



Value of inhaled treatment with
aztreonam lysine in bronchiectasis

TRuST: Unblinding

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- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST>
- Login details for unblinding will be different from TRuST access for researchers/pharmacy
- The password can be changed on the TRuST login screen, top right.
- Please refer to VitalBE Trust Unblinding User Guide

TRuST: Unblinding

- Emergency unblinding will be carried out by the PI or delegate.
- Any clinician requiring emergency unblinding of a participant should, where possible, discuss this with the Principal Investigator, however, this should not stall or delay in any way the unblinding of trial participant treatment in an emergency situations.
- If unblinding is required, the clinician should contact the local PI or delegate.
- TRuST access will be provided to the local PI for individual participant unblinding in the event of a medical emergency.
- Responsibility of the local PI to ensure that adequate training and instructions are given for anyone delegated this role to enable them to access and perform the emergency unblinding procedure.
- The CI is also able to unblind all participants across all sites if required.
- Unblinding result should be disclosed only to individuals involved in the participant's care.
- Where possible, the participant should remain blinded and continue with the trial visits.

TRuST: Unblinding

- Login to TRuST using emergency unblinding login details (this can be found in section 9 of ISF)



LOG IN

Please enter your username and password.

Account Information

Username:

Password:

Log In

- Click “Emergency Unblinding”



EMERGENCY UNBLINDING

Emergency Unblinding

Print Unblinding Form

TRuST: Unblinding

Complete:
Requester Details

Participant Details if known

Participant's ID* if known
(drop down menu)

Pack ID* if known

*If not known click "no"

Select "yes" for "Are you sure you want to unblind?"

"Unblind Participant" button will display – click to complete 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

Are you sure you want to unblind? Yes No

TRuST: Unblinding

- Click “Print Unblinding Form”
- Download & print the record of the unblinding



EMERGENCY UNBLINDING

Unblinding Result

Participant: 09007
Allocation: Aztreonam Lysine (Cayston) for inhalation 75mg three times per day

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

TRuST: Unblinding

The emergency unblinding results will be visible

- Sign & date the emergency unblinding form
- Inform treating clinician of unblinding result
- Document unblinding date and reason for unblinding in the participant's medical records
- The result should not be documented so not to unblind research team
- File emergency unblinding form in a sealed envelope in the ISF
- Sponsor, CI and PI will be notified of emergency unblinding occurring, but not of the result, by automatic email from TRuST

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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:	euvb2 - Fiona McLaren-Neil
Person Requesting the Unblinding:	Fiona McLaren-Neil
Role:	Trial Manager
Contact Number:	01383383830
Email:	fmclarenneil@dundee.ac.uk
Reason for Unblinding Request:	test
Date of Request:	01/02/2023

Study Participant ID:	09007	Site:	Tayside		
Pack ID:	Not Provided				
Date of birth:	11/11/1980	Initials:	GH	Gender:	Female

Unblinding Result

Aztreonam Lysine (Cayston) for inhalation 75mg three times per day/Matched placebo three times per day	Aztreonam Lysine (Cayston) for inhalation 75mg three times per day
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TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

Download Date: 01/02/2023 16:37:01