

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

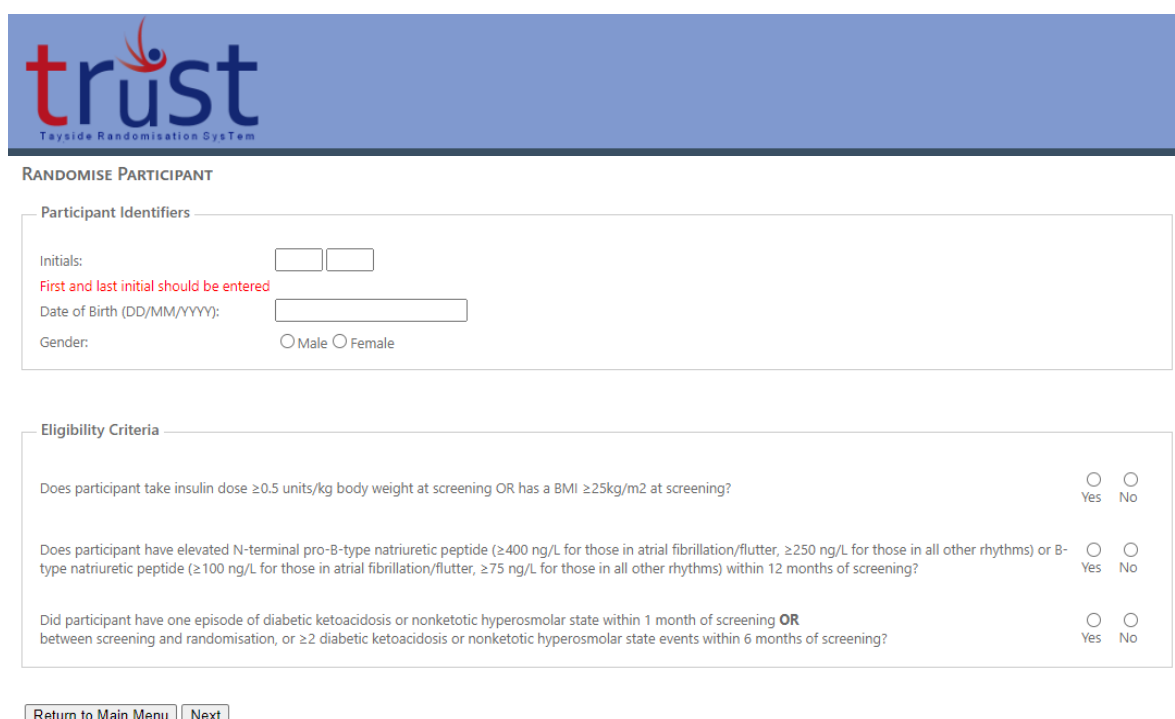
2.5 Logging out

- 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.



RANDOMISE PARTICIPANT

Participant Identifiers

Initials:

First and last initial should be entered

Date of Birth (DD/MM/YYYY):

Gender: Male Female

Eligibility Criteria

Does participant take insulin dose ≥ 0.5 units/kg body weight at screening OR has a BMI ≥ 25 kg/m² at screening? Yes No

Does participant have elevated N-terminal pro-B-type natriuretic peptide (≥ 400 ng/L for those in atrial fibrillation/flutter, ≥ 250 ng/L for those in all other rhythms) or B-type natriuretic peptide (≥ 100 ng/L for those in atrial fibrillation/flutter, ≥ 75 ng/L for those in all other rhythms) within 12 months of screening? Yes No

Did participant have one episode of diabetic ketoacidosis or nonketotic hyperosmolar state within 1 month of screening **OR** between screening and randomisation, or ≥ 2 diabetic ketoacidosis or nonketotic hyperosmolar state events within 6 months of screening? Yes No

- 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



RANDOMISE PARTICIPANT

Site: Site 2

Participant ID: 02

Does the participant have atrial fibrillation?: Yes No

Estimated Glomerular Filtration Rate (eGFR) at screening (ml/min/1.73m²): 25-59 equal to or more than 60

Haemoglobin A1c (HbA1c) at screening (mmol/mol): less than or equal to 69 more than 69

Most recent Left Ventricular Ejection Fraction (LVEF) (%): less than or equal to 40 more than 40

Has the CI/PI signed medical records to confirm eligibility of participant? Yes No

Does the participant meet eligibility criteria? Yes No



Randomisation notification will be displayed

RANDOMISE PARTICIPANT

Site: Site 2

Subject Identifier: 02005

Randomisation Allocation: Participant Successfully Randomised

Pack ID: 1017

2017

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 (**S**otagliflozin in **P**atients with **H**ear**t** fail**u**re **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

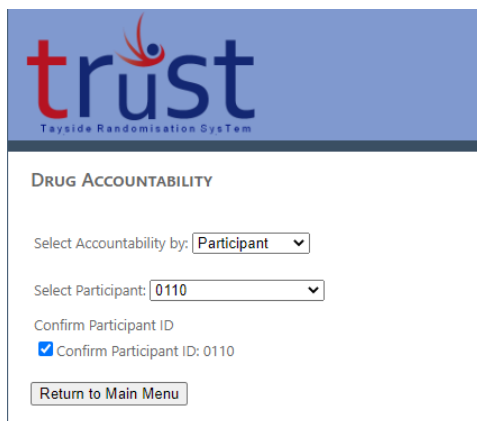
4.1 Randomisation details

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.



The screenshot shows the TRuST interface for Drug Accountability. At the top is the truSt logo. Below it, the heading "DRUG ACCOUNTABILITY" is displayed. The interface includes a dropdown menu for "Select Accountability by:" with "Participant" selected. Below that is another dropdown menu for "Select Participant:" with "0110" selected. A section titled "Confirm Participant ID" contains a checked checkbox and the text "Confirm Participant ID: 0110". At the bottom, there is a button labeled "Return to Main Menu".