



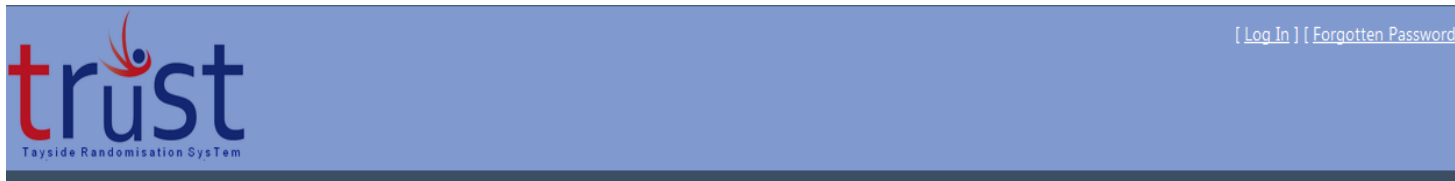
SFX-01 treatment for
**Acute Respiratory
Infections** (STAR-
Covid19)

Emergency unblinding procedure

- Unblinding for the STAR-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

- The Tayside Randomisation System (TRuST) can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST> or from the STAR-COVID19 website
- Login details for emergency unblinding are detailed on the Emergency Unblinding Procedure document, located in the ISF, section 9
- The TRuST Unblinding User Guide is located in the ISF

- 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

- Main menu

EMERGENCY UNBLINDING

Emergency Unblinding

Print Unblinding Form

- Click emergency unblinding

EMERGENCY UNBLINDING

Requester Details

Person Requesting the Unblinding(Name):

Role:

Contact Number:

Email:

Reason for code break?:

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 details of person requesting unblinding
- Enter
participant details
participant ID if known (dropdown menu)
pack ID if known

Are you sure you want to unblind? Yes No

- Select yes if you are sure you have the correct details and wish to unblind.

Are you sure you want to unblind? Yes No

Unblind Participant

- Unblind participant button appears
- Click unblind participant

EMERGENCY UNBLINDING

Unblinding Result

Participant: 01060

Allocation: SFX01 300mg 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

- Click print unblinding form

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.	1.002.20	EudraCT	2020-003486-19
Chief Investigator	Prof James Chalmers	IRAS	286251

Person Performing the Unblinding:	uSTARCOVID - Sarah		
Person Requesting the Unblinding:	Sarah Inglis		
Role:	Sponsor		
Contact Number:	01382383219		
Email:	s.k.inglis@dundee.ac.uk		
Reason for Unblinding Request:	Medical emergency		
Date of Request:	25/08/2020		

Study Participant ID:	01060	Site:	01 Tayside		
Pack ID:	Not Provided				
Date of birth:	04/05/1948	Initials:	jj	Gender:	Female

Unblinding Result

SFX01 300mg once daily/Placebo 300mg once daily	SFX01 300mg once daily
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TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

Download Date: 25/08/2020 16:03:11

- 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

- 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: star-covidTM@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