



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

# Randomisation using the Tayside Randomisation System (TRuST)

To randomise participants to the STAR-COVID19 trial you must:

- be delegated to carry out the randomise task on the Delegation log
- have completed the randomisation training– read this presentation and the TRuST User Guide

You will need:

- Internet access
- TRuST log-in
- Printer

- The Tayside Randomisation System (TRuST) can be accessed directly:  
<https://hicservices.dundee.ac.uk/TRuST> or from the STAR-COVID19 website
- 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, if you have been given access your username will be emailed to you.
- The TRuST User Guide is provided with the documents for the ISF

- Prior to randomisation of any participant to the STAR-COVID19 trial, the PI or delegate **MUST** have signed the medical record confirming eligibility

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



The screenshot shows the TRuST login interface. At the top left is the 'trust' logo with the tagline 'Tayside Randomisation System'. At the top right are two links: '[ Log In ]' and '[ Forgotten Password ]', with the latter highlighted by a red box. Below the header is a 'LOG IN' section with the instruction 'Please enter your username and password.' Underneath is a form titled 'Account Information' containing two input fields: 'Username:' and 'Password:'. A 'Log In' button is located at the bottom right of the form.

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

- If you have multiple projects using TRuST you will need to select the STAR-COVID19 trial from the dropdown menu.



The screenshot shows the TRuST (Tayside Randomisation System) interface. At the top, the logo for 'trust' is displayed in red and blue, with 'Tayside Randomisation System' written below it. Below the logo is a section titled 'Project Selection'. Inside this section, there is a 'Select Project:' label followed by a dropdown menu. The dropdown menu is open, showing three options: 'Please Select...', 'Adapt Test', and 'LACE Test'. To the right of the dropdown menu is a 'Confirm Project' button.

- Main menu

Site: Tayside

RANDOMISATION

Randomise Participant Randomisation Details Drug Accountability

Click randomise participant.

## RANDOMISE PARTICIPANT

Initials:

First and last initial should be entered

Date of Birth:

Gender:

 Male  Female

[Return to Main Menu](#)

[Next](#)

- Enter participant details.

- Click next



## RANDOMISE PARTICIPANT

Site: 01 Tayside

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

[Return to Main Menu](#)

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

[Randomise](#)

[Return to Main Menu](#)

- Enter participant ID. The first number is provided and is the site number (here 01). Enter the 3 further digits. E.g. for the first patient consented enter “001”.
- To confirm what Participant IDs have already been used at your site, go back to main menu and click randomisation details.
- Select whether participant’s CURB65 score is ‘less than 3’ or ‘3 to 5’.
- Confirm that the patient is eligible **and that this is confirmed in the medical record by a doctor delegated this task**

- Once the details are entered the “Randomise” button will appear – click to randomise

Site: 01 Tayside

Subject Identifier: 01100

Randomisation Allocation: Participant Successfully Randomised

Pack ID: 00006

[Return to Main Menu](#)

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

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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<b>Complete at Time of Bottle Dispensing</b>	
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

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

Site: Tayside

RANDOMISATION

Randomise Participant **Randomisation Details** Drug Accountability

- Details of all participants randomised at site will be shown

Site: Tayside

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RANDOMISATION

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

- To check Drug Accountability for participants at site go back to main menu and click the Drug Accountability button
- Drug accountability can be checked for site or individual participant
- 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: 01020

- 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: 01020

Participant ID	Pack ID	Date Allocated	By
01020	00003	28/07/2020	rSTARCOVID

- Pack ID issued for that participant will be displayed

- The TRuST User guide contains further contact and trouble shooting information