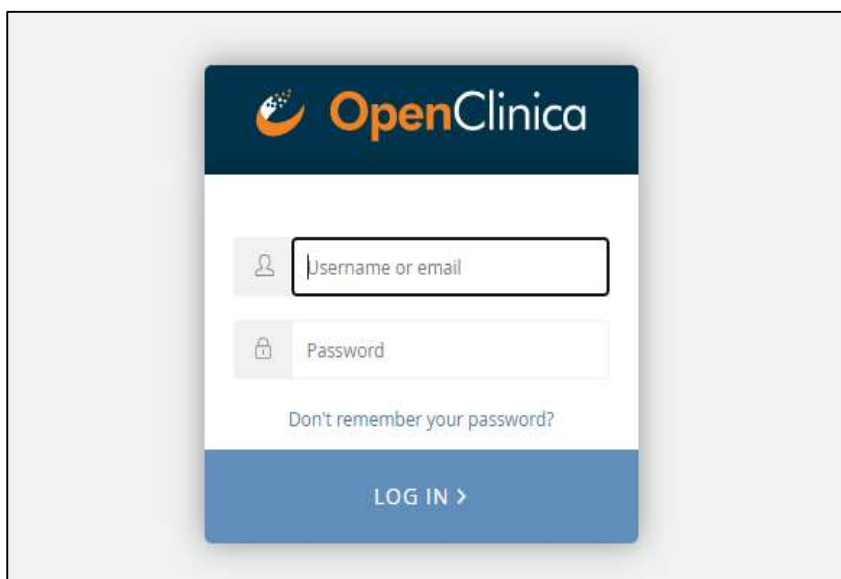
- Type: Time-based
- Algorithm: SHA1
- Digits: 6
- Interval: 30

Step 3: Enter the one-time code provided by the application in the box below and click Log In to finish the setup.

One-time code

LOG IN >

Once this is setup, the account is saved on Google Authenticator app and the 6-digit codes are generated automatically without the need for a QR Code or a key code each time you try to login.



OpenClinica

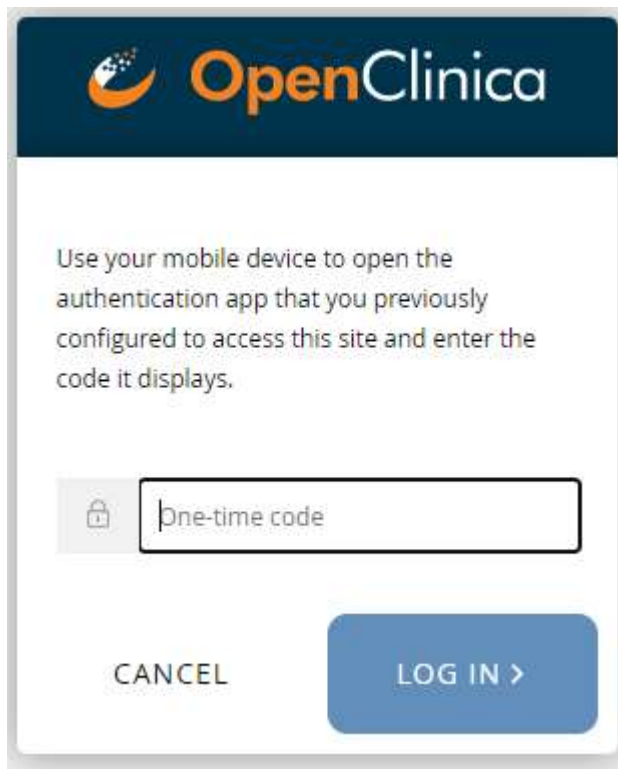
Username or email

Password

Don't remember your password?

LOG IN >

Once these details are entered, click “LOG IN”. The system will then display another screen in which to enter your one time code, this is generated by the Google Authenticator app on your smartphone. You will be required to download the Google Authenticator app to retrieve this code before you can access your study. Enter the code that appears in the authenticator app into the and click “LOG IN”

The image shows a mobile application interface for OpenClinica. At the top is a dark blue header with the OpenClinica logo. Below the header, the text reads: "Use your mobile device to open the authentication app that you previously configured to access this site and enter the code it displays." There is a text input field with a lock icon on the left and the placeholder text "One-time code". At the bottom, there are two buttons: a grey "CANCEL" button and a blue "LOG IN >" button.

The system will then display a **HOME** screen which is dependent on your user role. Monitor role will have a different home screen to Data Entry, CI and PI roles (Participant Matrix home screen will be displayed). The HOME screen showing this study information {Title, CI, Site etc.)

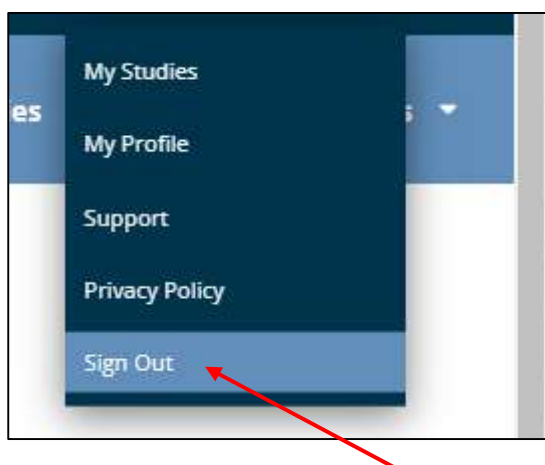
Participant Matrix for User Training

Participant ID	Screening	Baseline Visit	Visit 1	Visit 2	Visit 3	Pregnancy	Actions
DR1-001	☒	☒	☒	☒	☒	☒	☐ ☐ ☐
DR1-002	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
DR1-003	☐	☒	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-001	☒	☒	☒	☒	☒	☒	☐ ☐ ☐
OCTRaining-002	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-003	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-004	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-005	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-006	☐	☐	☐	☐	☐	☐	☐ ☐ ☐
OCTRaining-007	☐	☐	☐	☐	☐	☐	☐ ☐ ☐

It is good practice to log out once you have finished using the OpenClinica application. This is particularly important if you are not using your own computer.

After a set period of inactivity (1 hour by default) you will be automatically logged out of the system.

To log out click on the 'Sign Out' button in the navigation bar at the top right hand side of the page.



4. General Data Entry Guidelines

Data entry must be completed for ALL subjects. To adhere to **Good Clinical Practice (GCP)**:

- Data entry for a completed visit should be performed within **5** business days
- Data queries should be answered within **10** business days
- Data entry must only be completed by authorised personnel who have received trial-specific and OpenClinica training and are competent in eCRF completion
- Avoid using abbreviations in text fields (other than NA - **Not Applicable**, ND - **Not Done**, NK - **Not Known** and UNK - **Unknown**) and acronyms, unless they are approved medical abbreviations known to be acceptable.
- Avoid using abbreviations that are ambiguous or could be interpreted differently.
- Anywhere on the eCRF that '**other (specify)**' is selected, there is usually an entry in the space provided describing what 'other' means.
- Subject identifiers should not be used anywhere on the eCRF, such as subject's name, initials, address, hospital number etc., in order to maintain the confidentiality of the subject.

4.1 Study Home Page

After login and selecting the study, you will be directed to the respective eCRF. Here you find the 'Navigation Bar' and an overview about the status of the study which is the 'Participant Matrix'. The 'Icon Key' can also be found.

Participant Matrix for User Training

Participant ID | Screening | Baseline Visit | Visit 1 | Visit 2 | Visit 3 | Pregnancy | Actions

DR1-001 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | x2 | [Icon] | [Icon] | [Icon]

DR1-002 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

DR1-003 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-001 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-002 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-003 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-004 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-005 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-006 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

OTRaining-007 | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon] | [Icon]

4.2 Navigation Toolbar



The Navigation toolbar provides access to some additional task features:

Home: Use to navigate to the Home page designed for your study. which can be the **Welcome** screen, **Participant Matrix**, or **Source Data Verification** screen (depending on role)

Participant Matrix: This screen displays the Participant's general information, Events, and Forms.

Queries: Displays query statuses information on your study

Study Audit Log: Displays audit trail history for each participant in the study

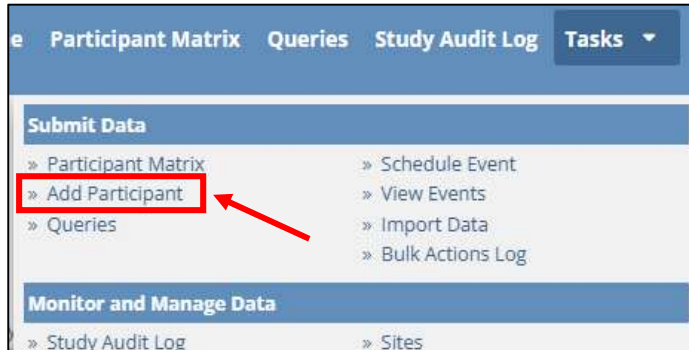
Tasks: Also lists associated tasks

4.3 Adding a Participant

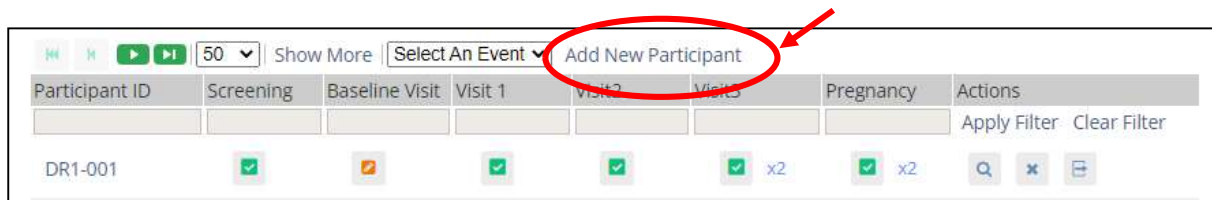
Participants can be added manually or automatically this will be dependent on the chosen method of creation for your study.

There are two options to create subjects:

Option 1: click on 'Tasks' in the Navigation Bar and then select '**Add Participant**'



Option 2: In the **Participant Matrix** screen, click **Add New Participant**



1. Click the **Add** button in the **Add New Participant** screen to generate a Participant ID.

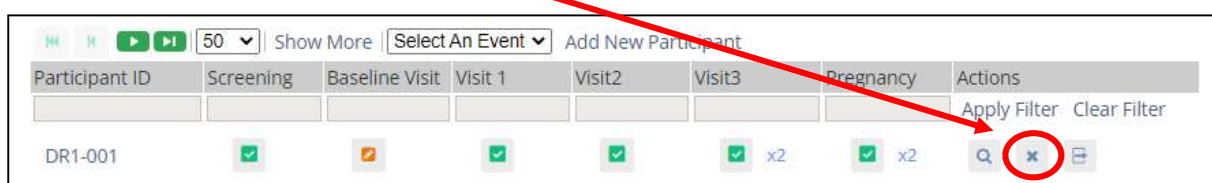
Add New Participant

Participant ID *
ID will be generated on Add

Cancel Add

5. Removing/ Restoring Participant Data

Data Manager and CI or PI user roles only - If you want to REMOVE a participant from the study, open the **Participant Matrix** and remove the subject by selecting the () icon in the **Actions** column.



You will be redirected to the screen **'Remove Participant from Study'** → Click **'Remove Study Participant'** to confirm you want to delete the subject from the eCRF.

This action can be undone by clicking on the Restore icon ().

6. Participant Information

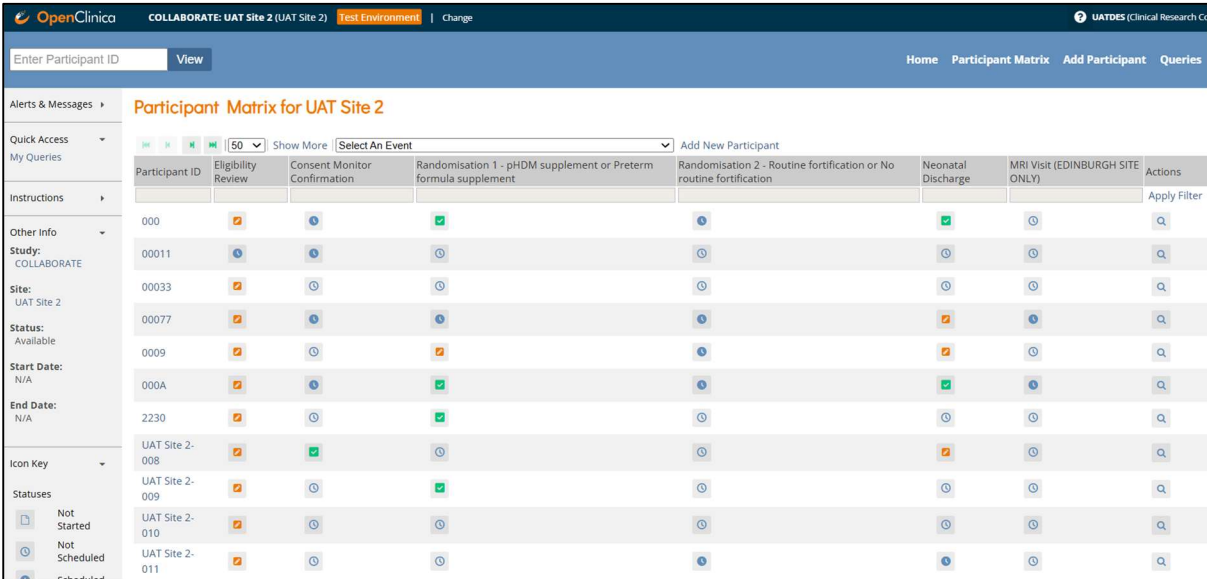
6.1 Participant Matrix

The 'Participant Matrix' displays a table for all participant subjects) and their data entry status in the Study (per site). One participant per row, with the Study Participant ID in the first column. The other columns are for Visit events.

You can view, enter, and change data for participants. Each cell in the matrix shows an icon that identifies the status of the CRF for the participant.

Move the cursor over an icon in the matrix to view and access participants data and to access actions you can perform for that CRF. Refer to the Icon Key in the sidebar for icon descriptions, and see about the Event Status for more details.

This layout provides the visit based events for subjects showing the overall statuses, definitions of each status is found in the icon key section , bottom left of the screen.



Participant ID	Eligibility Review	Consent Monitor Confirmation	Randomisation 1 - pHDM supplement or Preterm formula supplement	Randomisation 2 - Routine fortification or No routine fortification	Neonatal Discharge	MRI Visit (EDINBURGH SITE ONLY)	Actions
000							
00011							
00033							
00077							
0009							
000A							
2230							
UAT Site 2-008							
UAT Site 2-009							
UAT Site 2-010							
UAT Site 2-011							

6.2 Icon Key

Below displays the icon definitions which show the status of an Event:

Status/Action	Icon	Description
Not Started		The Event has not been started.

Not Scheduled		The Event has not been scheduled.
Scheduled		The Event has been scheduled, but no data has been entered.
Data Entry Started		A user has started to enter data. If the Event is in 'data entry started', you can't go back to previous Status.
Stopped		The Participant has temporarily stopped participating in the study. this status can be selected from the dropdown menu on the 'Update Event' screen when the current status is data entry started.
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.
Completed		A user has completed data entry for at least one Form in the Event. If further changes are needed in that Form, you are required to provide a reason for change.
Signed		The Study Event has been signed off. This icon appears in addition to the status. When the Investigator signs the casebook for a Participant, the OpenClinica system automatically sets the status for all Study Events for that Participant to 'signed.' After an Event status is 'Signed,' any changes to the CRF automatically change the Event status back to 'Completed.'
Locked		The Study Event has been locked. No data can be added, and the Event cannot be removed. This icon appears in addition to the status. This is performed by the Data Manager role. <u>Note:</u> You can set the status for a Study to 'frozen' or 'locked,' and while that does not change the status of any Events in the Study, it does prevent users from changing data.
Archived		The Study Event has been archived. . This icon appears in addition to the status. This is performed in Study Designer.
Removed		The Study Event has been removed for a participant is remove/

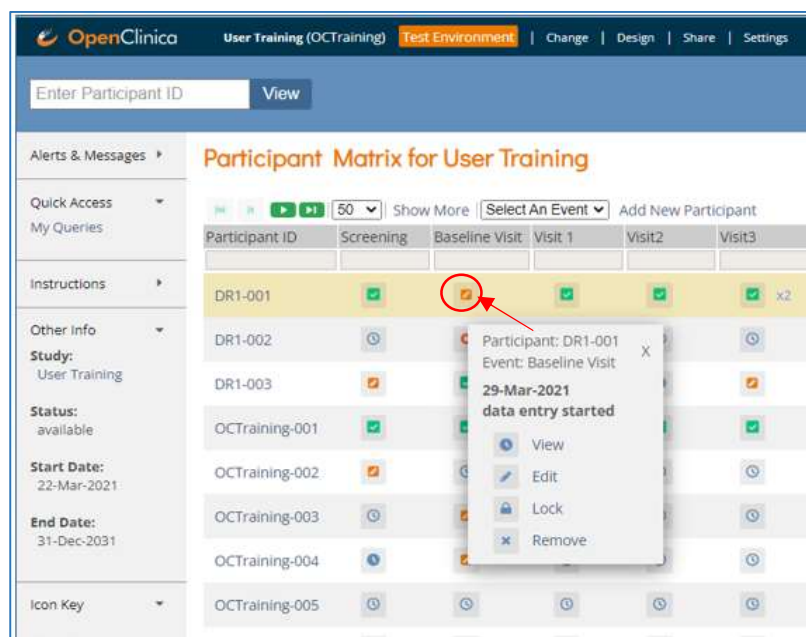
6.3 Events

A (Study) Event is the timepoint in the study where data has to be entered in the eCRF. The following events are defined for COLLABORATE on OpenClinica:

- **Eligibility Review**
- **Consent Monitor Confirmation (relevant to sponsor only)**
- **Randomisation 1**
- **Randomisation 2**
- **Neontal Discharge**
- **MRI Visit (relevant to the Royal Infirmary of Edinburgh site only)**

To view or Edit data for a participant

Click the icon for a **scheduled**, **data entry started**, or **completed** Event and select **View/Enter** to view the **Participant Details** screen



6.4 Scheduling a Study Event

If you want to enter data, you have to schedule the respective Event. This is done in the '**Participant Matrix**'. Please click on the Event you want to schedule. A window pops up and then click on '**Schedule**'.

Participant Matrix for User Training

50 Show More Select An Event Add New Participant

Participant ID	Screening	Baseline Visit	Visit 1	Visit2	Visit3	Pregnancy	Actions
DR1-001					x2	x2	
DR1-002							
DR1-003							
OCTraining-001							
OCTraining-002							
OCTraining-003							

Participant: DR1-002
Event: Screening
not scheduled
 Schedule

The 'Schedule Study Event' screen appears.

Schedule Study Event

Participant ID: **DR1-002**

Study Event Definition: Screening (Non-repeating) *

Start Date/Time: 15-Jun-2022 * (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**

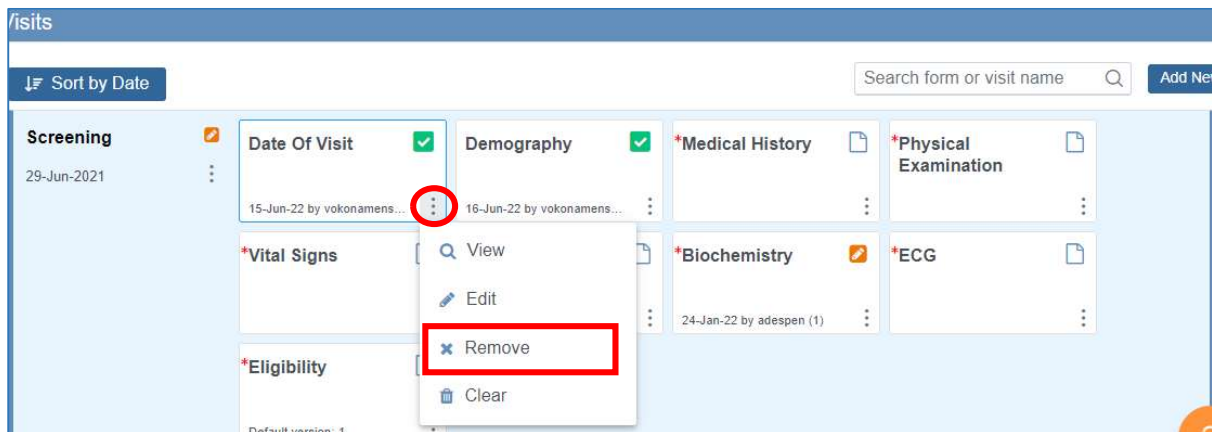
- Complete the screen details:
- **Study Event/Definition:** Select the respective event from the drop-down list.
- **Start Date/Time:** Default date is the current date when Event is scheduled in the eCRF or enter date required. This field is optional
- **End Date/Time:** Enter date, this field is optional

- Then click **'Proceed to Enter Data'** Now the respective event has been scheduled and you may start the data entry.

6.5 Removing an Event

If an Event has been entered in error you can remove that event or form (examples below are shown for an Event)

To remove the event Click the **Remove** button in the **three dots** menu on the **Participant Details** screen. This is replaced with the **Restore** button.



Alerts & Messages ▶
Quick Access ▶
Instructions ▼
Confirm REMOVAL of this event. Data in forms in this removed event will be retained and viewable on the forms, but not included in any extracted data sets. This removed event can be restored at any time. All queries associated with this event and its forms will be automatically closed.

If this event or participant is currently signed, the signature will be invalidated by this action.

Remove Event from Study

Event Definition Name:	Exam
Visit#:	1
Date Started:	01-Nov-2021
Date Ended:	
Status:	completed

Event CRFs

CRF Name	Version	Status
Physical Exam	1	data entry complete
Vital Signs	1	data entry complete

Remove Event from Study
Cancel

Note: If an Event is removed after being signed, the signature is invalidated, and if restored, the form must be signed again.

6.6 Restoring an Event

If you have removed an Event you want to restore, click the **Restore** button in the three dot **Event Actions** menu on the **Participant Details** screen. This is replaced with the **Remove** button.

Alerts & Messages ▶	Restore Event from Study										
Quick Access ▶	Event Definition Name:	Exam									
Instructions Confirm restoration of this event. Data associated with the forms in this event will be restored to this participant's record. If this event or participant is currently signed, the signature will be invalidated by this action.	Visit#:	1									
	Date Started:	01-Nov-2021									
	Date Ended:										
	Status:	completed									
Info ▶	Event CRFs <table border="1"> <thead> <tr> <th>CRF Name</th> <th>Version</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>Physical Exam</td> <td>1</td> <td>data entry complete</td> </tr> <tr> <td>Vital Signs</td> <td>1</td> <td>data entry complete</td> </tr> </tbody> </table>		CRF Name	Version	Status	Physical Exam	1	data entry complete	Vital Signs	1	data entry complete
CRF Name	Version	Status									
Physical Exam	1	data entry complete									
Vital Signs	1	data entry complete									
	Restore Event to Study Cancel										

Please note: If an Event is removed after being signed, the signature is invalidated, and if restored, the Form must be signed again. When data was entered on the Form prior to the Event being removed, The event this form is in has been removed **appears at the top of the Form.**

7. Entering Data

7.1 Data Entry Directly into a Form

1. Click the **Add New** button to add a form associated with the Event. This will open the form directly for you to document.
2. Click the **Edit** button in the **three dots** menu to open the form.
3. Enter information into each field.

The screenshot shows a web interface for managing eCRF forms. At the top, there's a 'Sort by Date' button and a search bar labeled 'Search form or visit name'. Below this, a list of forms is displayed. The first form is 'Baseline Visit' with a date of '20-Sep-2021'. To its right are two forms: '*Date Of Visit' and '*Pain Scale'. A red box highlights a dropdown menu that appears when clicking on the '*Pain Scale' form, showing 'View' and 'Edit' options. Further right are 'Randomisation Confirmation' and 'Randomisation Assignment Form', both dated '20-Sep-21 by audaya (1)'.

Alternatively

- Click on the pen icon to enter or edit data in the form.
- Click on the magnifier to view data in the form

This screenshot shows the 'Vital Signs' form. On the left is a sidebar with status filters: Stopped, Skipped, Completed, Signed, Locked, and Archived. The main area has a 'Vital Signs' header with an 'Add New' button and a search bar. Below is a table with columns: Actions, Form Status, Last Update, and Updated By. The first row shows 'data entry started' with a last update of '15-Jun-2022'. In the 'Actions' column, there are icons for edit (pen) and view (magnifier), both circled in red. A red arrow points from the magnifier icon to the 'View' button in the dropdown menu. At the bottom, it says 'Result 1-1 of 1 (filtered from 3 total)' and 'Show 10 per page'.

When you select the 'Pen Icon', the CRF form opens and you can start to enter data. Please fill in the entire form. When you have finished entering data, you can close the CRF Form and continue to enter data later or select '**Next**' or '**Complete**'

If you forget to enter data in at least one mandatory field, when you click 'Complete', you will receive an error message alert

Ethnicity

☐ White:

☐ Mixed Race:

☐ Asian or Asian British:

☐ Black or Black British:

☐ Other

This field is required

Back Close

✓ Complete

Return to Beginning Go to End

7.2 Navigating Between Forms

If you click **Next**, the system will automatically move you to the next page in the event form when it finishes saving the data. If you click **Back** you will go back to the previous section of the CRF. Closing the form saves all changes made.

Does the patient require a pregnancy test?

☐ Yes

☒ No

All changes saved.

Back Close Next

Return to Beginning Go to End

7.3 Marking the CRF Complete

The CRF must be marked complete, after finishing data entry for the complete CRF. When all sections (of an event) are complete, select '**Complete**'.

All changes saved.

Back Close

✓ Complete

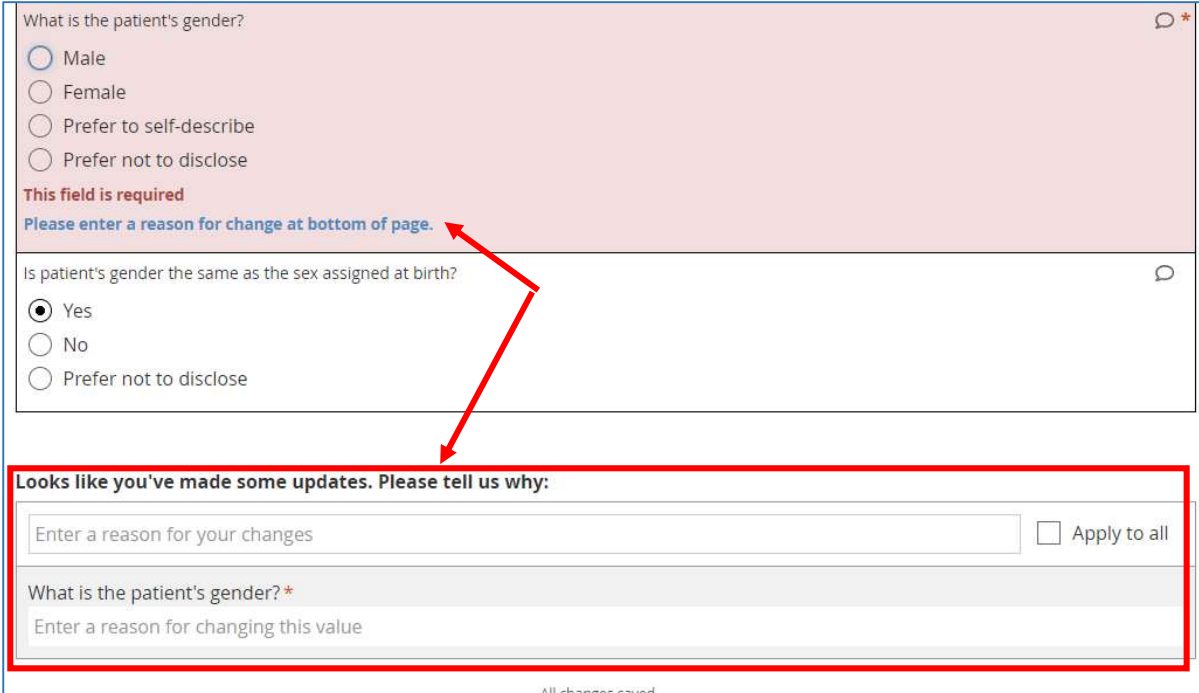
Return to Beginning Go to End

This will change the status of the CRF from 'Data Entry Started'  to 'Complete' 
The Status of the CRF will remain complete, even if the data is changed afterwards.

7.4 Changes made to a CRF Form after being marked Complete

If you make any changes to the data after it has been marked complete, an alert occurs and you will be required to enter a note indicating the reason for change at the bottom of the form.

Complete both fields



The screenshot shows a CRF form with two fields. The first field, 'What is the patient's gender?', is highlighted with a pink background and has a comment bubble icon with a red asterisk. It contains four radio button options: Male, Female, Prefer to self-describe, and Prefer not to disclose. Below the options, it says 'This field is required' and 'Please enter a reason for change at bottom of page.' The second field, 'Is patient's gender the same as the sex assigned at birth?', is a standard white field with three radio button options: Yes (selected), No, and Prefer not to disclose. A red arrow points from the pink field to a red-bordered box at the bottom. This box contains the text 'Looks like you've made some updates. Please tell us why:' followed by a text input field 'Enter a reason for your changes' and an 'Apply to all' checkbox. Below this is a summary row for the pink field, showing 'What is the patient's gender? *' and 'Enter a reason for changing this value'. At the very bottom of the form, it says 'All changes saved.'

The Rights group roles that can perform data entry in OpenClinica are:

- Data Entry - Study
- CI
- PI
- Data Entry - Site

7.5 Specific Field Types: Mandatory Fields

All mandatory fields will need to be completed – these fields will remain shaded with a pink background after the form has been submitted until they are completed. If any data are permanently missing because it is not done, unknown or not applicable, the site must click on the comment bubble icon and add an '**annotation**' in order to indicate this. Although this site should make every effort to complete mandatory fields wherever possible.



What is the patient's gender?

☐ Male

☐ Female

☐ Prefer to self-describe

☐ Prefer not to disclose

This field is required

A red circle highlights a comment bubble icon with a star in the top right corner of the field.

Pink shaded fields indicate this is **mandatory** and are required to be completed.

An annotation is added to a field to make a note and keep track of workflow.



Was a physical examination performed?

☐ Yes ☐ No

This field is required

View All History

Queries + New

Annotations + New

Add a new annotation

Add Annotation

No History

7.6 Specific Field Types: Empty Non Mandatory fields

If for any reason a field is blank for any of the regular fields, within this field will be a comment bubble icon and add an annotation.

7.7 Specific Field Types: Date Fields

All date parts of the DATE field must be completed wherever possible, but there may be instances where this may not occur. Some dates are set up to allow partial dates to be entered. Where a date field is unknown this should be entered on the system. Your study requirements will have pre-defined date formats where applicable on the CRF forms.

7.8 Specific Field Types: Auto Calculate

You may see a field that does not have an area for you to enter data, but instead is a blank greyed out space. This is an auto calculated field i.e. either a mapping field from another entered field or a calculated field. When you enter the information the system will take some of the information recorded and uses a formula to calculate a response for that field. You do not have to do anything except enter the data in the provided fields and submit.

Was vital signs performed? ☒ Yes ☐ No	Height <i>m</i> 1.6	Weight <i>kg</i> 80
Body Mass Index <i>kg/m²</i> 31.25		
Temperature	Pulse	Systolic BP
		Diastolic BP

BMI automatically populated by the eCRF System

Data Entered and Saved - BMI has been calculated from entered height and weight.

7.9 Study Event Repeats

Repeating Events are used for entering multiple records of data into the same form i.e. Adverse Events, Concomitant Medications.

When you first access a repeating form, you will see an empty summary. Click the **Add New** button to access the questions and create one form for entry.

Adverse Event

Adverse Event Form **Add New**

Search here

Actions	Form Status ↑↓	Last Update ↑↓	Updated By ↑↓
No matching records found			

Result 0-0 of 0 (filtered from 1 total) Show 10 per page < 1 >

Once you have completed the questions on the form, click the **Complete** button to save the data.

The saved record will then appear on the summary entries.

Adverse Event

Adverse Event Form [Add New](#)

Actions	Form Status ↑↓	Last Update ↑↓	Updated By ↑↓
	completed	07-Apr-2021	
	completed	23-Feb-2022	

Result 1-2 of 2 (filtered from 3 total) Show per page

Create new, additional forms by clicking on the **'Add New'** button for additional entries as needed.

7.10 Adding Unscheduled Events

If an unscheduled event is required to be added; the **'Participants Details'** include an unscheduled section.

Participant OCTraining-002 [Custom View On](#)

General Information

Edit

Participant ID	OCTraining-002	Status	Available
Study Name	User Training	Site Name	Site 1 Test

Visits

Unscheduled

Protocol Deviations

Adverse Event

Concomitant Medications

EOS

Unblinding

Navigate to an unscheduled visit for the participant, if the subject does not have any unscheduled visits, in the content pane, click **'Add New'** to display a blank event at the bottom of the page.

Unscheduled

Vital Signs **Add New** Search here

Actions	Form Status ↑↓	Last Update ↑↓	Updated By ↑↓
No data available in table			

Result 0-0 of 0 Show 10 per page < 1 >

Physical Examination **Add New**

7.11 Modifying Saved Data

Once data are saved into a form, data can be modified as follows:

Click **Edit** in the **three dots** menu on the **Participant Details** screen. If you have permission to access the Form, you can start entering or editing data.

You can access the form the same way by clicking on the field that needs modifying. Correct the data as needed and provide a reason for change.

If you edit a form that has already been completed, you must enter a reason for change.

Ethnicity ⓘ

☐ Hispanic/Latino

☒ Not Hispanic/Latino

Please enter a reason for change at bottom of page.

Race ⓘ

☒ White

☐ Black/African American

☐ Asian

☐ Native Hawaiian/Other Pacific Islander

☐ Other

Comorbidities ⓘ

☒ Hypertension

☐ High Cholesterol

☐ Coronary Heart Disease

☐ Stroke

☐ Retinopathy

☐ Neuropathy

☐ Other

Smoking Status ⓘ

☐ Current Smoker

☒ Former Smoker

☐ Non-Smoker

Please enter a reason for change at bottom of page.

Changes made to form.

Reason for change should be recorded in the box below

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

Enter a reason for your changes ☐ Apply to all

Ethnicity *

Enter a reason for changing this value

Smoking Status *

Enter a reason for changing this value

If your changes do not meet form requirements, such as constraints, you will see a message alerting you that specific values have errors and must be changed.

7.12 Signing an Event

After data entry of a CRF is completed, reviewed and all discrepancies are resolved, a PI (person of the site having the 'Investigator' rights in OpenClinica) must sign the CRF. When the PI signs an Event, they provide their approval of all CRF data for the CRF for the participant. CRFs are eligible for signature once the Study Events are in a "final" state i.e. (Not Scheduled, Complete, Stopped, or Skipped)

Please Note: If you update a signed form with a data update, OpenClinica will invalidate the previous signature and update the signature listings and each form to indicate that the form or case report book must be signed again.

To sign a study event

- Go to the **Participant Matrix**, then click the **Event** you want to sign.
- Select **Sign** from the drop-down list (**Sign** only appears if the event is in a final state as stated above).

The screenshot shows the OpenClinica Participant Matrix interface. At the top, there are filters for '50' items, 'Show More', 'Select An Event', and 'Add New Participant'. The table has columns: Sign, Participant ID, Eligibility & Consent, Exam, Treatment, Daily, Final Treatment, and Actions. A row for participant 'a12345' is highlighted in yellow. A dropdown menu is open for this row, showing details for 'Participant: a12345', 'Event: Eligibility & Consent', and '30-Nov-2021 completed'. The menu options are View, Edit, Remove, and Sign. The 'Sign' option is highlighted with a red rectangle.

Or

- Click the **View** icon for the participant with an event you want to sign
- Find the **Event** you want to sign, and select **Sign** in the **Actions** drop-down list

The screenshot shows the OpenClinica Participant Matrix interface. At the top, there are filters for '50' items, 'Show More', 'Select An Event', and 'Add New Participant'. The table has columns: Sign, Participant ID, Baseline, Exam, Treatment, Follow up, Final Treatment, and Actions. A row for participant 'a1234' is highlighted. The 'Actions' column for this row shows a dropdown menu with options: View, Edit, Remove, and Sign. The 'Sign' option is highlighted with a red rectangle.

The screenshot shows the 'Visits' interface. At the top, there's a 'Sort by Date' button and a search bar. Below, visits are listed in a grid. The 'Exam (1)' visit on 01-Nov-2021 is selected, and a context menu is displayed with the 'Sign' option highlighted in a red box.

If all Events for a participant are in a final state (Not Scheduled, Completed, Stopped, or Skipped), then the entire participant record can be signed.

The screenshot shows the 'Participant Matrix for New Test Site'. It includes a table with columns: Sign, Participant ID, Eligibility & Consent, Exam, Treatment, Daily, Final Treatment, and Actions. The row for participant 'a1234' is highlighted with a red box, and the 'Sign' icon in the Actions column is also highlighted with a red box.

The Electronic signature screen appears

Electronic signatures in OpenClinica are considered a legal signature and verification of the attestation provided. Signatures are applied through the use of an OpenClinica account and its associated username and password, so keep this information secure.

1. The **Electronic Signature** screen includes an attestation, your full name, a listing of the records you are signing, and a prompt to enter your username and password.
2. Scroll to the bottom of the page to see a list of forms in the Event and the status of queries for each of those Forms:
3. Enter your username and password and click **Submit** to complete the electronic signature process.

Sign Event Eligibility & Consent for Participant a1234

Enter your user name and password below to signify agreement with the following statement:

"I confirm that the data for this participant are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

This signature applies to the following forms in this event: Physical Exam, Vital Signs.

User Full Name: Riley Bianchi-PI
Date/Time:
 (The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator

User Name :
 Password :

Study Event

Participant ID	a1234
Study Event	Eligibility & Consent
Location	
Start Date	01-Nov-2021
End Date/Time	
Event Status	completed
Last Updated by	rbianchi+PI (18-Nov-2021)

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Queries	Actions
Physical Exam	1.2		rbianchi+PI	0 New 0 Updated 0 Closed	

Annotations:

- Enter User Name and Password to sign
- Attestation and summary of what you are signing
- Links to review the data you are signing

- You will be taken back to the **Participant Details** screen to view the **Signed** icon on the event.

Final Treatment

04-Nov-2021

Exam

18-Nov-21 by rbianchi+PI (1)

8. Query management

8.1 Answering System Queries

Once data entry has been performed and you click the **'Complete'** button, the system compares the data to the system queries associated with the page. The system creates queries automatically if you close a form that has unaddressed errors. You can also manually create queries as needed.

There are two options to respond to this query.

- If the data was entered incorrectly, you can modify the data. If the updated data no longer meets the query conditions, the query will automatically close.

- You can respond to the query with an explanation as to why the data is correct as entered.

Query will then change to an **“Updated”** status.

To review data associated with a query You can either:



View Query Only



View Query within record

You can access these options from the **Actions** column of the **Queries** table.

Queries

Summary count by status (based on table filters)

New	3
Updated	--
Closed	--
Not Applicable	--
Closed Modified	2
Total	5

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
			Query										Apply Filter Clear Filter
4	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_week	11	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	B Q
5	002	1234567	Query	New	19	19	Headache	Other Symptoms	how_many_times_a_month	12	Automatic query for: Value not allowed	Kerry Tamm (ktamm)	B Q
3	004	1234567	Query	New	82	82	Eligibility & Consent	Eligibility	participant_is_18_years_of_age_or_older	yes	Check this	Kerry Tamm (ktammminvadmin)	B Q

View Query Only

View All History

Queries [+ New](#)

#31 Automatic query for: Value changed and no reason for change provided

Annotations [+ New](#)

Respond to query

Assign to: CDS DE UAT (UA) ☐ Email? [Close This Query](#) [Update](#)

☐ R 20 hours
☐ VO 21 hours
☐ VO 21 hours

Automatic query for: Value changed and no reason for change provided
#31 assigned to vokonomensah, Status: new

Value changed from "White (1)" to ""

Value changed from "" to "White (1)"

☒ Show value changes

Mixed Race:

☐ White & Black Caribbean

☐ White & Black African

☐ White & Asian

☐ Other mixed background

View Query Within Record

Vitals (Collected at BL, C1D1, C2D1, C3D1, C4D1)

Visit collected:  none selected	Temperature:  °C 78	Heart Rate:  [beats/min] This field is required	Mean Arterial Pressure:  mmHg This field is required	Systolic arterial blood pressure:  mmHg This field is required	Diastolic arterial blood pressure:  mmHg This field is required
---	---	---	--	--	---

View All History

Queries + New

#1  Automatic query for: The expected range for temperature is 34-41°C, please verify your response.

Annotations + New

R 1 day  Automatic query for: The expected range for temperature is 34-41°C, please verify your response.
#1 assigned to rbianchi+crc. Status: new

RB 1 day Value changed from "" to "78"

☒ Show value changes

Respond to query

Assign to: r b (rbianchi+crc) ☐ Email? Update



Icon - indicates an **Open** query.

If data is changed, they will be prompted to enter a reason for change.

8.1.1 Answering System Queries: Modifying Data

- Open a Form.
- Click the **Query Bubble** in the field you want to create a query for.
- Select the query you want to respond to and/or update.
- If you need to change information in a form, close the **Query** widget, and make changes to the Form manually. You must provide a **Reason for Change** before completing the Form (Optional).
- In the **Respond to query** field, enter text explaining the query response.
- Select a user from the drop-down list next to **Assign to**. If you want to email that user to notify them about the query, check the box next to **Email**. When a query notification email is sent, it includes the Query ID for easy access (Optional)
- Click the **Update** button to add the response and leave the query open.

8.1.2 Answering System Queries: Providing an Explanation

If the data is correct as entered, you can respond by providing more details either by responding to the query and/or updating the field, and the query status will change. Click the **'Update'** button.



Icon - indicates an **Updated** query.

Query status is now changed to **Updated**.

8.1.3 Answering Queries: Other Query Types

Manual Queries are entered by OpenClinica users that have permission rights, for example, a Monitor. Therefore, they do not open as an automatic query when the page is saved but may appear at any time during the conduct of the study. You have the same options to respond – to change the data or to provide an explanation. You will be required to respond to each of these queries.

9. Study Specific Guidelines

9.1 CRFs relevant to all sites

COLLABORATE eCRF Completion Guidelines Version 1.0 05/02/2026

Ref: SOP_DM013 Case Report Form Design

SOP_TEM_DM018 v1.0 Effective 12-JUL-2022

Please follow the steps above regarding adding a new participant.

9.1.1 Eligibility Review Visit (applicable to all sites)

Participating sites in COLLABORATE will have been assigned different site types depending on if the site is participating in just Randomisation 1 (pHDM supplement compared to formula supplement), in just Randomisation 2 (routine fortification compared to no routine fortification), or in both study randomisations. This will determine the relevant CRFs that appear when the Eligibility review visit is scheduled.

All sites should add the Eligibility review visit by clicking 'add new' in the Visits section of the participant record. You can leave the start date that auto populates, and no end-date is required.

The screenshot shows the 'Add Visits' modal in the COLLABORATE system. The modal is titled 'Add Visits' and displays the 'Participant ID: UAT Site 2-013'. Below the title, there is a list of visit types with a search bar and a dropdown arrow. The list includes: 'Eligibility Review (Non-repeating)', 'Consent Monitor Confirmation (Non-repeating)', 'Randomisation 1 - pHDM supplement or Preterm formula supplement (Non-repeating)', 'Randomisation 2 - Routine fortification or No routine fortification (Non-repeating)', and 'Neonatal Discharge (Non-repeating)'. The 'Add Visits' button is located at the bottom right of the modal.

Sites participating in Randomisation 1 only

The following CRFs will be visible after adding the Eligibility Review visit:

- R1 verbal consent
- Eligibility
- Participant ID
- Randomisation stratification

Sites participating in Randomisation 2 only

The following CRFs will be visible after adding the Eligibility Review visit:

- R2 verbal consent
- Eligibility
- Participant ID
- Randomisation stratification

Sites participating in Both Randomisation 1 and 2

The following CRFs will be visible after adding the Eligibility Review visit:

- R1 and R2 verbal consent

- Eligibility
- Participant ID
- Randomisation stratification

Edinburgh site taking part in the mechanistic sub-study

The following CRFs will be visible after adding the Eligibility Review visit:

- R1 and R2 verbal consent
- Eligibility
- Sub study Consent
- Sub Study eligibility
- Participant ID
- Randomisation stratification

Please see the below instruction on how to complete each CRF in the Eligibility review visit.
Note – Instructions for the Edinburgh site taking part in the mechanistic study for completion of Sub study consent and sub study eligibility can be found in section 9.2.

9.1.1.1 R1 Verbal consent statement CRF

The consent statement should be completed directly into OpenClinica, if you have used a paper version of this form to collect the data, please transcribe the data directly into this electronic form. An example of a fully completed form is below. A copy of the completed form should be provided to the parent and uploaded to the medical record. Click complete and then Confirm when the form has been fully completed.

To download a PDF or print a copy of the completed consent form, once the form has been completed, open it up again in 'view mode' and you will see the print icon in the top right of the page. Please click on the icon and then **untick the 'show history' field in the options selection** before clicking 'prepare'. You can then choose to print the form or save it as a PDF.

Notes about specific fields:

- Baby's full name is optional field in case this has not been decided by the parent yet
- All other fields on the consent form are mandatory to be completed
- When you populate the "Consent for donor milk supplement vs formula supplement (Randomisation 1)" field, with **yes**, the additional fields will appear
- The date of consent date needs to match the date at the bottom alongside the 'staff name' sign-off field
- If parents agree to 'Consent to recontact parent/guardians for future research' and/or 'consent provided to share study updates and results', additional fields will pop up to

collect the parent email, mobile number and postal address – please enter correct contact details.

- Emails must be entered with @ in
- Mobile numbers must be entered with +44 and then a space

You're in review-only mode.



ST2-002: Verbal Consent Statement (Randomisation 1 pHDM supplement or Preterm formula supplement)

COLLABORATE Study

Baby's Full Name (First Name and Surname)	
test	
Name of parent/guardian who gave verbal consent	
test	
I confirm the study was discussed with the parent/guardian, that they had opportunity to ask any questions, and they are aware they are free to withdraw their baby at any time	
☒ Yes ☐ No	

The following consents were given:

Consent for donor milk supplement vs formula supplement (Randomisation 1)		Date of Consent
☒ Yes ☐ No		2026-02-05
Consent to use data obtained in COLLABORATE in future approved research studies		
☒ Yes ☐ No		
Consent to recontact parent/guardians for future research		
☒ Yes ☐ No		
PIS Part 1 Version Number Used	PIS Part 2 Version Number Used	Verbal Consent Form Version Number Used
11	1	1

» Optional (Opt-out) Clause

Consent provided to share study updates and results
☒ Yes ☐ No

Parent / Legal Guardian Contact Details

Email Email must be in format: xxx@xxxx.xxx test@test.com	Mobile Number Please enter +44, then a space, then write the mobile number +44 876543123	Postal Address test
--	---	------------------------

Staff Details

Staff Name test	Date 2026-02-05
REMINDER: Please select the print icon in the top right-hand corner of this page to print a copy for the parents/legal guardian and baby's medical records.	

9.1.1.2 R2 Verbal consent statement CRF

The consent statement should be completed directly into OpenClinica, if you have used a paper version of this form to collect the data, please transcribe the data directly into this electronic form. An example of a fully completed form is below. A copy of the completed form should be provided to the parent and uploaded to the medical record. Click complete and then Confirm when the form has been fully completed.

To download a PDF or print a copy of the completed consent form, once the form has been completed, open it up again in 'view mode' and you will see the print icon in the top right of the page. Please click on the icon and then **untick the 'show history' field in the options selection** before clicking 'prepare'. You can then choose to print the form or save it as a PDF.

Notes about specific fields:

- Baby's full name is optional field in case this has not been decided by the parent yet
- All other fields on the consent form are mandatory to be completed
- When you populate the "Consent for routine fortification vs no routine fortification (Randomisation 2)" field, with **yes**, the additional fields will appear
- The date of consent date needs to match the date at the bottom alongside the 'staff name' sign-off field
- If parents agree to 'Consent to recontact parent/guardians for future research' and or 'Consent provided to share study updates and results', additional fields will pop up to collect the parent email, mobile number and postal address – please enter correct contact details.
 - Emails should be entered with @ in
 - Mobile numbers should be entered with +44 and then a space

You're in review-only mode.



ST3-001: Verbal Consent Statement (Randomisation 2 Routine fortification or No routine fortification)

COLLABORATE Study

Baby's Full Name (First Name and Surname) test	
Name of parent/guardian who gave verbal consent test	
I confirm the study was discussed with the parent/guardian, that they had opportunity to ask any questions, and they are aware they are free to withdraw their baby at any time	
☒ Yes ☐ No	

The following consents were given:

Consent for routine fortification vs no routine fortification (Randomisation 2) ☒ Yes ☐ No	Date of Consent 2026-02-05
Consent to use data obtained in COLLABORATE in future approved research studies ☒ Yes ☐ No	
Consent to recontact parent/guardians for future research ☒ Yes ☐ No	
PIS Part 1 Version Number Used 1	PIS Part 2 Version Number Used 1
Verbal Consent Form Version Number Used 1	

» Optional (Opt-out) Clause

Consent provided to share study updates and results ☒ Yes ☐ No

Parent / Legal Guardian Contact Details

Email <i>Email must be in format xxx@xxx.xxx</i> test@test.com	Mobile Number <i>Please enter +44, then a space, then write the mobile number</i> +44 765432123	Postal Address test
--	---	------------------------

Staff Details

Staff Name test	Date 2026-02-05
REMINDER: Please select the print icon in the top right-hand corner of this page to print a copy for the parents/legal guardian and baby's medical records.	

9.1.1.3 R1 and R2 verbal consent statement form

The consent statement should be completed directly into OpenClinica, if you have used a paper version of this form to collect the data, please transcribe the data directly into this electronic form. An example of a fully completed form is below. A copy of the completed form should be provided to the parent and uploaded to the medical record. Click complete and then Confirm when the form has been fully completed.

To download a PDF or print a copy of the completed consent form, once the form has been completed, open it up again in 'view mode' and you will see the print icon in the top right of the page. Please click on the icon and then **untick the 'show history' field in the options selection** before clicking 'prepare'. You can then choose to print the form or save it as a PDF.

Notes about specific fields:

- Baby's full name is optional field in case this has not been decided by the parent yet
- All other fields on the consent form are mandatory to be completed
- When you populate the either the "Consent for donor milk supplement vs formula supplement (Randomisation 1) field or "Consent for routine fortification vs no routine fortification (Randomisation 2)" field, with **yes**, the additional fields will appear
- The date of consent date needs to match the date at the bottom alongside the 'staff name' sign-off field
- If parents agree to 'Consent to recontact parent/guardians for future research' and or 'Consent provided to share study updates and results', additional fields will pop up to collect the parent email, mobile number and postal address – please enter correct contact details.
 - o Emails must be entered with @ in
 - o Mobile numbers must be entered with +44 and then a space

ST4-001: Verbal Consent Statement (Randomisation 1 pHDM supplement or Preterm formula supplement AND Randomisation 2 Routine fortification or No routine fortification)

COLLABORATE Study

 Collaborate improving newborn care together	
Baby's Full Name (First Name and Surname)	
test	
Name of parent/guardian who gave verbal consent	
test	
I confirm the study was discussed with the parent/guardian, that they had opportunity to ask any questions, and they are aware they are free to withdraw their baby at any time	
☒ Yes ☐ No	

The following consents were given:

If the parent/guardian does not wish to consent to both randomisations now, please leave the field blank, and come back to complete this field once the decision has been made.		
Consent for donor milk supplement vs formula supplement (Randomisation 1)	☒ Yes ☐ No	Date of Consent 2026-02-04
Consent for routine fortification vs no routine fortification (Randomisation 2)	☒ Yes ☐ No	Date of Consent 2026-02-04
The statements about future use of data and future contact apply to either or both of the randomisations to which the parent has consented		
Consent to use data obtained in COLLABORATE in future approved research studies		
☒ Yes ☐ No		
Consent to recontact parent/guardians for future research		
☒ Yes ☐ No		
PIS Part 1 Version Number Used	PIS Part 2 Version Number Used	Verbal Consent Form Version Number Used
1	1	1

» Optional (Opt-out) Clause

Consent provided to share study updates and results
☒ Yes ☐ No

Parent / Legal Guardian Contact Details

Email Email must be in format: name.surname test@test.com	Mobile Number Please enter full, three figures, international mobile number +44 1237461523	Postal Address Test
--	---	------------------------

Staff Details

Staff Name	Date
Test	2026-02-04
REMINDER: Please select the print icon in the top right-hand corner of this page to print a copy for the parent/legal guardian and baby's medical records.	

9.1.1.4 Eligibility CRF

Depending on which consent has been given on the consent form, this information is piped into the eligibility CRF.

All inclusion and exclusion criteria needs to be confirmed for the participant. For the baby to be eligible, all inclusion criteria needs to be answered Yes and all exclusion criteria needs to be answered No. Enter the relevant data and then click Complete and Confirm.

Final eligibility check:

- If Yes is answered, staff member inputs their name to confirm eligibility
- If No is answered, please confirm if the inclusion or exclusion criteria has been violated.

UAT Site 2-013: Eligibility

Consent for donor milk supplement vs formula supplement (Randomisation 1) Mapped from Verbal Consent Statement form ☒ Yes ☐ No	Consent for routine fortification vs not routine fortification (Randomisation 2) Mapped from Verbal Consent Statement form ☐ Yes ☐ No
--	--

Donor Milk supplement vs Formula supplement (Randomisation 1)

Inclusion Criteria

These criteria need to be answered Yes for inclusion criteria to be met.

Born <29 weeks gestation
☐ Yes
☐ No

No condition precluding enteral feeding
☐ Yes
☐ No

Maternal intention to express breast milk
☐ Yes
☐ No

Parent/legal guardian verbal consent
☐ Yes
☐ No

Exclusion Criteria

This criteria needs to be answered No for the exclusion criteria to be met.

Baby has already received pHDM or Preterm Formula
☐ Yes
☐ No

Final Eligibility Check

Is the subject eligible to participate in Randomisation 1 (donor milk supplement vs formula supplement)?
☐ Yes
☐ No

All changes saved.

Close
 Complete

9.1.1.5 Participant ID CRF

- Enter the NHS, CHI or H&C number (you can leave blank if this has not been assigned yet, and complete it later)
 - o NHS CHI or H&C number needs to be 10 digits

- Enter the Badger ID and re-enter the ID number, an error message will flag if the IDs do not match
- If the parent has been registered to the ePARCA-R questionnaire please put yes and provide the ID number
 - If this discussion has not been had with the parent, leave this blank and come back later to complete
 - If the parent did not wish to be registered or if the site does not wish to use ePARCA-R, select 'No' and state the reason
 - **The ePARCA-R database is not currently live, further instructions will be provided to sites in section 9.3 when you can start registering parents to ePARCA-R. For now, please leave this question blank. If the participant is discharged before you have been able to register the parent to ePARCA-R, use the contact details provided in the parent medical records to send the invitation to ePARCA-R.**

ST4-001: Participant ID

NHS, CHI or H&C Number	🔍 *
If the NHS number is not yet assigned, please leave this blank and come back to complete it later.	
Badger ID	🔍 *
Please re-enter Badger ID	🔍 *
Has the participant been registered on the Routine ePARCA-R study? ☐ Yes ☐ No	🔍 *
If the ePARCA-R registration has not been completed yet, please leave this blank and come back to complete the ID later.	

- Click complete and confirm when data has been entered.

9.1.1.6 Randomisation Stratification CRF

Please complete the relevant stratification factors required for randomisation (neonatal network, gestational age category, severe growth restriction). Click complete and confirm when data has been entered.

UAT Site 2-013: Randomisation Stratification Factors

Neonatal Network Stratification Factor ☐ East Midlands ☐ East of England ☐ North West ☒ London ☐ Northern ☐ Kent, Surrey and Sussex ☐ South West ☐ Thames Valley & Wessex ☐ West Midlands ☐ Yorkshire & Humber ☐ Wales ☐ Northern Ireland ☐ Scotland	Gestational Age Category Stratification Factor ☐ < 26 weeks ☒ ≥ 26 weeks	Severe Growth Restriction Stratification Factor (based on standard criteria) ☒ < 10% centile ☐ ≥ 10% centile
---	--	--

All changes saved.

Close

✓ Complete

9.1.2 Randomisation 1 visit (applicable to sites taking part in randomisation 1)

Schedule the Randomisation 1 visit, the following CRFs will be visible:

- Randomisation 1 eligibility
- Randomisation 1 assignment

9.1.2.1 Randomisation 1 Eligibility CRF

The previously completed stratification data will automatically appear on this CRF.

If the participant is eligible for randomisation, select Yes on the CRF.

- Select randomise, the date of randomisation and the site ID of randomisation auto populates. Please do not edit the site ID unless agreed by collaborate@imperial.ac.uk, as this is a required field for data analysis.
- When you click Complete, the randomisation assignment will be populated on the next CRF (Randomisation assignment CRF).

If the participant is not eligible, select No and then complete and confirm the form.

IMPORTANT: once this form has been completed and confirmed, do not re-open this form in edit mode, only 'view' mode. This is to ensure the auto inputted stratification data remains correct.

ST4-001: Randomisation 1 Eligibility - pHDM supplement or Preterm formula supplement

Confirm the participant details and eligibility in order to randomise this participant.

Study Name: COLLABORATE		Participant ID ST4-001	
Randomise			
Neonatal Network Stratification Factor ☐ East Midlands ☐ East of England ☐ North West ☒ London ☐ Northern ☐ Kent, Surrey and Sussex ☐ South West ☐ Thames Valley & Wessex ☐ West Midlands ☐ Yorkshire & Humber ☐ Wales ☐ Northern Ireland ☐ Scotland	Gestational Age Category Stratification Factor ☐ < 26 weeks ☒ >= 26 weeks	Severe Growth Restriction Stratification Factor ☒ < 10% centile ☐ >= 10% centile	
Is the participant eligible for randomisation? ☒ Yes ☐ No			
Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant in Randomisation 1 (Donor milk vs Formula). ☒ Randomise		Date of Randomisation 2026-02-04	Site ID of Randomisation S_ST4(TEST)
Click 'Complete' and the allocation will be populated in the Randomisation 1 Assignment - pHDM supplement or Preterm formula supplement form.			

9.1.2.2 Randomisation 1 assignment CRF

Open the assignment CRF, and the participant's allocation will be visible. **You may need to exit the form and re-open the form if the allocation does not show immediately, the data may only update on the second time.**

Please click complete and confirm when the assignment has populated.

UAT Site 2-013: Randomisation 1 Assignment - pHDM supplement or Preterm formula supplement

Participant details:

Study Name: COLLABORATE	Participant ID UAT Site 2-013
-------------------------	-------------------------------

Allocation:

Allocation: Preterm formula supplement

All changes saved.

Close

✓ Complete

9.1.3 Randomisation 2 visit (applicable to sites taking part in randomisation 2)

Schedule the Randomisation 2 visit, the following CRFs will be visible:

- Randomisation 2 eligibility
- Randomisation 2 assignment

9.1.3.1 Randomisation 2 Eligibility CRF

The previously completed stratification data will automatically appear on this CRF.

If the participant is eligible for randomisation, select Yes on the CRF.

- Then select randomise, the date of randomisation and the site ID of randomisation auto populates. Please do not edit the site ID unless agreed by collaborate@imperial.ac.uk, as this is a required field for data analysis.
- When you click Complete, the randomisation assignment will be populated on the next CRF.

If the participant is not eligible, select No and then complete and confirm the form.

IMPORTANT: once this form has been completed and confirmed, do not re-open this form in edit mode, only 'view' mode. This is to ensure the auto inputted stratification data remains correct.

ST4-001: Randomisation 2 Eligibility - Routine fortification or No routine fortification			
Confirm the participant details and eligibility in order to randomise this participant.			
Study Name: COLLABORATE		Participant ID ST4-001	
Randomise			
Neonatal Network Stratification Factor ☐ East Midlands ☐ East of England ☐ North West ☒ London ☐ Northern ☐ Kent, Surrey and Sussex ☐ South West ☐ Thames Valley & Wessex ☐ West Midlands ☐ Yorkshire & Humber ☐ Wales ☐ Northern Ireland ☐ Scotland	Gestational Age Category Stratification Factor ☐ < 26 weeks ☒ >= 26 weeks	Severe Growth Restriction Stratification Factor ☒ < 10% centile ☐ >= 10% centile	
Is the participant eligible for randomisation?			
☒ Yes ☐ No			
Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant in Randomisation 2 (Routine fortification vs No routine fortification). ☒ Randomise		Date of Randomisation 2026-02-04	Site ID of Randomisation S_ST4(TEST)
Click 'Complete' and the allocation will be populated in the Randomisation Assignment 2 - Routine fortification or No routine fortification form.			

9.1.3.2 Randomisation 2 Assignment CRF

Open the assignment CRF, and the participant's allocation will be visible. **You may need to exit the form and re-open the form if the allocation does not show immediately, the data may only update on the second time.** Click complete and confirm when the assignment has been populated.

ST4-001: Randomisation 2 Assignment - Routine fortification or No routine fortification

Participant details:

Study Name: COLLABORATE	Participant ID ST4-001
-------------------------	------------------------

Allocation:

Allocation:
Routine multicomponent fortifier

All changes saved.

Close

✓ Complete

9.1.4 Neonatal Discharge Visit (applicable to all sites)

Schedule the Neonatal Discharge Visit, the following CRFs will appear:

- Laboratory results
- Clinical Outcomes
- Reminders

Neonatal Discharge

04-Feb-2026

- *Laboratory Results
- *Clinical Outcomes
- *Reminders

9.1.4.1 Laboratory results CRF completion

Please complete the three fields. If you select Yes to any of the below fields, you will be prompted to enter the Maximum serum Urea during NNU Stay, and the result date. Please complete data fully. As per the protocol, please enter the maximum measures during overall NNU stay. The fields are set to trigger queries for 'unexpected values':

- The maximum serum urea has an expected range of 0-15
- Maximum serum creatinine has an expected range of 0-400
- The Maximum alkaline phosphatase has an expected range of 100-2000.

Please double check the data if this alert pops up.

- Click Complete and Confirm if all is correct.

UAT Site 2-010: Laboratory Results

Serum Urea

Was serum urea measured while in NNU?  *

☐ Yes
☐ No

Serum Creatinine

Was creatinine measured while in NNU?  *

☐ Yes
☐ No

Alkaline Phosphatase

Was alkaline phosphatase (ALP) measured while in NNU?  *

☐ Yes
☐ No

UAT Site 2-010: Laboratory Results

Serum Urea

Was serum urea measured while in NNU? 	Maximum serum urea during NNU stay  *	Result Date  *
☒ Yes ☐ No	mmol/L	yyyy-mm-dd 

Serum Creatinine

Was creatinine measured while in NNU? 	Maximum serum creatinine during NNU stay  *	Result Date  *
☒ Yes ☐ No	µmol/L	yyyy-mm-dd 

Alkaline Phosphatase

Was alkaline phosphatase (ALP) measured while in NNU? 	Maximum ALP during NNU stay  *	Result Date  *
☒ Yes ☐ No	U/L	yyyy-mm-dd 

All changes saved.

9.1.4.2 Clinical outcomes CRF completion

When you open the CRF the following view will be displayed with 3 fields. The second field autocompletes depending on whether the participant is taking part in the second randomisation. Please complete all fields.

- If Yes is selected to 'Is the participant taking part in routine fortification vs no routine fortification (randomisation 2) then an additional question will be asked: 'Was rescue fortification required- Yes/No)
 - o If Yes is answered to this question , then the date that routine fortification was started is required to be inputted.

ST4-001: Clinical Outcomes

Has there been a diagnosis of milk curd obstruction?	💬 *
☐ Yes ☐ No	
Is the participant taking part in Routine fortification vs No routine fortification (Randomisation 2)? If Randomise is selected on the Randomisation 2 Eligibility (Routine Fortification vs Not Routine Fortification) form, Yes is auto selected. Otherwise No is auto selected.	💬
☒ Yes ☐ No	
Was rescue fortification required?	💬 *
☐ Yes ☐ No	
Did the participant undergo surgery for NEC prior to initial discharge?	💬 *
☐ Yes ☐ No	

- If Yes is selected to 'Did the participant undergo surgery for NEC prior to initial discharge' the following 6 fields appear:

Did the participant undergo surgery for NEC prior to initial discharge?	💬
☒ Yes ☐ No	
Was a drain inserted prior to surgery?	💬 *
☐ Yes ☐ No	
Was a diagnosis of short bowel syndrome made?	💬 *
☐ Yes ☐ No	
Was a diagnosis of intestinal failure-associated liver disease made?	💬 *
☐ Yes ☐ No	
Length of bowel resected cm	💬 *
Type of primary surgical procedure	💬 *
☐ Ileostomy ☐ Colostomy ☐ End-to-end anastomosis ☐ Other	
Was a re-operation needed?	💬 *
☐ Yes ☐ No	

If Yes is selected to 'Was a reoperation needed', a field opens to enter in the number of reoperations (excluding the primary operation required)

If 'Other' is selected in 'Type of primary surgical procedure' – a field to specify opens.

9.1.4.3 Reminders

COLLABORATE eCRF Completion Guidelines Version 1.0 05/02/2026

Ref: SOP_DM013 Case Report Form Design

SOP_TEM_DM018 v1.0 Effective 12-JUL-2022

Please complete the fields on this CRF to confirm if there have been any **new unexpected SARs**, and if the participant has been transferred to another unit. Complete and Confirm to complete this CRF.

UAT Site 2-009: Reminders

Have there been any new or changes to existing Serious Adverse Reactions?
(Please note - COLLABORATE is only collecting unexpected Serious Adverse Reactions, that are not already listed as study endpoints in the protocol)

☐ Yes

☐ No

Has the participant been transferred to another neonatal unit?

☐ Yes

☐ No

9.1.5 Participant Transfer form (relevant when baby is transferred to a step down unit)

Before transfer on open clinica:

If a participant has been/or will be transferred to a step-down or another neonatal unit soon:

- Please contact collaborate@imperial.ac.uk for further instructions and to organise the transfer of the baby on OpenClinica.
- Please ensure all data entry on the CRFs is as up to date and accurate as possible for the baby, and that all required fields up to that time point have been completed. When a baby has been transferred to a new site on OpenClinica, staff from the original recruiting site will no longer have access to the patient record on OpenClinica, so it is imperative that data is as complete as possible, and all data queries have been actioned and resolved.
- Please ensure the study PI is aware that the baby is moving neonatal units, and that arrangements have been made with the step-down unit to continue the baby's participation on the study (including randomised treatment where applicable). Note – if the step down site is not set up as a site for the COLLABORATE study, please contact collaborate@imperial.ac.uk for further instructions.
- Please ensure the parent has been registered to the ePARCA-R database prior to transfer to a step-down site. **(Note e-PARCA-R is not currently live – further details to be provided to sites in section 9.3)**

After transfer on OpenClinica:

The stepdown site should complete the participant transfer form on Open Clinica, (once the baby has been transferred on OpenClinica and the step down site has OpenClinica access). This form is automatically on each participant record, it does not need to be scheduled.

Participant Transfer

Participant Transfer [Add New](#)

Actions	Location participant was trans...	Date of transfer	Location participant was trans...	Form Status	Last Updated	Updated By
No data available in table						

Show 10 per page < 1 >

Please click 'add new' and then complete the relevant information:

- Name of hospital the participant was transferred from
- Date of transfer
- Name of hospital the participant was transferred to

Please click complete and confirm when the required data has been added.

This is a repeating form and so you can add additional transfer forms if needed

ST4-001: Participant Transfer

This form should be completed by the site receiving the transfer of the participant. It should be completed after transfer.

Has the participant transferred to another neonatal unit?

☒ Yes
☐ No

Location participant was transferred from (hospital name)

Date of transfer
yyyy-mm-dd

Location participant was transferred to (hospital name)

All changes saved.

Close

✓ Complete

If the new site needs to randomise a participant (in instances where the participant had not met the criteria for one of the randomisations prior to transfer, e.g. for randomisation 2), please ensure you update the stratification randomisation data for R2, and this will auto populate into the new R2 randomisation eligibility CRF.

If the patient was previously randomised (for example for R1), then the previous stratification data will remain correct on the R1 randomisation eligibility form as long as it is only opened in view mode. IMPORTANT: please do not open the previous randomisation form in edit more.

9.1.6 Serious Adverse reaction form

This form is automatically on each participant record, it does not need to be scheduled. Please click 'add new' and then complete the relevant information.

This form takes a little longer to load than the other forms, due to the medical coding section of the form (the coding is completed by the trial monitor).

Please refer to the safety reporting manual for detailed information on safety reporting for the study, including definitions of adverse events and severity of adverse events. **COLLABORATE requires only Unexpected Serious Adverse Reactions to be reported**, this means the event needs to be Unexpected (not listed in study protocol as an end point), Serious (see definitions in safety manual), and related to the study intervention (assigned as definitely, probably or possibly related).

Assignment of severity and causality should be undertaken by the PI (if medically qualified), and will also be reviewed by the Chief Investigator.

Please enter all required information on this form.

Notes on specific fields where relevant:

- SAR number: for the first SAR for a participant please put 1, for the second please put 2, for the third 3 and so on.
 - o If you want to update details on a previously reported SAR, please do not add a new record but update the original record with the new data. When you update the data you can update the type of report to interim or final. Any changes to the form will be captured in the audit trail, and you will also be asked to provide a reason for the data change.
- Type of report: If it is the first report of a particular SAR please select 'first report', if you are updating the report change it to 'interim' or a 'final'
- Why was the event serious: please refer to the protocol and safety reporting guide for further information on definitions
- SAR Term: Please enter the name of the medical event that occurred
- SAR description: Please describe the SAR
- Date of notification: the date the local team was notified of the event
- Severity: please refer to the protocol and safety reporting guide for further information on definitions

- Relationship to study intervention: Only definitely, probably and possible counts as a 'related' event and should be reported for Collaborate.
 - o As Collaborate has 2 randomisations, there are two fields here so you can indicate relationship to either of the randomisation
- **PI assessment**
 - o To be completed by PI only
- **Medical coding**
 - o Not to be completed by site staff, this is completed by the central study monitor only.

The SAR is a repeating form and so you can add additional forms if needed.

Please select complete and confirm when the data has been completed.

ST4-001: Serious Adverse Reaction Form

The safety reporting window for this trial is from randomisation (1 or 2) until 34 weeks PMA, discharge from neonatal care, or death, whichever is sooner. All expected SARs have been listed as study endpoints, these events will be excluded from safety reporting. As justified in the study protocol, only Unexpected and Related SARs require reporting

SAR Report

SAR Number	Type of Report ☐ First ☐ Interim ☐ Final
Date of Randomisation to Donor milk supplement vs Formula supplement (Randomisation 1); 2020-02-04	
Date of Randomisation to Routine fortification vs No routine fortification (Randomisation 2); 2020-02-04	
Why was the event serious? (Choose most serious) ☐ Resulted in death ☐ Life-threatening ☐ Required inpatient hospitalisation or prolongation of existing hospitalisation ☐ Resulted in persistent or significant disability/incapacity ☐ Other medically important event	

Details of SAR

Serious Adverse Reaction Term			
Briefly describe SAR (Include relevant symptoms, body site, lab tests and treatments received for management of the SAR)			
Date of Notification yyyy-mm-dd	Date of Onset yyyy-mm-dd	Severity ☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or disabling ☐ Fatal	Outcome ☐ Resolved ☐ Resolved with Sequelae ☐ Persisting ☐ Worsened ☐ Fatal ☐ Not Assessable
Relationship to Study Intervention - Donor milk supplement vs Formula supplement (Randomisation 1) ☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not Related ☐ Not Assessable	Relationship to Study Intervention - Routine fortification vs No routine fortification (Randomisation 2) ☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not Related ☐ Not Assessable	Is the event expected in line with the study endpoints? ☐ Expected ☐ Unexpected	Action Taken ☐ None ☐ Intervention Reduction ☐ Intervention Delayed ☐ Intervention Delayed and Reduced ☐ Intervention Permanently Stopped

PI Assessment (TO BE COMPLETED BY PI ONLY)

Assessment of the implications, if any, for the safety of study participants	How will these be addressed
--	-----------------------------

Medical Coding (To be completed by the ICTU Study Monitor)

SAR Verbatim:

9.1.7 Protocol Deviation form

This form is automatically on each participant record, it does not need to be scheduled. Please click 'add new' and then complete the relevant information.

Please complete all fields on the form.

If after review of the completed protocol violation form, the sponsor decides Corrective and Preventative Action is Needed (CAPA), the trial manager/monitor will get in touch with the site to confirm the actions required. Sites would then document this in the field titled 'Response to Deviation / Violation (e.g. CAPA)' field

Click complete and confirm when all the data has been entered.

This is a repeating form and so you can add additional forms if needed.

Protocol Deviations
Add New
Search here

Actions	Classification of Protocol Dev...	Description of Deviation/Viola...	Date of Deviation/Violation	Form Status	Last Updated	Updated By
No data available in table						

Show 10 per page
1

ST4-001: Protocol Deviations

Date Deviation/Violation Reported yyyy-mm-dd	Protocol Deviation or Violation ☐ Protocol Deviation ☐ Protocol Violation
How was Deviation / Violation Identified? ☐ Monitoring Visit ☐ By Coordinating Centre ☐ By Site ☐ Other	
Classification of Protocol Deviation/Violation ☐ Inclusion/exclusion criteria ☐ Study intervention administration ☐ Sampling / laboratory measurements ☐ Consent issue ☐ Compliance ☐ Missed study visit ☐ Study measurements/assessments ☐ Safety reporting ☐ Randomisation ☐ Implementation of document prior to research approval ☐ License/certification/calibration/servicing (labs and equipment) ☐ Delegation log/authorisation ☐ Dose interruptions / modifications not specified in the protocol ☐ Variation in clinical management of participant ☐ Withdrawal issue ☐ Falsifying research or medical records ☐ Repeated protocol deviations (of same type) ☐ Other	
Description of Deviation/Violation	Date of Deviation/Violation yyyy-mm-dd
Response to Deviation / Violation (e.g. CAPA) CAPA - Corrective Action Preventive Action	

All changes saved.

☐ Add another Protocol Deviations

Close

✓ Complete

Powered by OpenClinica

9.1.8 End of Study CRFs

These forms are automatically on each participant record, they do not need to be scheduled. Please click 'add new' to complete the relevant form.

End Of Study

Permanent Discontinuation of Study Intervention or Procedures

Add New Search here

Actions	Form Status	Last Updated	Updated By
No data available in table			

Death Record Add New Search here

Actions	Form Status	Last Updated	Updated By
No data available in table			

End Of Study Add New Search here

Actions	Form Status	Last Updated	Updated By
No data available in table			

9.1.8.1 Permanent discontinuation of study intervention or procedures form

The randomised study intervention should be continued until 34 weeks Post Menstrual Age (PMA). **Please ignore the current note on this form that mentions study procedures should continue until 2 years, we will be correcting this in the database.** If there has been a permanent discontinuation of study intervention before 34 weeks PMA please complete this form. When you first open this form you will be asked if either of the study interventions have been stopped. Please complete yes or no as appropriate.

ST4-001: Permanent Discontinuation of Study Intervention or Procedures

Date of Randomisation to Donor milk supplement vs Formula supplement (Randomisation 1); 2026-02-04

Date of Randomisation to Routine fortification vs No routine fortification (Randomisation 2); 2026-02-04

Was Randomisation 1 (Donor milk supplement vs Formula supplement) study intervention stopped?

☐ Yes
 ☒ No

Was Randomisation 2 (Routine fortification vs No routine fortification) study intervention stopped?

☐ Yes
 ☐ No

All changes saved.

Close

✓ Complete

If you select yes to either intervention being stopped, the following additional fields will appear:

COLLABORATE eCRF Completion Guidelines Version 1.0 05/02/2026

Ref: SOP_DM013 Case Report Form Design

SOP_TEM_DM018 v1.0 Effective 12-JUL-2022

- Date intervention was stopped
- Reason intervention was stopped (if you select 'other' there is a free text field that pops up)

Please select complete and confirm when the data has been completed.

ST4-001: Permanent Discontinuation of Study Intervention or Procedures	
Date of Randomisation to Donor milk supplement vs Formula supplement (Randomisation 1); 2026-02-04	
Date of Randomisation to Routine fortification vs No routine fortification (Randomisation 2); 2026-02-04	
Was Randomisation 1 (Donor milk supplement vs Formula supplement) study intervention stopped? ☒ Yes ☐ No	Date Randomisation 1 Study Intervention was stopped: yyyy-mm-dd
Primary reason Randomisation 1 Study Intervention was stopped ☐ Parent/legal guardian's decision ☐ Serious Adverse Event or unacceptable toxicities ☐ Severe non-compliance to this protocol as judged by the Clinician ☐ Allergic reaction to study procedure ☐ Clinician considers participant's health will be compromised due to adverse events or concomitant illnesses that develop after entering the study ☐ Other	
Was Randomisation 2 (Routine fortification vs No routine fortification) study intervention stopped? ☒ Yes ☐ No	Date Randomisation 2 Study Intervention was stopped: yyyy-mm-dd
Primary reason Randomisation 2 Study Intervention was stopped ☐ Parent/legal guardian's decision ☐ Serious Adverse Event or unacceptable toxicities ☐ Severe non-compliance to this protocol as judged by the Clinician ☐ Allergic reaction to study procedure ☐ Clinician considers participant's health will be compromised due to adverse events or concomitant illnesses that develop after entering the study ☐ Other	
Participants should continue to be followed up and complete all protocol procedures until the end of study at 2 years, unless consent is explicitly withdrawn.	

9.1.8.2 Death record

Please complete this form if the participant passed away prior to discharge from NNU.

ST4-002: Death Record
Did the participant pass away prior to discharge from NNU? ☐ Yes ☐ No
Close ✓ Complete

If Yes is selected, please input the date of participants death, and the cause of death as recorded exactly on the death certificate. Please select complete and confirm when the data has been completed.

ST4-002: Death Record

Did the participant pass away prior to discharge from NNU? ☒ Yes ☐ No	Date of Death yyyy-mm-dd
Cause of death as recorded on the death certificate (please enter all information included on the death certificate).	

All changes saved.

Close

✓ Complete

9.1.8.3 End of study form

Please complete this CRF at Neonatal discharge.

Please confirm if the participant completed the study according to the protocol, and if Yes enter the date of completion. Please note, the formal end of participants involvement on the study is at the 2-year ePARCA-R timepoint, which is collected on a separate database.

ST4-002: End Of Study

If study treatment was permanently stopped before end of study, please also complete the Permanent Discontinuation of Study Intervention or Procedures form.	
Did the subject complete the study according to the protocol? ☒ Yes ☐ No	Date of Completion yyyy-mm-dd

All changes saved.

Close

✓ Complete

If you select no, please confirm if the participant has:

- Had consent withdrawn for data collection in NNRD (if so please enter date)

COLLABORATE eCRF Completion Guidelines Version 1.0 05/02/2026

Ref: SOP_DM013 Case Report Form Design

SOP_TEM_DM018 v1.0 Effective 12-JUL-2022

- Has withdrawn from Randomisation 1
- Has withdrawn from Randomisation 2
- Has withdrawn from the sub-study (only applicable to Edinburgh site)

If the participant has withdrawn from randomisation 1 or 2, please also complete the permanent discontinuation of study interventions and procedures form (9.1.8.1)

ST4-002: End Of Study

If study treatment was permanently stopped before end of study, please also complete the Permanent Discontinuation of Study Intervention or Procedures form.

Did the subject complete the study according to the protocol?

☐ Yes
☒ No

NNRD

Has the participant withdrawn consent for data collection in NNRD?

☐ Yes
☒ No

COLLABORATE Study

Which part of COLLABORATE did the participant withdraw from?

☐ Donor milk supplement vs Formula supplement (Randomisation 1)
☐ Routine fortification vs No routine fortification (Randomisation 2)
☐ Sub-study

This field is required

All changes saved.

Close

✓ Complete

If the participant has withdrawn from either of the randomised studies, please complete the additional details:

- Date of withdrawal
- Primary reason for withdrawal

» Donor milk supplement vs Formula supplement (Randomisation 1)

Date of Withdrawal 🔍 *

yyyy-mm-dd 🔄

Primary reason for Withdrawal 🔍 *

☐ Adverse Event
☐ Parent/Legal Guardian Withdrew Consent
☐ Lost to follow-Up
☐ Non-Compliance
☐ Protocol Violation
☐ Sponsor/Regulator Decision
☐ Clinician Decision
☐ Death
☐ Other

All changes saved.

Please select complete and confirm when the data has been completed.

9.2 CRFs relevant to Edinburgh site only – mechanistic sub- study

9.2.1 Eligibility Review (Edinburgh)

When you schedule the eligibility visit, you will see the following CRFs. Please refer to instructions in 9.1.1 'Eligibility review' for instructions with completing the consent form, eligibility form, participant ID form, and randomisation stratification. The additional CRFs relevant to the Edinburgh site only will be 'Sub study consent' and 'sub study eligibility'.

Visits

1 visit added ×

Sort by Date

Search form or visit name 🔍 Add New

Eligibility Review	R1 and R2 Verbal Consent...	*Eligibility	Sub Study Consent	Sub Study Eligibility	*Participant ID	*Randomisation Stratification...
05-Feb-2026						

9.2.1.1 Sub study consent

When you first open this CRF, you will be asked if written consent has been obtained from the main collaborate study. **Please only proceed with documenting sub-study consent, if consent has been obtained for the main study.**

The sub study uses a paper consent form which must be fully completed in all cases prior to transcribing the consent data into the OpenClinica consent form.

ST1-004: Sub Study Consent

Has written informed consent been obtained of the COLLABORATE sub-study?  *

☐ Yes
☐ No

When you select, 'Yes', the full sub study consent form will appear with the following fields at the top of the page:

- Date of sub study consent
- PIS version
- ICF version
- Staff member taking consent
- Which study aspects is the baby taking part in

ST1-004: Sub Study Consent

Has written informed consent been obtained of the COLLABORATE sub-study?  *

☒ Yes
☐ No

Date of Sub Study Consent  *	PIS Version  *	ICF Version  *
yyyy-mm-dd 		
Staff member taking consent  *	Which study aspects is the baby taking part in?  *	
	☐ MRI ☐ Stool Samples	

Please indicate whether the baby is taking part in the MRI study and or/ the stool samples study. Depending on your selection here, this will determine the relevant questions on the remainder of the consent form.

The optional clauses on the consent form appear regardless of which part of the sub-study the baby will be participating in. If any of the optional clauses are answered 'Yes' then a contact details section appears at the bottom of the form to enter in the parent email, mobile number and address.

Please complete all the relevant fields, transcribing the data exactly as it has been completed on the paper consent form.

Imaging clauses:

- Both must be answered yes in order to consent for MRI imaging

Stool sample clauses:

- The first and the last clause must be answered yes in order to consent to the stool samples
- The middle clause is optional – please ensure either Yes or No is completed.

A fully completed consent form for the sub-study, with the baby participating in both the MRI and the stool samples section, looks like this:

ST1-004: Sub Study Consent		
Has written informed consent been obtained of the COLLABORATE sub-study?		
☒ Yes ☐ No		
Date of Sub Study Consent	PIS Version	ICF Version
2026-02-05	1	1
Staff member taking consent	Which study aspects is the baby taking part in?	
test	☒ MRI ☒ Stool Samples	
Optional Clauses		
Consent given for use of information in future research		
☒ Yes ☐ No		
Consent given to share contact details for study updates		
☒ Yes ☐ No		
Consent given to share contact details for contact regarding future studies		
☒ Yes ☐ No		
Imaging Clauses		
I agree to my baby undergoing an MRI scan as part of the COLLABORATE imaging sub-study		
☒ Yes ☐ No		
I give permission for my baby's GP to be informed of participation in this imaging study		
☒ Yes ☐ No		
Stool Sample Clauses		
I agree to the collection and storage of stool (faeces) from my baby for studies of the effect of milk type on gut bacteria, health and brain development, including analysis of the bacterial DNA		
☒ Yes ☐ No		
OPTIONAL: I give consent for samples collected to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial College has ensured will keep this information secure)		
☒ Yes ☐ No		
I understand that if I withdraw my baby from the study, any stool samples already collected can still be used, unless I request for them to be destroyed		
☒ Yes ☐ No		
Contact Details		
Email Email must be in format xxx@xxxx.xxx	Mobile Number Please enter +44, then a space, then write the mobile number	Postal Address
test@test.com	+44 098763526	test

Please select complete and confirm when all the data has been entered.

9.2.1.2 Sub study Eligibility

Please complete the required fields.

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SOP_TEM_DM018 v1.0 Effective 12-JUL-2022

All inclusion criteria needs to be answered yes.

If the participant is taking part in the MRI, the imaging exclusion criteria needs to be answered No.

There is no specific exclusion criteria for the stool sample collection.

Once the data has been entered, please complete the final eligibility check confirming if the participant is eligible to participate in the sub study.

- When you select Yes – you will then add in the details of the staff member confirming eligibility and enter the date that eligibility has been confirmed.

Select complete and confirm when the form has been completed.

ST1-004: Sub Study Eligibility**Inclusion Criteria**

These criteria need to be answered Yes for inclusion criteria to be met.

Participants in randomisation 1 recruited at the Royal Infirmary of Edinburgh

☒ Yes
☐ No

Parent written consent

☒ Yes
☐ No

Consent given for the imaging collection

☒ Yes
☐ No
Imaging Exclusion Criteria

These criteria need to be answered No for the exclusion criteria to be met.

Infants with congenital anomalies: structural or functional anomalies (e.g. metabolic disorders) that occur during intrauterine life and can be identified prenatally, at birth or later in life (WHO definition)

☐ Yes
☒ No

Infants with a contraindication to MRI at 3Tesla

☐ Yes
☒ No
Stool Samples Exclusion Criteria

Note: There are no specific exclusion criteria for the stool sample collection

Final Eligibility Check

Is the subject eligible to participate in the COLLABORATE sub-study?

☒ Yes
☐ No

Staff member confirming eligibility

test

Date eligibility confirmed

2026-02-05

All changes saved.

Close

✓ Complete

9.2.2 MRI Visit

Please schedule this visit if the participant is taking part in the MRI aspect of the sub study. Note this is only relevant to participants at the Edinburgh site.

When you schedule this visit, you will see the following CRFs:

- MRI
- Reminders

9.2.2.1 MRI CRF

Please complete the question 'was an MRI completed whilst on the study'.

- If you answer Yes, then a field will pop up with the date of the MRI scan, please enter this information
- The complete and confirm the form to submit

9.2.2.2 Reminders CRF

Please complete this form to confirm at the time of the MRI scan:

- To confirm if there have been any new unexpected SARs
- To confirm if the participant has been transferred to another neonatal unit
- Click complete and confirm when these two fields have been completed.

ST1-004: Reminders

Have there been any new or changes to existing Serious Adverse Reactions?
(Please note - COLLABORATE is only collecting unexpected Serious Adverse Reactions, that are not already listed as study endpoints in the protocol)

- ☐ Yes
☒ No

Has the participant been transferred to another neonatal unit?

- ☐ Yes
☒ No

Close

✓ Complete

9.2.3 Stool samples log

Please complete this form to record details of stool samples taken as part of the sub study.
Click 'add new'

Stool Samples Log

Stool Samples Log

Add New

Search here



Actions Form Status Last Updated Updated By

No data available in table

ST1-001: Stool Samples Log

Was a stool sample collected while on study?

- ☐ Yes
☐ No



*

Close

✓ Complete

If a stool sample has been collected please click 'yes', you will then be prompted to enter the date of collection and the sample ID.

You can add multiple samples by selecting the '+' button. Select complete and confirm when the form is fully completed.

ST1-001: Stool Samples Log

Was a stool sample collected while on study?

☒ Yes
 ☐ No

Please document all stool samples collected throughout the study

Stool Sample Number	Date of Collection	Sample ID
1	yyyy-mm-dd	

+

All changes saved.

Close

✓ Complete

ST1-001: Stool Samples Log

Was a stool sample collected while on study?

☒ Yes
 ☐ No

Please document all stool samples collected throughout the study

Stool Sample Number	Date of Collection	Sample ID
1	yyyy-mm-dd	
2	yyyy-mm-dd	
3	yyyy-mm-dd	

+

9.3 ePARCA-R database

Registering parents to the ePARCA-R questionnaire will be completed via a separate OpenClinica database. Full instructions will be provided to sites on the process for this, when this database is live.

9.4 NNRD data imports

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The majority of COLLABORATE outcome data comes from data held in the National Neonatal research Database, which will be automatically imported into the OpenClinica database in the NNRD data import forms section (Note this section is not currently live). No action is required for sites or site staff to enter or review any data in these sections.

10. CRF Completion Queries

If you have any questions, please contact the Trial Management Team
collaborate@imperial.ac.uk.

11. Version History

Version Number	Date	Author	Description
1.0	05/02/2026	Rosie Way (Trial Manager)	First Version

12. Amendments

Section	Amendment