IMPERIAL

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OpenClinica eCRF Completion Guidelines for the COLLABORATE Study – consent and randomisation

Version: **V1.0**

Date: **19/06/2026**

CONTENTS

1. OpenClinica Support

Contact Clinical Data Systems (CDS) Production Support for study database queries:

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

By phone: +44 (0)207 5942614

OpenClinica training modules are available at:

https://www.imperial.ac.uk/clinical-trials-unit/clinical-data-systems/cds-openclinica/training-openclinica-40/ Passcode is: CDSTraining_123

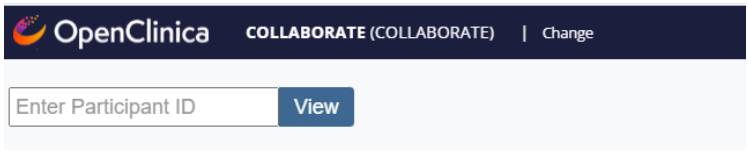
2. Study Database Access

After completion of OpenClinica role(s) based and study specific training, and receiving study manager approval, you will receive a time sensitive email from OpenClinica (donotreply@openclinica.io) with a link to setup your password. This link is valid for 14 days – if it expires, contact CDS Production Support for a new invitation.

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

Once your account is activated, login using your unique username and password (do not share these).

Ensure you have selected 'COLLABORATE' study when logged in (you can change studies via the 'change' button)



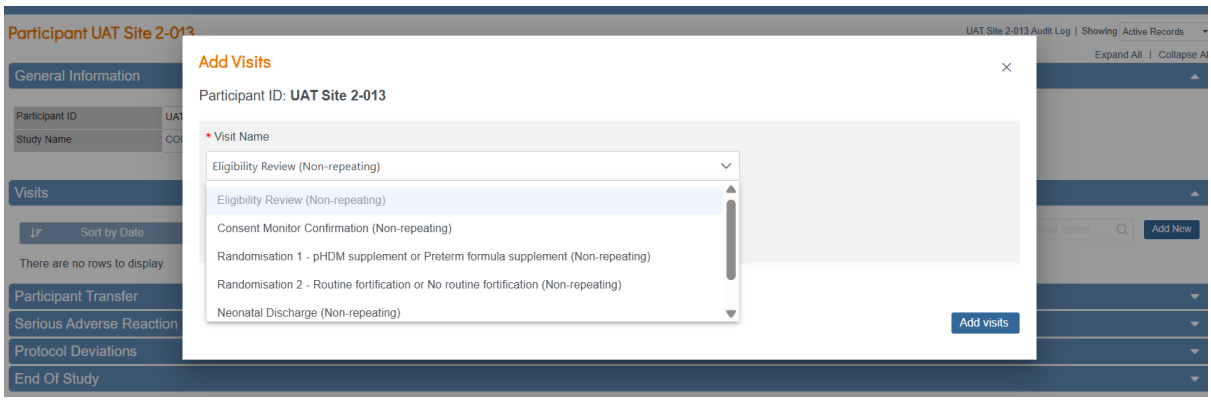
3. Study Specific Guidelines

To consent a participant, please schedule the Eligibility Review visit.

If the participant has not yet been added to OpenClinica, when you log in please **Add a New participant** by clicking either 'Tasks' (in the navigation bar) or from the Participant Matrix ('Add new Participant' is at the top of the screen). The ID will automatically generate when you click 'Add'.

3.1.1 Eligibility Review Visit (applicable to all sites)

All sites must add the Eligibility Review visit by clicking ‘add new’ in the Visits section. The auto populated start date can be used, and no end-date is required.



Sites are required to complete the CRFs within the Eligibility Review visit below before scheduling the randomisation visit:

- Verbal consent
- Eligibility
- Participant ID
- Randomisation Stratification

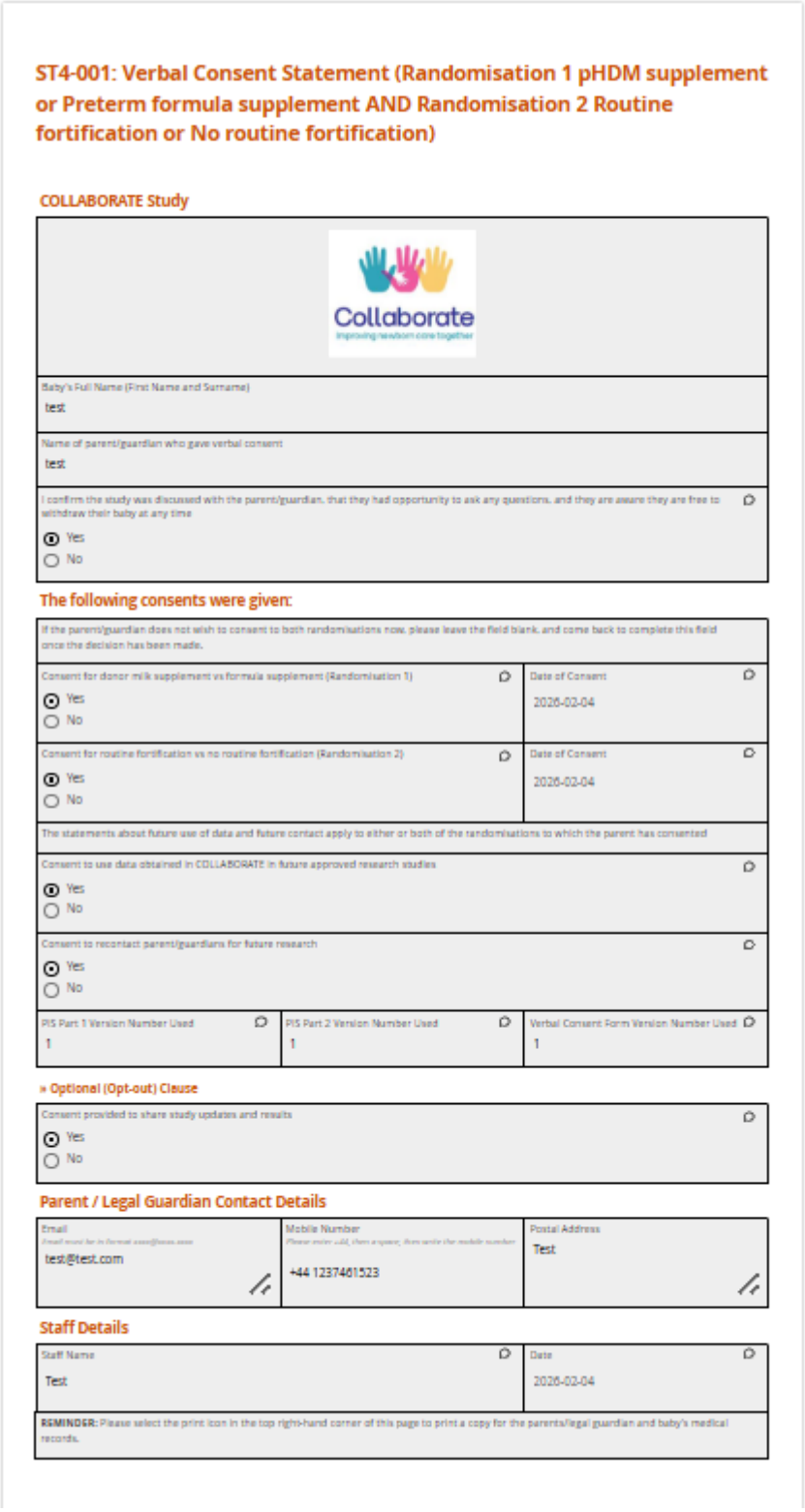
3.1.1.1 Verbal consent statement CRFs

The consent statement should be completed directly in OpenClinica. If consent was first documented on the paper version of this form, please transcribe data to the electronic form. The paper copy should not be retained and is a temporary transcription aid only. Once the electronic form is fully completed, click ‘Complete’ to confirm.

Notes about specific fields:

- Baby’s full name is optional
- All other fields are mandatory
- Selecting ‘Yes’ for either consent field “Consent for donor milk supplement vs formula supplement (Randomisation 1) or “Consent for routine fortification vs no routine fortification (Randomisation 2)”, will display additional fields to complete
    - If using the combined consent form, and the parent is only consenting to one of the randomisations at the point of completing the form, please leave the question about consent for the other randomisation blank. A query will be automatically generated. Once consent has been obtained or refused for the next randomisation, please ensure this has been documented on the consent form.
    - If your hospital is only taking part in one of the randomisations, ensure to inform the parent/guardian, and select ‘No’ to consent provided for the other randomisation, an N/A option will be added to the form in a future upgrade.
- Consent date must match staff sign-off date
- If parents provide ‘Consent to recontact parent/guardians for future research’ and or’ Consent provided to share study updates and results’, additional fields will appear to collect contact details (email, mobile, postal address)
    - Emails must include @
    - Mobile numbers must start with +44 and then a space

A copy of the completed form should be provided to the parent and uploaded to the baby's medical record. To download or print the completed electronic consent form, open it in 'view mode' and click the print icon (top right). Untick 'show history', select 'prepare' and choose to print or save as a PDF.



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

COLLABORATE Study

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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)	Date of Consent
(•) Yes ( ) No	2026-02-04

Consent for routine fortification vs no routine fortification (Randomisation 2)	Date of Consent
(•) Yes ( ) No	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	Mobile Number	Postal Address
test@test.com	+44 1237461523	Test

Staff Details

Staff Name	Date
Test	2026-02-04

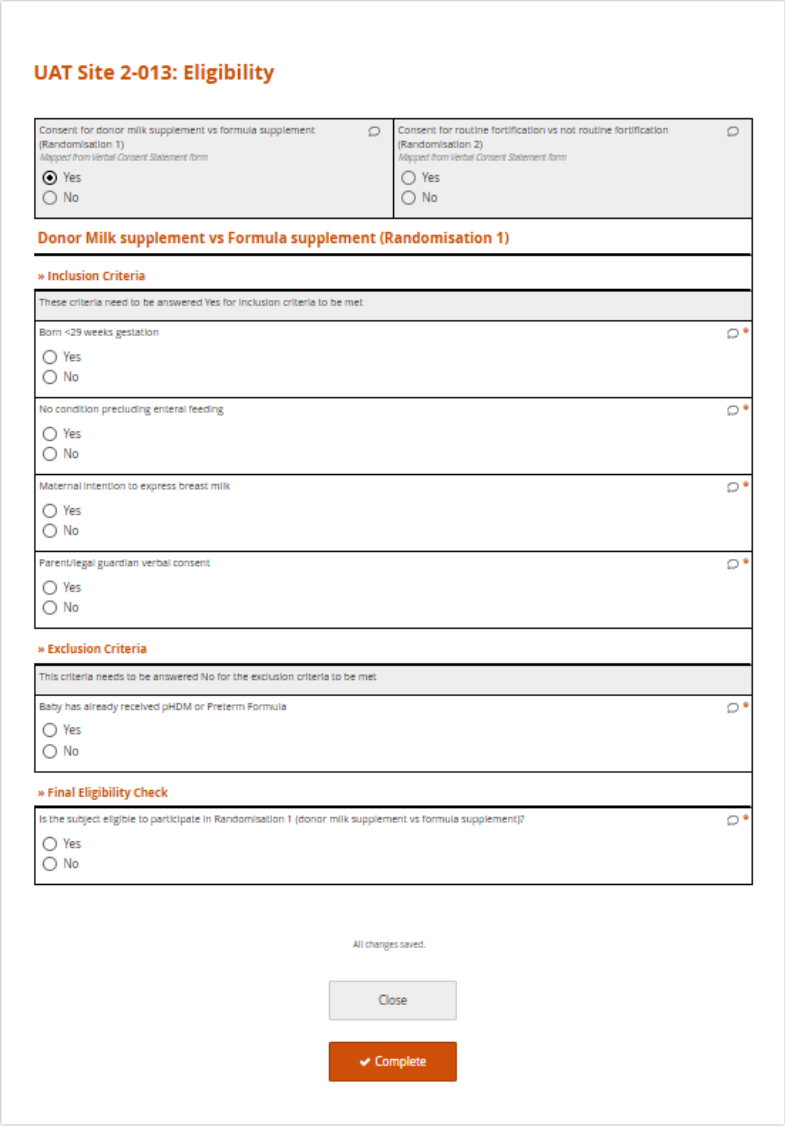
REMINDER: Please select the print icon in the top right-hand corner of this page to print a copy for the parents/legal guardian and baby's medical records.

3.1.1.2 Eligibility CRF

Consent responses are automatically populated to the eligibility CRF. All inclusion criteria must be 'Yes' and all exclusion criteria 'No' to confirm the baby's eligibility. Enter the data and click 'Complete' to confirm.

Final eligibility check:

- If 'Yes', staff confirms eligibility by entering their name
- If 'No', specify the inclusion or exclusion criteria that was not met.



If the parent has consented to both R1 and R2 but eligibility can not be confirmed yet for one of the randomisations (e.g. the form is being completed confirming eligibility for R1, and R2 eligibility will be confirmed at a later timepoint), it is fine to leave the eligibility questions blank for the other randomisation. A query will be generated for each question that has been left blank. Please ensure that this data is completed as soon as eligibility is able to be confirmed.

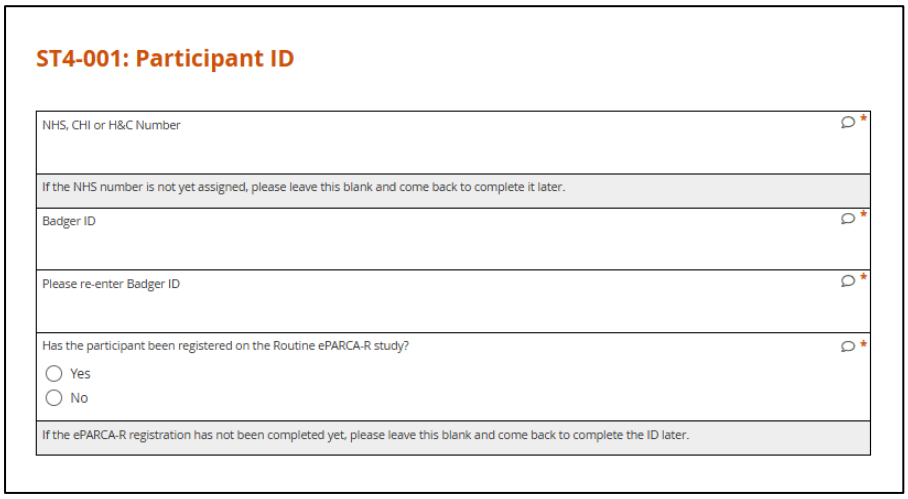
3.1.1.3 Participant ID CRF

- Enter the NHS, CHI or H&C number (10 digits; can be completed later if unavailable)
- Enter the Badger ID twice (error message will flag if the IDs do not match)
- Indicate if the parent is registered for the ePARCA-R questionnaire and enter ID number from the ePARCA-R database*

- If not yet discussed, leave blank and complete later
- If declined, select 'No' and provide a reason

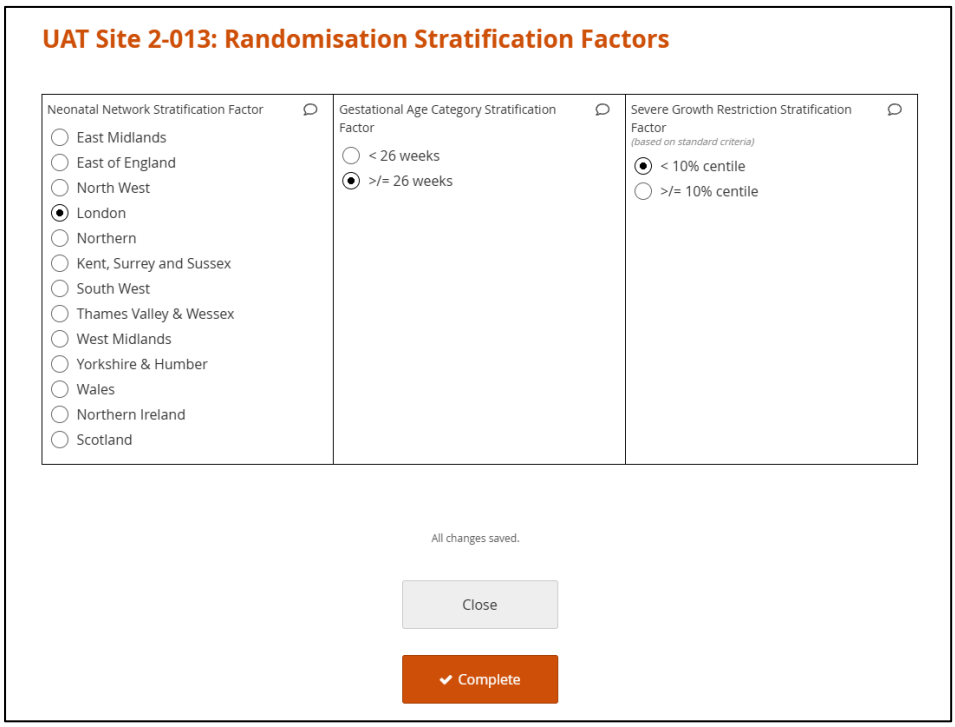
- Click 'Complete' to confirm when data has been entered.

***The ePARCA-R database is not yet live, further instructions will be provided in section 9.3 once live. Please leave this question blank for now. If the participant is discharged before registration is available, please use contact details (mobile number or email address) from medical records to send the invitation.**



3.1.1.4 Randomisation Stratification CRF

Complete the required stratification factors (neonatal network, gestational age category, severe growth restriction). Click 'Complete' to confirm.



3.1.2 Randomisation visit (R1 and R2)

If the baby is taking part in Randomisation 1 and/or 2, schedule the relevant visit by clicking 'Add New' in the visits section (same steps to be followed for R1 and or R2). The following CRFs will appear:

- Eligibility
- Assignment

3.1.2.1 Eligibility CRF

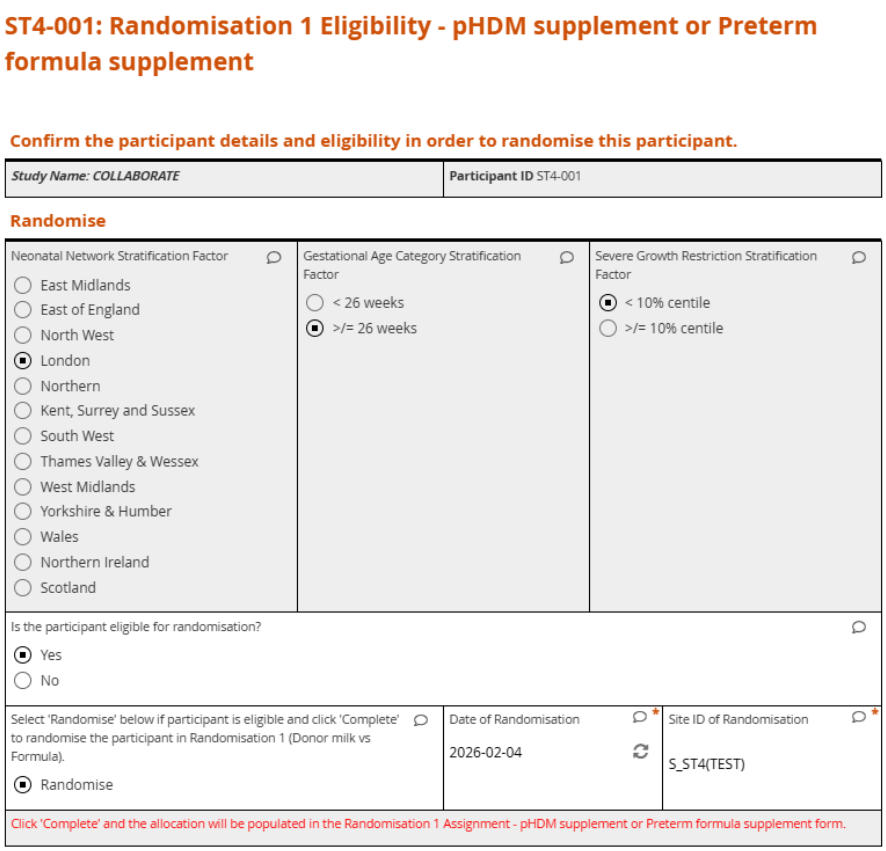
The stratification data will auto-populate on the CRF.

If the participant is eligible for randomisation, select 'Yes', and click '**Randomise'** on the CRF.

- The date of randomisation and site ID will auto populate. Do not edit the site ID; this is a required data analysis field.
- Once you click 'Complete' to confirm, the randomisation assignment will be generated on the Randomisation assignment CRF. (**Randomisation assignment may take 10-20 seconds to appear. Please wait until the Randomisation Assignment form status changes to "Data Entry Started" (orange pencil icon) before opening the form to view the allocation**).

If the participant is not eligible, select 'No' and then 'Complete' to confirm.

IMPORTANT: Do not re-open in edit mode after confirming, only open in '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	Gestational Age Category Stratification Factor	Severe Growth Restriction 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	○ < 26 weeks ◉ >/= 26 weeks	◉ < 10% centile ○ >/= 10% centile

Is the participant eligible for randomisation?
◉ Yes
○ No

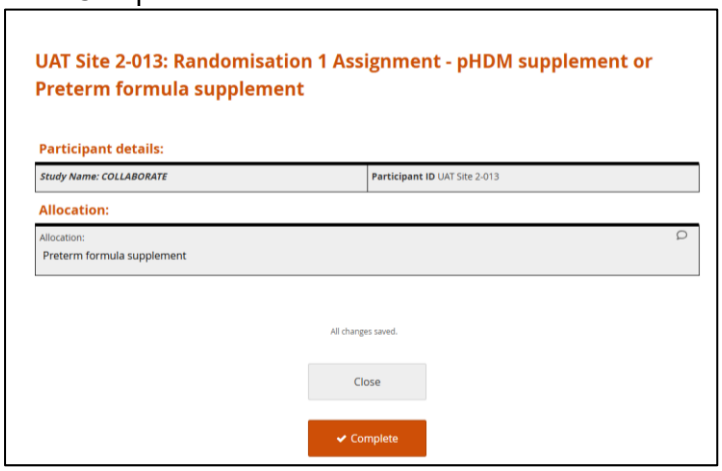
Select 'Randomise' below if participant is eligible and click 'Complete' to randomise the participant in Randomisation 1 (Donor milk vs Formula).	Date of Randomisation *	Site ID of Randomisation *
◉ Randomise	2026-02-04	S_ST4(TEST)

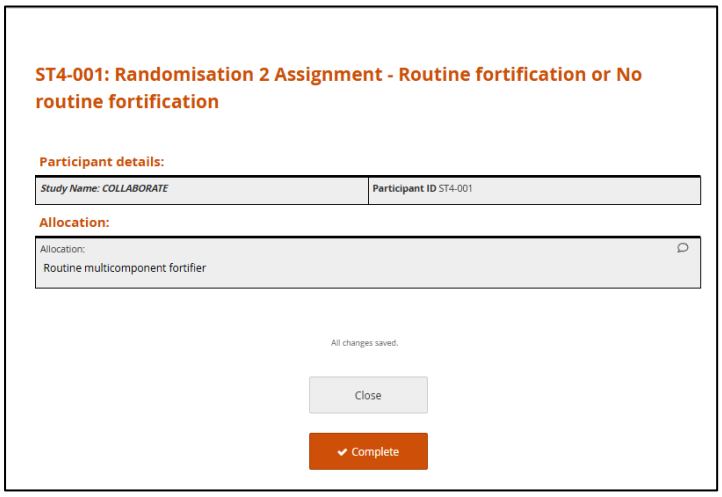
Click 'Complete' and the allocation will be populated in the Randomisation 1 Assignment - pHDM supplement or Preterm formula supplement form.

3.1.2.2 Assignment CRF

Randomisation assignment may take 10-20 seconds to appear. Please wait until the Randomisation Assignment form status changes to "Data Entry Started" (orange pencil icon) before opening the form to view the allocation.

Once the orange pencil icon is visible, open the assignment form to view the allocation. Then click 'Complete' to confirm and close the form.

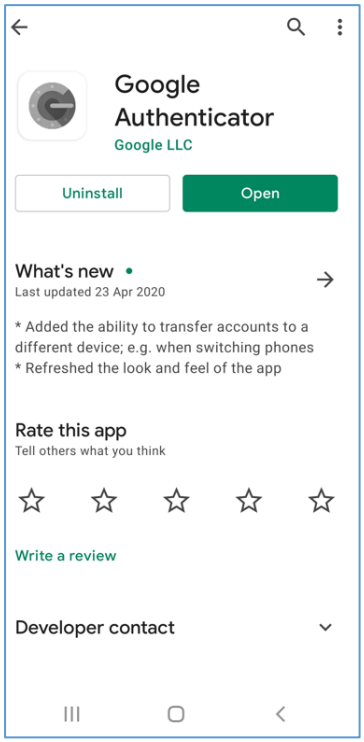




Please ensure the allocation is also recorded in the medical notes and on a Cot card (provided by the study team).

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

1. Install **Google Authenticator** on your mobile device; it is required each time you sign into OpenClinica.

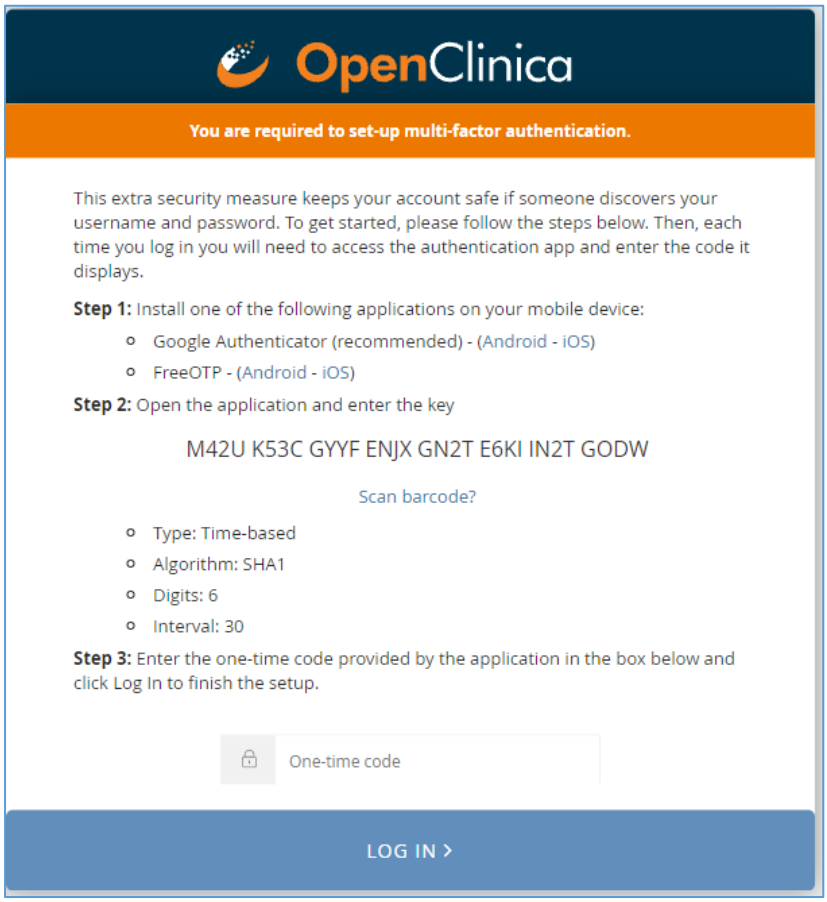


2. Log in to OpenClinica (https://imperial.openclinica.io/OpenClinica/MainMenu) on your computer using your username and password. Open **Google Authenticator** on your mobile and scan the QR code displayed.

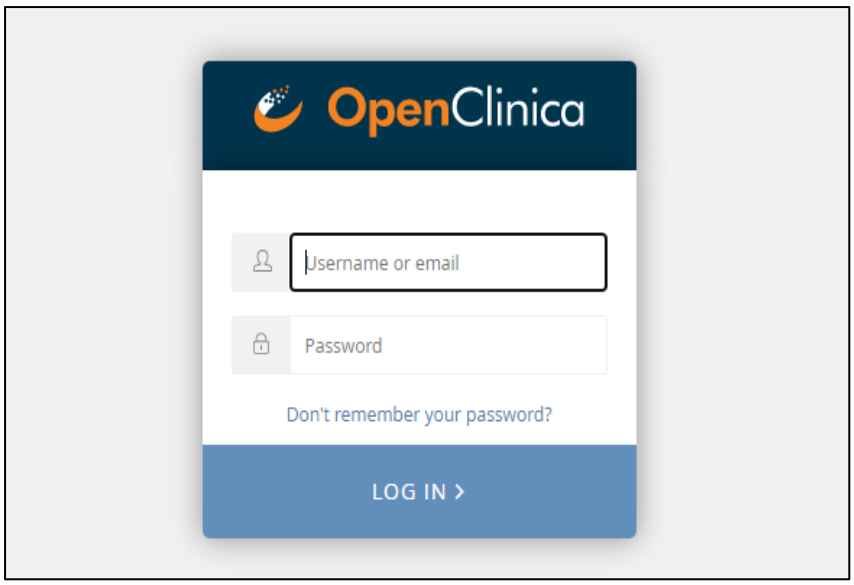
3. You will be provided with a 6-digit code on your mobile device after scanning the QR code on the computer screen.
4. Enter the 6-digit code into the field on the OpenClinica login page and click on “Log in”.

If you are unable to scan a QR Code

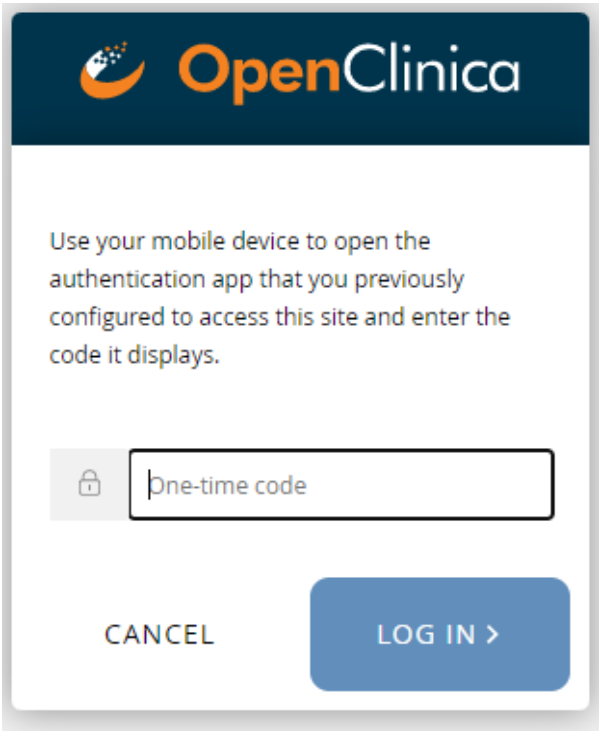
1. If you are unable to scan the QR code, click “**Unable to scan**” after entering your login details. This will provide 32-key code.
2. In the **Google Authenticator** app, select “**Enter a setup key**” and enter the 32-key code. This will generate a 6-digit code that will need to be entered into the OpenClinica login page and click on “Log in”.
3. Scanning the QR code (or entering the 32-digit key code) is a one-time step.



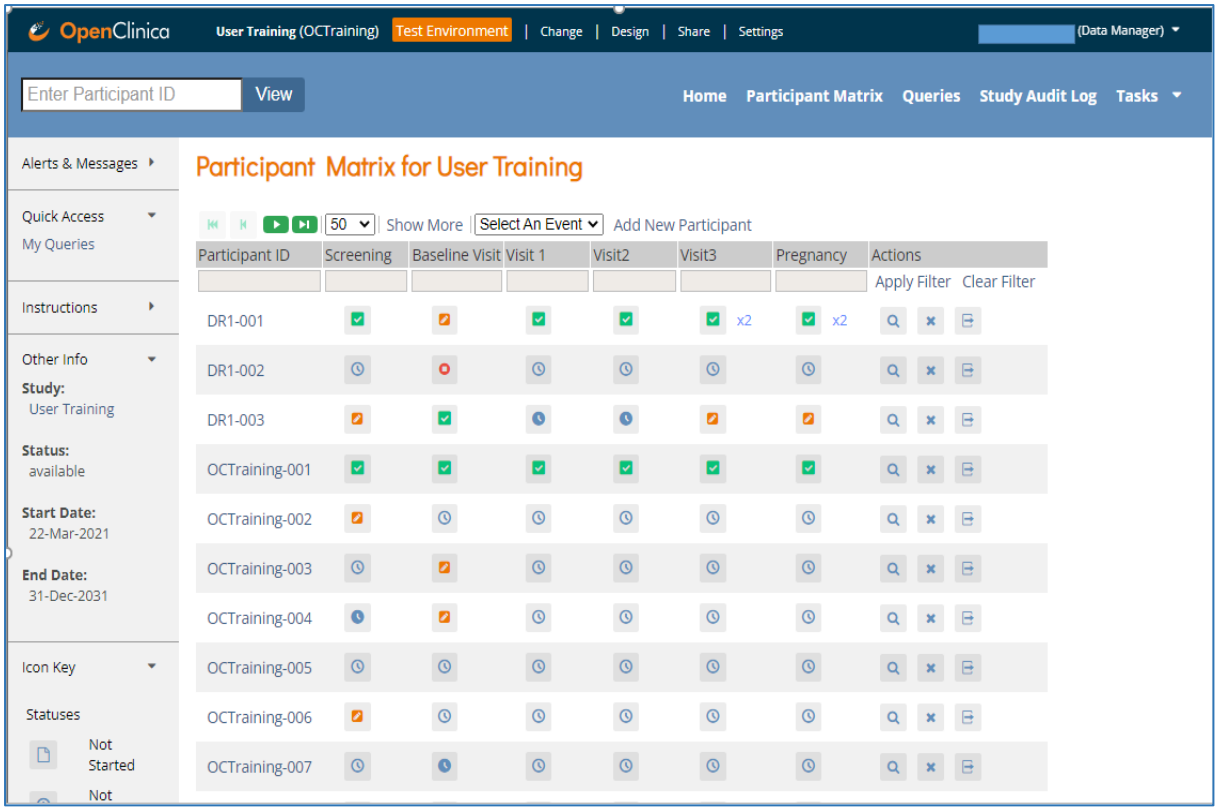
Once set up, the account is saved in the Google Authenticator app, and 6-digit codes are generated automatically for each login.



After entering your details, click “LOG IN”, then enter the one-time code generated by the Google Authenticator app. Click “LOG IN” to access your study.



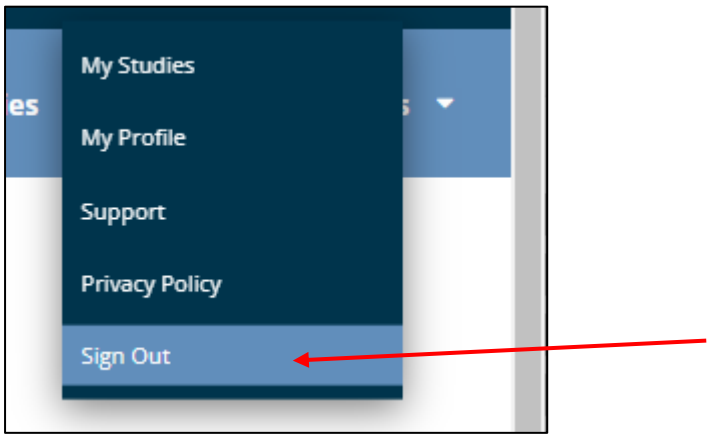
The system will display a **HOME** screen based on your user role.



Log out of OpenClinica after use, especially on shared devices.

You will be automatically logged out after 1 hour of inactivity.

To log out manually, click 'Sign Out' at the top right of the page.



5. General Data Entry Guidelines

Data entry must be completed for ALL participants in accordance with **Good Clinical Practice (GCP)**:

- Enter data for completed timepoints within **5** business days
- Resolve data queries within **10** business days
- Only trained, authorised staff are to complete data entry
- Use clear, approved abbreviations (NA - **Not Applicable**, ND - **Not Done**, NK - **Not Known** and UNK - **Unknown**) and acronyms only
- Avoid using abbreviations that are ambiguous or could be interpreted differently
- When **'other (specify)'** is selected, provide details where applicable
- Do not include participant identifiers (e.g. name, initials, address, hospital number) to maintain confidentiality

6. CRF Completion Queries

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

7. Version History

Version Number	Date	Author	Description
1.0	19/06/2026	Rosie Way (Trial Manager)	First Version – shortened version of the main guidelines for consent and randomisation tasks

8. Amendments

Section	Amendment