

OpenClinica Quick Guide for Randomisation

Link to sign in:

https://auth.openclinica.io/auth/realms/imperial/protocol/openid-connect/auth?response_type=code&client_id=bridge&redirect_uri=https%3A%2F%2Fimperial.openclinica.io%2FOpenClinica%2Ffso%2Flogin&state=9021ca7d-b3de-4b2f-be1d-6de4aa65a96c&login=true&scope=openid

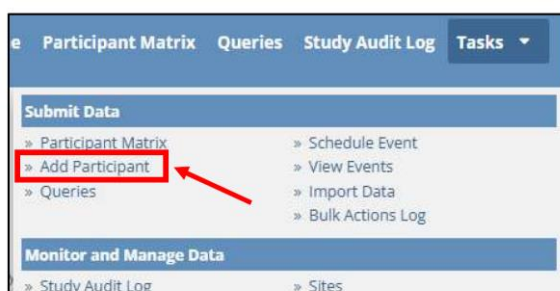
Copy and paste into a browser

You will need to set this up with google authenticator on your phone

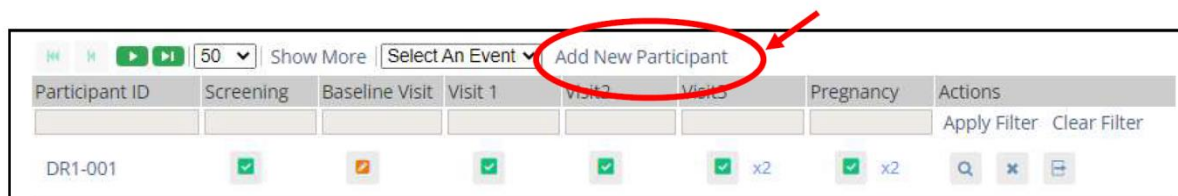
Adding a Participant

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**



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

Add New Participant

Participant ID *

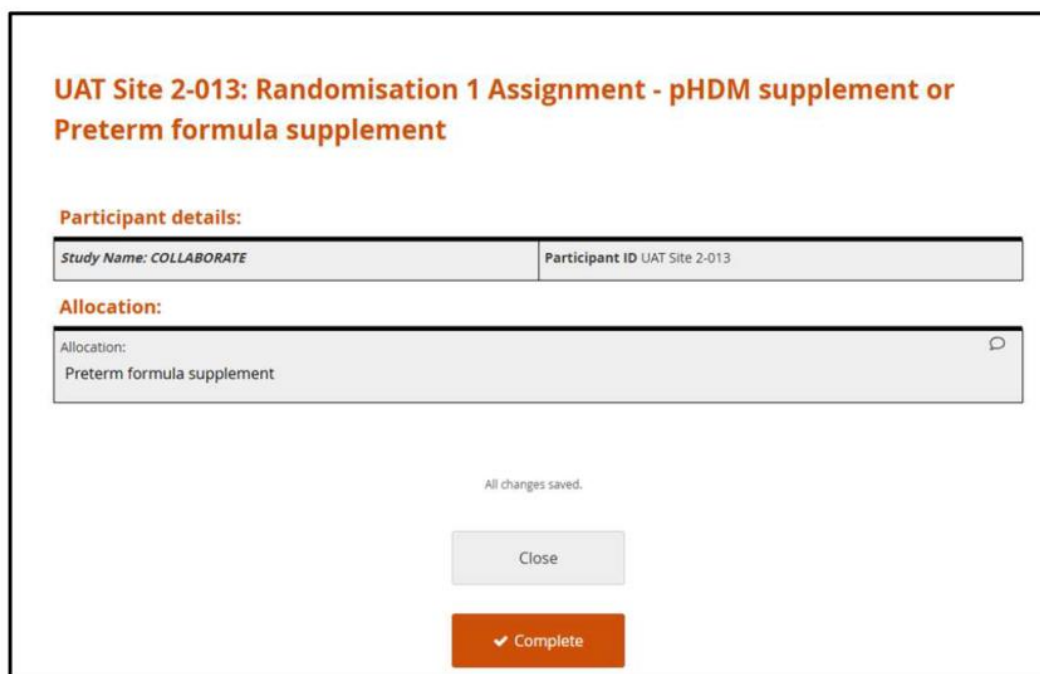
Randomisation 1

To **randomise** the following CRF forms need filled in:

- R1 verbal consent
- Randomisation 1 Eligibility
- Participant ID
- Randomisation stratification

Then Randomisation 1 assignment CRF should display allocation outcome -please follow this allocation.

It will appear blank – go out and back into the page to see the randomisation arm.



The screenshot displays a web form titled "UAT Site 2-013: Randomisation 1 Assignment - pHDM supplement or Preterm formula supplement". Under "Participant details:", there are two fields: "Study Name: COLLABORATE" and "Participant ID UAT Site 2-013". Under "Allocation:", there is a dropdown menu showing "Preterm formula supplement". Below the form, a message states "All changes saved." and there are two buttons: a grey "Close" button and an orange "Complete" button with a checkmark icon.

Randomisation 2

To **randomise** the following CRF forms need filled in:

- R2 verbal consent
- Randomisation 2 Eligibility

Then Randomisation 2 assignment CRF should display allocation outcome -please follow this allocation.

It will appear blank – go out and back into the page to see the randomisation arm.

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

Participant details:

Study Name: COLLABORATE	Participant ID ST4-001
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Allocation:

Allocation: Routine multicomponent fortifier	
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All changes saved.

Close

✔ Complete