

STOP- COVID19

Superiority Trial
Of Protease
inhibition in
COVID-19

Randomisation using the Tayside
Randomisation System (TRuST)



University
of Dundee



Randomisation: Requirement

- Delegated to randomise on Delegation Log
- Randomisation training completed – this presentation and read the TRuST User Guide
- Medical Record signed by PI/delegate confirming eligibility
- Internet access
- TRuST log-in
- Participant ID
- Printer

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Randomisation: TRuST System

- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST> or from the STOP-COVID19 website <http://www.stop-covid19.org.uk>
- 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.
- TRuST User Guide is provided with the documents for the ISF



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



trust
Tayside Randomisation SysTem

[Log In] [Forgotten Password]

LOG IN

Please enter your username and password.

Account Information

Username:

Password:

Log In

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

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Randomisation: TRuST System

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



trust
Tayside Randomisation System

Project Selection

Select Project: Please Select... Confirm Project

Please Select...
Adapt Test
LACE Test

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Randomisation: TRuST System

- Main menu.

Site: Tayside

RANDOMISATION

Randomise Participant Randomisation Details Drug Accountability

- Click randomise participant.

Randomisation: TRuST System

- Enter participant details.
- Click next
- Enter participant ID. The first number is provided and is the site number. 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.
- Enter participant’s age
- Confirm that the patient is eligible and that this is confirmed in the medical record by a doctor

RANDOMISE PARTICIPANT

Initials:

First and last initial should be entered

Date of Birth:

Gender:

 Male Female

[Return to Main Menu](#)

[Next](#)

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](#)

Randomisation: TRuST System

RANDOMISE PARTICIPANT

Site: Tayside

Participant ID: 010 1 2

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](#)

Site: Tayside

Subject Identifier: 01012

Randomisation Allocation: Participant Successfully Randomised

Pack ID: 50010

[Return to Main Menu](#)

- A randomise button will appear – click to randomise.
- Randomisation will be confirmed and the pack ID assigned to this individual will be displayed
- You will receive an email confirming this allocation

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Randomisation: TRuST System

STOP-COVID19: Superiority Trial of Protease inhibition in COVID-19
CLINICAL TRIAL REQUEST FORM

EudraCT	2020-001643-13	Sponsor	University of Dundee and NHS Tayside
IRAS	281986	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	Brensocatib (IN S1007) / Placebo 1 bottle of 35 tablets
Dose	25mg – 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 STOP-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

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Randomisation: TRuST System

- 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

Randomisation: TRuST System

Site: Tayside

RANDOMISATION

Randomise Participant Randomisation Details **Drug Accountability**

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

- 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 ID for all drug allocated at site will listed with participant ID

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Randomisation: TRuST System

Select Accountability by: Participant ▼

Select Participant: Select a Participant ID ▼

Select Participant: 01012 ▼

Confirm Participant ID

Confirm Participant ID: 01012

Participant ID: 01012

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

- 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
- Pack ID issued for that participant will be displayed

Randomisation: TRuST System

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

