
Tayside Randomisation System

Research Nurse Users Guide

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1 Introduction to TRuST

TRuST is the web based randomisation system being used by both Research Nurses and Clinical Trial Pharmacy Staff for all sites participating in the STOP-COVID19 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 STOP-COVID19 trial will use TRuST for the following activities:

- Randomisation of participants.

TRuST has a system of email alerts built-in to notify the research team on several occasions. 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://hicservices.dundee.ac.uk/TRuST>

The link to TRuST is on the STOP-COVID19 website.

2.1 Logging in

- Enter **username** & **password**.
- On first log-in you will be asked to change your password



The screenshot shows the TRuST login interface. At the top left is the 'truSt' logo with 'Tayside Randomisation System' below it. At the top right are links for '[Log In]' and '[Forgotten Password]'. The main heading is 'LOG IN' with the instruction 'Please enter your username and password.' Below this is a section titled 'Account Information' containing two input fields: 'Username:' and 'Password:'. A 'Log In' button is positioned below the password field. At the bottom left is the 'TASC' logo (Tayside Medical Science Centre) and at the bottom right is the 'tctu' logo (Tayside Clinical Trials Unit).

2.2 Recovering a Lost Password

- Click **Forgotten Password**.

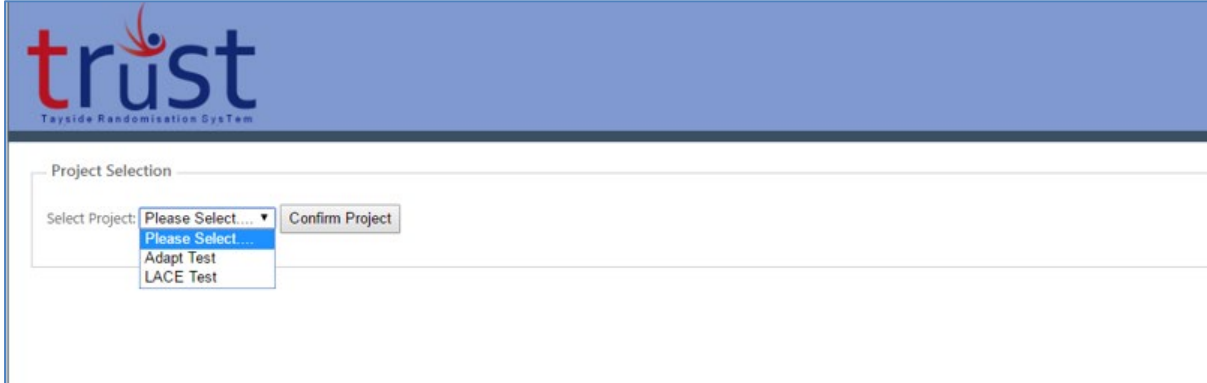


The screenshot shows the Trust login page. At the top right, there are links for 'Log In' and 'Forgotten Password', with the latter highlighted by a red box. The main content area is titled 'LOG IN' and contains the instruction 'Please enter your username and password.' Below this is a form titled 'Account Information' with fields for 'Username:' and 'Password:'. A 'Log In' button is located at the bottom of the form.

➤ Your new password will be emailed to you.

2.3 Project Selection

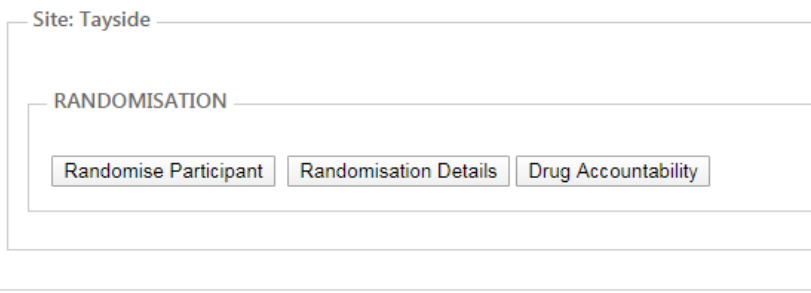
The first page you will see allows you to choose which project you wish to work on. For sites with multiple projects on TRuST the drop down menu below will present, for sites only working on STOP-COVID19, you will not have to choose.



The screenshot shows the Trust project selection page. It features a 'Project Selection' section with a dropdown menu labeled 'Select Project:' containing options: 'Please Select...', 'Please Select...', 'Adapt Test', and 'LACE Test'. A 'Confirm Project' button is positioned to the right of the dropdown.

2.4 Main menu

The first page will display a menu of options, return to this page to start each task.



The screenshot shows the Trust main menu. At the top, it displays 'Site: Tayside'. Below this is a section titled 'RANDOMISATION' which contains three buttons: 'Randomise Participant', 'Randomisation Details', and 'Drug Accountability'.

2.5 Changing Your Password

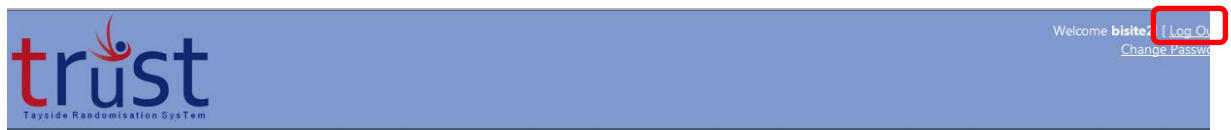
➤ From the Main Menu page click [Change Password](#).



- Enter Old Password, New Password, Confirm New Password.
- Click Change Password

2.6 Logging out

- Click Log Out when finished



The system will automatically log out the user if there has been no activity for 10 minutes.

3 Randomising a Participant

3.1 Randomise Participant

- From the Main Menu click on [Randomise participant](#).

Site: Tayside

RANDOMISATION

[Randomise Participant](#) [Randomisation Details](#) [Drug Accountability](#)

- From the Main Menu click on [Randomise participant](#).

RANDOMISE PARTICIPANT

Site: 01 Tayside

Participant ID: 01

- Enter the details as required

Age: Less than 65 years
 Greater than or equal to 65 years

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

Does the participant meet eligibility criteria? Yes No

[Return to Main Menu](#)

- Enter the [participant ID](#); ensure that you enter the three digits after the site ID. So, for example, the first participant would be entered as 0 0 1.

RANDOMISE PARTICIPANT

Site: 01 Tayside

Participant ID: 01

Age: Less than 65 years
 Greater than or equal to 65 years

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

Does the participant meet eligibility criteria? Yes No

[Return to Main Menu](#)

➤ Click to confirm that the CI/PI has confirmed eligibility by signing the medical record and that the participant is eligible for the study. It is an MHRA and GCP requirement that a medical doctor confirms eligibility prior to randomisation

➤ Once you have entered participant ID and confirmed eligibility a randomise button will appear. [Click](#) this button to randomise.

RANDOMISE PARTICIPANT

Site: Tayside

Participant ID: 01 0 1 2

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

Does the participant meet eligibility criteria? Yes No

[Randomise](#)

[Return to Main Menu](#)

- Randomisation will be confirmed and the pack ID assigned to this individual will be displayed.
- You will also receive an email confirming this allocation

Site: Tayside

Subject Identifier: 01012

Randomisation Allocation: Participant Successfully Randomised

Pack ID: 50010

[Return to Main Menu](#)

- To check the randomisation details go back to the [main menu](#)
- Click on the Randomisation Details button

Site: Tayside

RANDOMISATION

Randomise Participant **Randomisation Details** Drug Accountability

➤ Details of all participants randomised at site will be shown

- To check Drug Accountability for participants at site click [Drug Accountability](#) from the main menu

Site: Tayside

RANDOMISATION

Randomise Participant Randomisation Details **Drug Accountability**

- Drug Accountability can be checked for site or for individual participant.
- For site select [Site](#) from the dropdown menu

Participant ID	Pack ID	Date Allocated	By
01001	50001	29/04/2020	rCovid
01111	50003	04/05/2020	rCovid
01211	50002	04/05/2020	rCovid
01333	50008	04/05/2020	rCovid
01444	50004	04/05/2020	rCOVID
01234	50006	05/05/2020	rCovid
01a14	50007	05/05/2020	rCovid
01FAI	50005	05/05/2020	rCovid
01235	50012	08/05/2020	rCovid
01958	50011	14/05/2020	rCovid
01011	50009	15/05/2020	rcovid
01012	50010	15/05/2020	rcovid

- Details of pack ID for all drug allocated at site will be listed against participant ID.

➤ Drug Accountability can be checked for site or for individual participant.
➤ For participant select [Participant](#) from the dropdown menu

Select Accountability by:

Select Participant:

➤ Click on [Select a participant ID](#) to select the participant you require from the dropdown menu.

Select Accountability by:

Select Participant:

Confirm Participant ID

Confirm Participant ID: 01012

➤ Click the box to confirm the participant ID you selected.

➤ Drug accountability for that participant will be displayed.

Select Accountability by:

Participant ID: 01012

Participant ID	Pack ID	Date Allocated By
01012	50010	15/05/2020 rcovid

➤ Click [Return to Main Menu](#) to continue in the system or [Logout](#) if finished.

4 Trouble Shooting & Contacts

4.1 Requesting New User Accounts

Requests for new user accounts should be emailed to the Clinical Trial Manager (see below). Please include the person's full name and email address and role in the trial. Before user accounts will be issued the Clinical Trial Manager will require a copy of the Delegation Log and Training Logs to confirm the person has been delegated the role and has had training in using TRuST.

4.2 Unable to Access TRuST

Please see Operations Manual if unable to access TRuST for the process of randomising participants.

If internet access is possible but the TRuST system is not working please contact the Clinical Trial Manager.

Sites will be informed of any planned downtime for TRuST.

The Clinical Trial Manager will inform sites as soon as they are aware that TRuST is down and will notify them when this is corrected.

4.3 Contacts

Clinical Trial Manager: stop-covid19@dundee.ac.uk