
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 STAR-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 STAR-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.

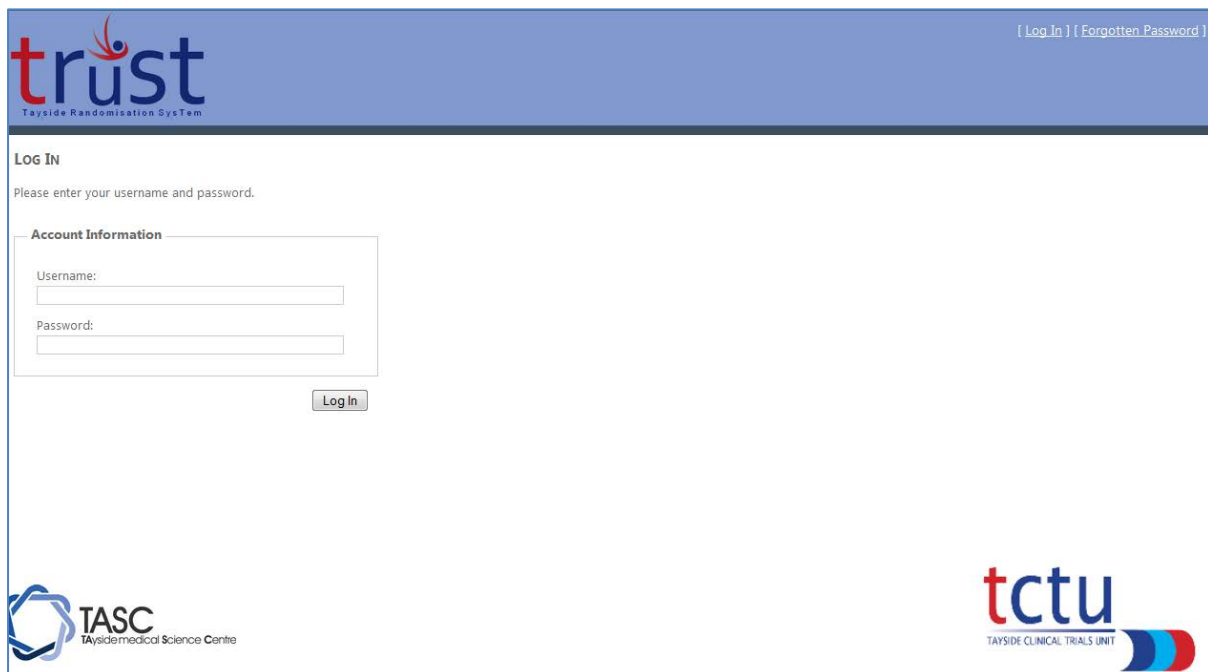
2 Getting Started

- Go to the TRuST website: <https://hicservices.dundee.ac.uk/TRuST>

The link to TRuST is on the STAR-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 right, there 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 form titled "Account Information" containing two input fields: "Username:" and "Password:". A "Log In" button is positioned below the password field. At the bottom left, the TASC logo (Tayside Medical Science Centre) is displayed. At the bottom right, the tctu logo (Tayside Clinical Trials Unit) is shown.

2.2 Recovering a Lost Password

➤ Click Forgotten Password.



The screenshot shows the TRuST login page. At the top right, there are two links: 'Log In' and 'Forgotten Password'. The 'Forgotten Password' link is highlighted with a red rectangular box. Below the header is a 'LOG IN' section with the instruction 'Please enter your username and password.' It contains a form with 'Account Information' fields for 'Username:' and 'Password:', and a 'Log In' button.

➤ Your new password will be emailed to you.

2.3 Project Selection

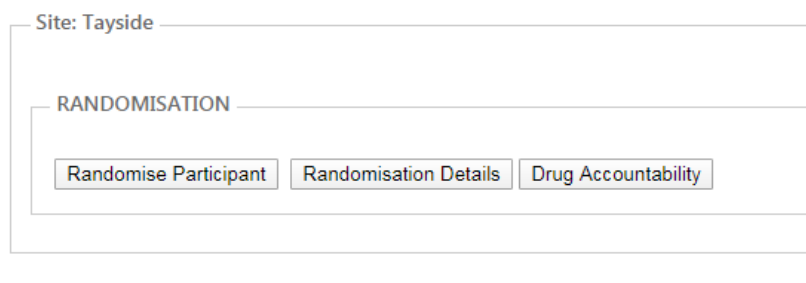
The first page you will see allows you to choose which project you wish to work on. For sites with multiple projects on TRuST the drop down menu below will present, for sites only working on STAR-COVID19, you will not have to choose.



The screenshot shows the 'Project Selection' page. It features a 'Select Project:' dropdown menu with the following options: 'Please Select...', 'Please Select...', 'Adapt Test', and 'LACE Test'. A 'Confirm Project' button is located to the right of the dropdown menu.

2.4 Main menu

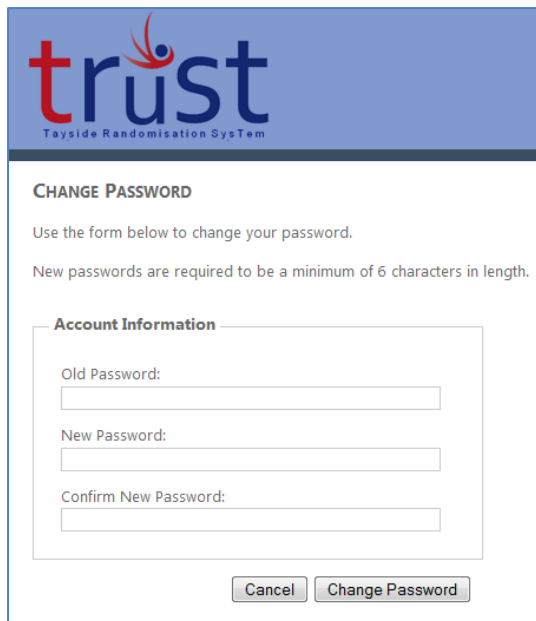
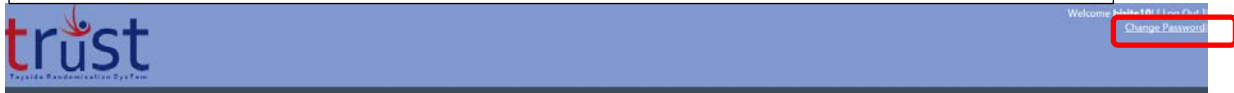
The first page will display a menu of options, return to this page to start each task.



The screenshot shows the main menu. At the top, it says 'Site: Tayside'. Below that 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.



CHANGE PASSWORD

Use the form below to change your password.

New passwords are required to be a minimum of 6 characters in length.

Account Information

Old Password:

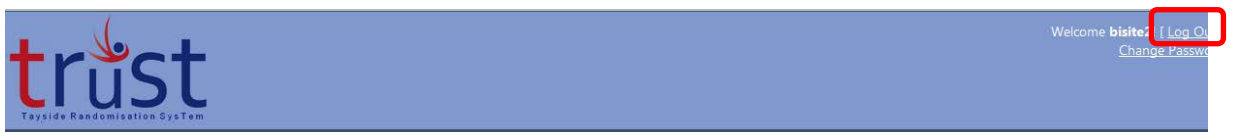
New Password:

Confirm New 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

RANDOMISE PARTICIPANT

Site: 01 Tayside

Participant ID: 01

CURB65 score: score less than 3
 score 3 to 5

- Enter the participant ID; the first number is provided and is the site number (here 01). Enter the three digits after the site ID. So, for example, the first participant would be entered as 0 0 1.
- Select whether the participant CURB65 score is “less than 3” or “3 to 5”

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 or delegate 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**



Participant ID: 01

CURB65 score: score less than 3
 score 3 to 5

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

Does the participant meet eligibility criteria?

Yes No

Once you have entered the details the Randomise button will appear. Click this button to randomise.

Site: Tayside
Subject Identifier: 01012
Randomisation Allocation: Participant Successfully Randomised
Pack ID: 50010

Randomisation will be confirmed and the pack ID assigned to this individual will be displayed.

You will also receive an email confirming this allocation

3.2 Complete clinical trial request form

STAR-COVID19: SFX-01 treatment for Acute Respiratory Infections (STAR-Covid19)

CLINICAL TRIAL REQUEST FORM

EudraCT	2020-003486-19	Sponsor	University of Dundee and NHS Tayside
IRAS	286251	Local CTP ID	

Chief Investigator	Prof James Chalmers	Tel No	01382 386 131
Principal Investigator		Tel No	

Participant ID:	
Participant Name:	
Date of Birth:	
Hospital Number/CHI:	
Date:	

Please Supply	SFX-01 / Placebo 1 bottle of 14 tablets
Dose	300mg – one tablet once per day
Pack ID	

Investigator's or delegate's Signature:		Date:	
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Complete at Time of Bottle Dispensing	
Selected and labeled By:	Date:
Checked By:	Date:

Complete a STAR-COVID19 clinical trial request form for pharmacy.

Enter the pack ID allocated to the participant you have randomised

Ensure that the form is signed by PI or delegate

Take the form plus copy of the TRuST randomisation email to clinical trial pharmacy

The form will be filed in the PSF

3.3 Confirmation of randomisation details

To check the randomisation details go back to the [main menu](#)

Site: Tayside

RANDOMISATION

Randomise Participant **Randomisation Details** Drug Accountability

Click on the Randomisation Details button

Details of all participants randomised at site will be shown

3.4 Drug allocation check

To check drug allocation go to main menu and click the Drug Accountability button

Site: Tayside

RANDOMISATION

Randomise Participant Randomisation Details **Drug Accountability**

Drug Accountability can be checked for site or for individual participant.

Select Accountability by: ▼

Participant ID	Pack ID	Date Allocated	By
01999	00001	27/07/2020	rSTARCOVID
01006	00004	28/07/2020	rSTARCOVID
01007	00002	28/07/2020	rSTARCOVID
01010	00007	28/07/2020	rSTARCOVID
01020	00003	28/07/2020	rSTARCOVID
01021	00008	28/07/2020	rSTARCOVID
01030	00011	28/07/2020	rSTARCOVID
01040	00005	28/07/2020	rSTARCOVID
01100	00006	25/08/2020	rSTARCOVID
01060	00012	25/08/2020	rSTARCOVID
01050	00013	25/08/2020	rSTARCOVID

For site select Site from the dropdown menu

Details of Pack IDs for all drug allocated at site will be listed with participant ID

Select Accountability by:

Select Participant:

Confirm Participant ID

Confirm Participant ID: 01012

To check drug accountability for an individual participant select Participant from the dropdown menu

Select the participant ID you require from the dropdown menu

Click the box to confirm the participant ID you selected

Select Accountability by:

Participant ID: 01012

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

Pack ID issued for that participant will be displayed

➤ 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. TRuST training slides are on the STAR-COVID19 website.

4.2 Unable to Access TRuST

If internet access is possible but the TRuST system is not working please contact the Clinical Trial Manager in the first instance and the TCTU contact email (see below).

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: star-covidTM@dundee.ac.uk

Tayside Clinical Trials Unit: tctu@dundee.ac.uk