Tayside Randomisation System

SOPHIST TRuST User Guide

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1. Introduction to TRuST

1.1 Overview of TRuST

TRuST is the web-based randomisation system being used by both Research Nurses for all sites participating in the SOPHIST trial. The Clinical Trial Manager and trial monitors will have access to TRuST to enable them to check randomisation and drug accountability remotely.

The Research Nurses at all sites participating in the SOPHIST trial will use TRuST for the following activities:

- Randomisation of participants
- Allocation of IMP or placebo pack IDs

TRuST has a system of email alerts built-in to notify the research team. The Research Nurses will be informed when:

- Participant has been randomised.

Emails generated by TRuST should either be printed and filed in the ISF or held electronically with a file note in the ISF stating where they are held.

2. Getting Started

- Go to the TRuST website: https://trust.hicservices.dundee.ac.uk
- The link is also on the SOPHIST website: https://sites.dundee.ac.uk/sophist-trial/

2.1 Logging in

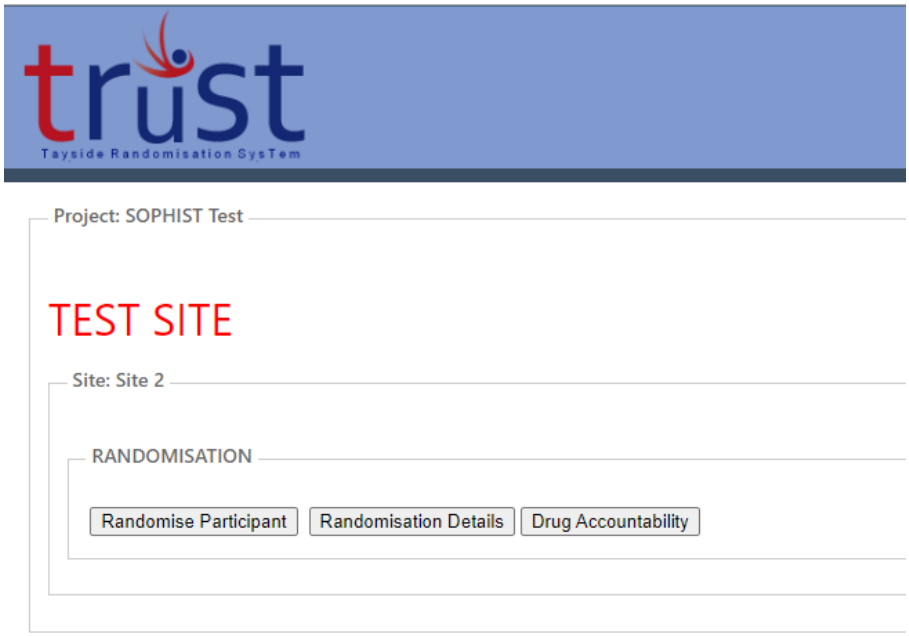
- Enter your email address as username
- Click “Change Password”
- Your new password will be emailed to you.

2.2 Project selection

- For sites with multiple projects on TRuST choose project from dropdown.
- For sites only working on SOPHIST, you will not have to choose.

2.3 Main menu

The first page will display the “Main Menu”, return to this page to start each task.



2.4 Changing your password

- From the main menu, click “Change Password” at the top right of the page.
- Enter Old Password, New Password, Confirm New Password.
- Click Change Password

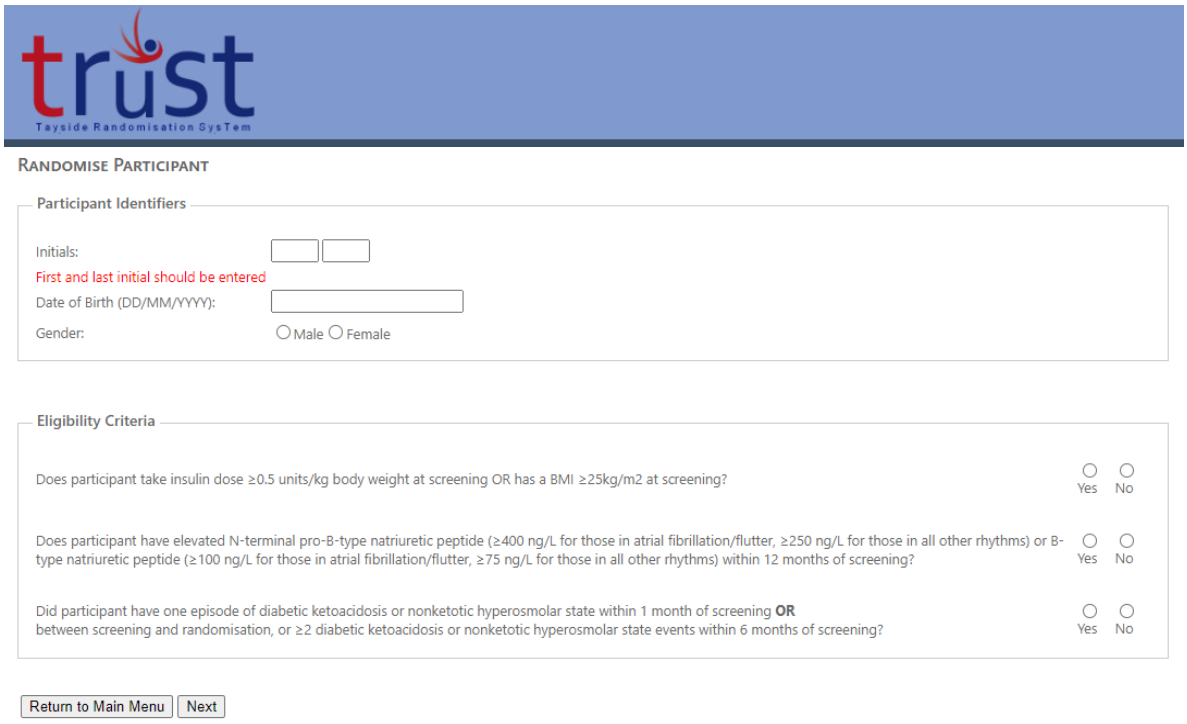
2.5 Logging out

- Click log out when you are finished.
- The system will automatically log out the user if there has been no activity for 10 minutes.

3. Randomising a Participant & Pack Allocation

3.1 Randomising a Participant

- From the Main Menu, click on “Randomise Participant”
- Enter the participant identifiers: initials, date of birth & gender.
- **Important: either use the calendar to select date of birth or use the format dd/mm/yyyy. Do not use the format dd-mm-yyyy**
- Complete eligibility criteria questions.
- Click next.



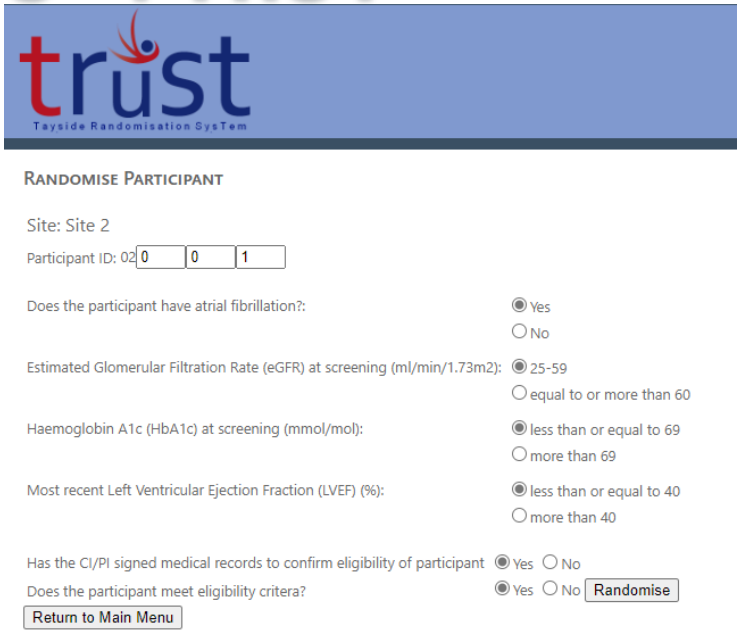
- Enter the participant ID; the first number is provided and is the site number.

Enter participant number, three digits. For example, the first participant would be entered as 001. Participant IDs will then follow numerically in sequence (002, 003 etc.). 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



Randomisation notification will be displayed

You will also receive an email confirming this allocation. Print this email to take to CTP along with the Clinical Trial Request/Release Form.

3.2 Pack Allocation

The Pack IDs are generated when the participant is randomised. The Pack IDs are included in the email that is sent when the participant is randomised.

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

3.3 Clinical Trial Request/Release Form

- Complete the Clinical Trial Request Form by filling in the participant details and the Pack IDs
- The Request Form should be signed and dated by the PI or their delegate named in the Delegation Log
- The Request Form should then be taken to the Clinical Trial Pharmacy along with a copy of the randomisation email.
- CTP will check the Clinical Trial Request/Release Form against the randomisation email and dispense the trial drugs as per usual local practice.
- The Clinical Trial Request Forms will be filed in the Pharmacy Site File.

Example Clinical Trial Request/Release Form:

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:

4. Other TRuST functionality

4.1 Randomisation details

The “Randomisation Details” tab displays a table of participant IDs, blinded treatment, the date of randomisation and who performed the randomisation.

4.2 Drug accountability

The “Drug Accountability” can be viewed as either a whole site or for individual participants. Drug accountability displays pack IDs and does not display which treatment each participant has been allocated to.

Drug accountability displays: Participant ID, pack IDs, date of allocation and who allocated them.