Randomisation

Randomisation: Blinded

- The SOPHIST trial is double blinded; all participants and trial staff are blinded to allocation.
- Unblinding will only occur in an emergency, for reporting of SUSARs and at the end of the trial after data lock has occurred.
- Participants will not be able to request to be unblinded.
- Participants will be informed of the results of the trial and their treatment allocation once the trial results have been published.

TRuST – Tayside Randomisation System

- Web-based randomisation system used by Research Nurses.

- Trial Manager and trial monitors have access to TRuST to enable them to check blinded randomisation and drug accountability details remotely.

- Research Nurses will use TRuST for the following:
  - Randomisation of participants.
  - Overview of randomisation details.
  - Overview of pack allocation for site and/or participant.

Randomisation: Requirement

- Delegated to randomise on Delegation Log.
- Randomisation training completed – this presentation and read the TRuST User Guide.
- Medical Record signed by PI/delegate confirming eligibility.
- Internet access/TRuST log-in.
- Participant ID, gender, initials (i.e. for first and last name), date of birth and eligibility.
- Printer.

Randomisation: TRuST System

- TRuST can be accessed directly https://trust.hicservices.dundee.ac.uk or from the SOPHIST trial website resources page https://sites.dundee.ac.uk/sophist-trial/sophist-trial-resources/

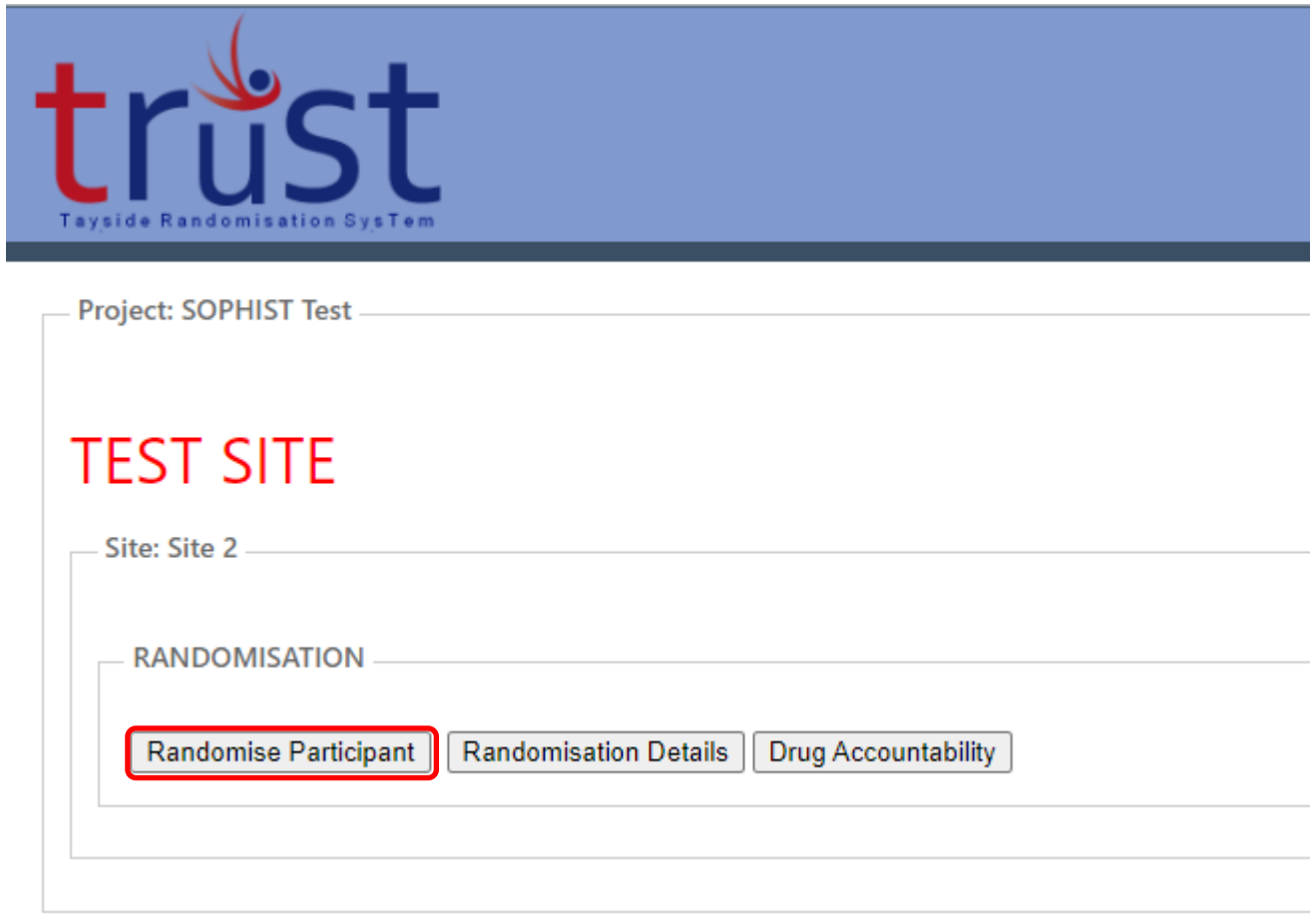
- Login details will be sent out after training has taken place. If not received, click on “Forgotten Password” and enter your email as your username.

- Login with your details; on first login you will be asked to change your password.

If you forget your password, click the forgotten password link and your new password will be emailed to you.

For staff with multiple projects on TRuST select the SOPHIST trial from the dropdown menu.

Randomising a participant

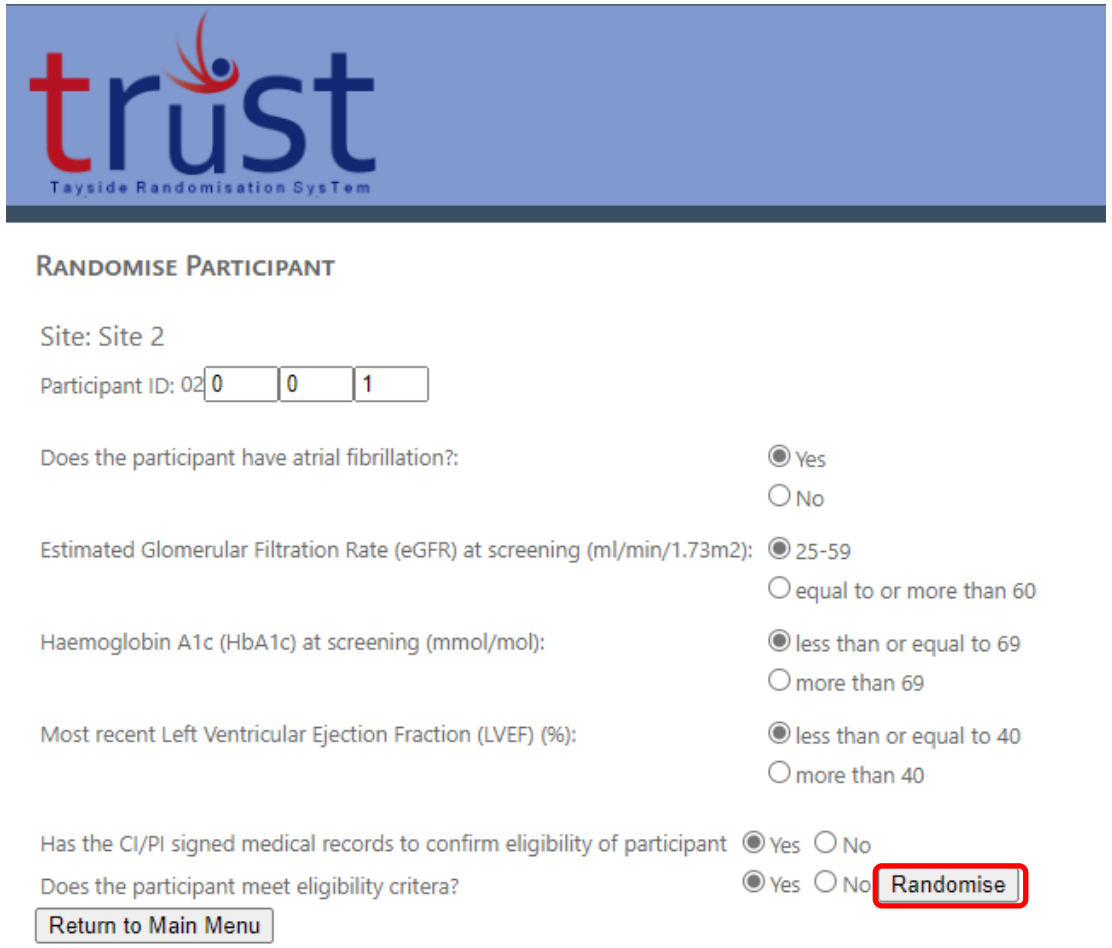


- Main menu.
- Click randomise participant.

Randomising a participant

- Enter participant identifiers.
- Complete eligibility criteria questions.
- Click “Next”.

Randomising a participant



- Enter participant ID. The first number is provided and is the site number. Enter the 3 further digits. E.g. for the first patient consented enter “001”.
- If unsure about Participant ID consult site enrolment and randomisation log.
- Complete randomisation questions
- **It is an MHRA and GCP requirement that a medical doctor confirms eligibility prior to randomisation.**
- Click “Randomise” button

Randomising a participant

- Randomisation notification will be displayed.
- You will receive an email confirming this allocation.
- Pack IDs are generated.

Insufficient IMP stock

- If the Pack Allocation does not display any pack IDs, this indicates that your site has no remaining stock for that treatment allocation.

- If the number of pack IDs listed under Pack Allocation is less than the correct amount for the treatment, this indicates that your site has insufficient stock of the randomised treatment.

- **Do not proceed with the randomisation and contact the trial manager immediately.**

Clinical Trial Request/Release Form – (Visit 3)

- This form is not generated by TRuST.
- Research nurse should complete the participant details & fill out the Pack IDs.
- The SOPHIST Clinical Trial Request/Release form must be signed by the PI or their delegate named on the Delegation Log.
- Take the completed SOPHIST Clinical Trial Request/Release form to the Clinical Trials Pharmacy along with a printed copy of the randomisation email generated by TRuST.
- The clinical trial request form should be filed in the PSF.

SOPHIST

SOPHIST (**SO**tagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes)

CLINICAL TRIAL REQUEST/RELEASE FORM FOR PHARMACY

IRAS	**1007807**	Sponsor	**University of Dundee and NHS Tayside**
Protocol No.		Local CTP ID	

Chief Investigator	**Dr Ify Mordi**	Tel No	**01382385591**
Principal Investigator		Tel No	

Participant trial ID:			
Participant Name:			
Date of Birth:		CHI/hospital number:	
Visit Number:		Visit Date:	

Sotagliflozin 200mg or Placebo 200mg	
Total number of tablets:	**120 (one bottle of 90 tablets and one bottle of 30 tablets)**
Pack ID:	
Pack ID:	
Dosage schedule:	**1 tablet per day for a total of 16 weeks**

PI or delegate doctor's signature:	Date:
Print name:	

Released By:	Date:
Checked By:	Date:
Collected By:	Date:

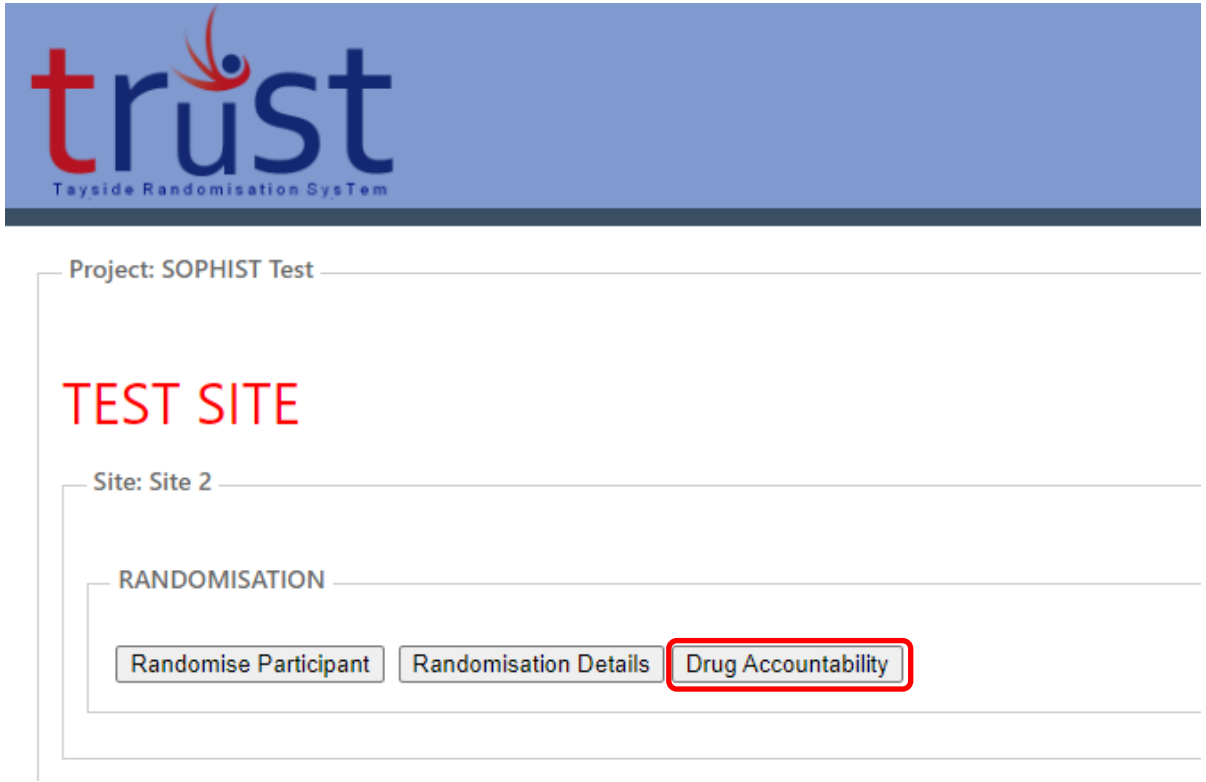
SOPHIST IMP Request-Release Form V1 22-02-2024.docx

Site Randomisation Details

- To check the randomisation details go back to main menu and click the “Randomisation Details” button.

- Details of all participants randomised at site will be shown.

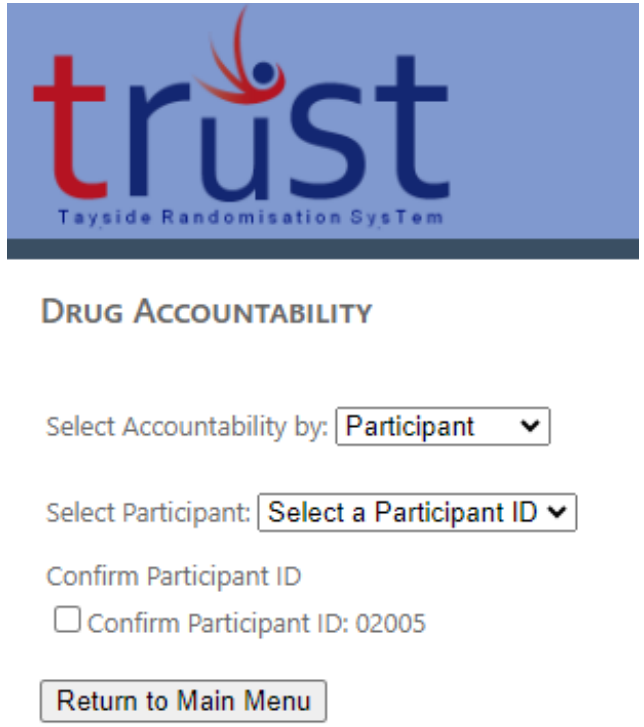
Drug Accountability



- To check Drug Accountability for participants at site (i.e. display participant ID and pack IDs without treatment allocation) go back to main menu and click the Drug Accountability button.

- Drug accountability can be checked for “site” or individual “participant” from a dropdown menu.

- To check drug accountability for an individual participant select “Participant” from the dropdown menu.
- Select participant ID.
- Click “Confirm Participant ID”.



Please contact the trial management team if you have any questions or issues:

SOPHIST-trial@dundee.ac.uk