

STOP- COVID19

Superiority Trial
Of Protease
inhibition in
COVID-19

Emergency unblinding procedure



University
of Dundee



- Unblinding for the STOP-COVID19 trial will be carried out using the web-based Tayside Randomisation System (TRuST)
- Unblinding can be carried out by the PI or other research staff listed on the delegation log
- Any person delegated to carry out emergency unblinding must have completed training, including a test unblinding

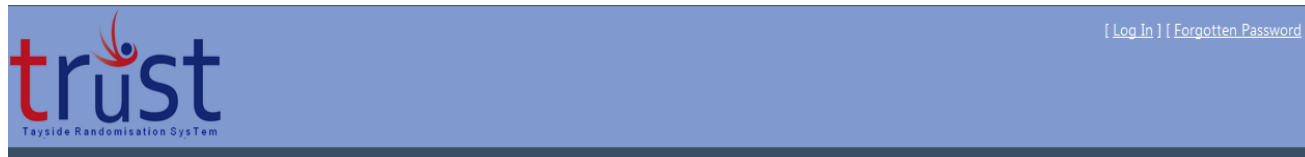


- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST> or from the STOP-COVID19 website <http://www.stop-covid19.org.uk>
- Trust Unblinding User Guide is located in the ISF
- Login details for emergency unblinding are detailed on the Emergency Unblinding Procedure document, located in the ISF, section 9



Unblinding procedure

- Login with the username and password found in the Emergency Unblinding Procedure document in section 9 of the ISF



LOG IN

Please enter your username and password.

Account Information

Username:

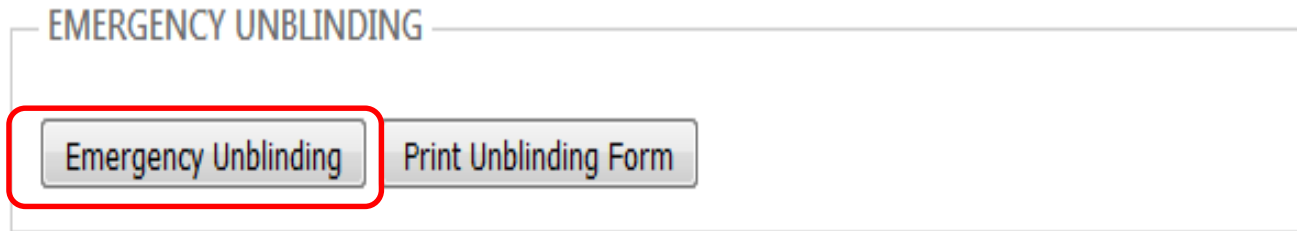
Password:

Please enter your name:

- When prompted, enter your name

Unblinding procedure

- Main menu.



- Click emergency unblinding.

Unblinding procedure

EMERGENCY UNBLINDING

Requester Details

Person Requesting the Unblinding(Name):

Role:

Contact Number:

Email:

Reason for code break?:

- Details of person requesting unblinding

Participant Details

Gender: Male Female

Date of Birth:

Initials: *First and last initial should be entered*

Participant ID Known: Yes No

Pack ID Known: Yes No

- Enter participant details
participant ID if known (dropdown menu)
pack ID if known



Unblinding procedure

Are you sure you want to unblind? Yes No

Are you sure you want to unblind? Yes No

Unblind Participant

- Select yes if you are sure you have the correct details and wish to unblind.
- Unblind participant button appears
- Click unblind participant

Unblinding procedure

EMERGENCY UNBLINDING

Unblinding Result

Participant: 01025
Allocation: Placebo 25mg once daily

[Return to Main Menu](#) [Print Unblinding Form](#)

- The unblinding result will be displayed.
- If no match found, or more than one match found, 'unable to match unless patient ID or bottle number known' will be displayed
- Select print unblinding form

Unblinding procedure

EMERGENCY UNBLINDING FORM

Unblinding should only occur when patient safety is compromised. Ensure there is a genuine need to perform unblinding

Sponsor	University of Dundee and NHS Tayside		
Protocol No.	2016RC27	EudraCT	2018-001590-24
Chief Investigator	Prof James Chalmers	IRAS	252929

Person Performing the Unblinding:	uVitalBE - M Band
Person Requesting the Unblinding:	M band
Role:	CI
Contact Number:	01382 383097
Email:	m.band@dundee.ac.uk
Reason for Unblinding Request:	Medical emergency
Date of Request:	30/07/2019

Study Participant ID:	01678	Site:	Royal Brompton
Pack ID:	Not Provided		
Date of birth:	08/07/2019	Initials:	qw
Gender:	Male		

Unblinding Result

Cayston three times per day/Cayston twice per day/Placebo three times per day/Placebo twice per day	Cayston twice per day
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TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

Download Date: 30/07/2019 16:44:38

- Emergency unblinding form will be generated
- Check details are correct
- Print form
- Complete “Performed by” section at end
- Place in sealed envelope labelled with participant’s ID number and “Emergency unblinding details – do not open unless information required for clinical purposes”.
- File in ISF section 9.2.

Unblinding procedure

- If participant ID and pack ID are not available, unblinding can be performed using participant identifiers: gender, date of birth and initials
- If it is not possible to print unblinding form immediately the form will be available on TRuST for 24 hours and MUST be completed in that time
- If internet access is possible but TRuST is inaccessible please contact the Clinical Trial Manager or Chief Investigator during working hours. Out of working hours please contact the NHS Tayside on-call pharmacist

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

Chief Investigator, Professor James Chalmers: 0774 0124 122
j.chalmers@dundee.ac.uk

NHS Tayside On-call Pharmacist 01382 660111 ask for On-call Pharmacist