



Tayside Randomisation and Stock Control System (TRuST)

Research Nurse Users Guide





Contents

ntroduction to TRuST	2
Getting Started	3
Randomise a Participant	4
Printing Participant and Nurse Appointment Sheets	7
Recording Subsequent Visits	8
Re-order Lost Drugs	9
Recording that a Participant has stopped taking their trial drugs1	0
Trouble Shooting & Contacts1	1

Introduction to TRuST

TRuST is the web-based randomisation and stock control system being used by Research Nurses and Clinical Trial Pharmacy Staff for all sites participating in the VitalBE trial.

In the Clinical Trial Pharmacies TRuST will be used for

- stock control
- drug accountability
- generating Clinical Trial Release Forms and
- documenting returns and IMP destruction.

The Research Nurses at all sites participating in the VitalBE trial will use TRuST for the following activities:

- Randomisation of participants.
- Printing of Participant Appointment and Nurse Appointment sheets.
- Printing Clinical Trial Request Forms to request IMP from the Clinical Trial Pharmacies.
- Re-ordering IMP lost by a participant.
- Recording that a participant has stopped their trial medication.

TRuST is designed to have automatic stock control with stock being delivered to sites as required for both new participants and when new supplies are required for existing participants. The system will not allow the release of IMP which would expire within the time the participant requires it.

TRuST has a system of email alerts built-in to notify the research team on several occasions. The Research Nurses will be informed when:

- Participant has been randomised.
- Participant has had a visit recorded.





Emails generated by TRuST should either be printed and filed in the ISF or held electronically with a file note in the ISF stating where they are held.

The Clinical Trial Manager and trial monitors will have access to TRuST to enable them to check randomisation and drug accountability remotely.

Getting Started

You will be issued with a log in and password for the TRuST system.

Go to <u>https://hicservices.ac.uk/TRuST</u> and log in using the username and password assigned to you.

If this is the first time you are logging in to TRuST you will be asked to change your password.

If you forget your password:

- Click on forgotten password from the top right menu bar.
- A new password will be emailed to you.

If you already have access to TRuST for other trials please log in using your current user name and password, and in **Project Selection** choose VitalBE from the drop-down list.

The first page will display a menu of options, return to this page to start each task.

RANDOMISATION
Randomise Participant Randomisation Details Drug Accountability
Record Visit Discontinued Study Drugs Re-order Lost Drugs
Print Participant Appointments Print Nurse Appointments Print Request Form

When finished all task click Log Out



The system will automatically log out a user if there has been no activity for 10 minutes.





Randomise a Participant

From the main menu select "randomise participant"

RANDOMISATION
Randomise Participant Randomisation Details Drug Accountability
Record Visit Discontinued Study Drugs Re-order Lost Drugs
Print Participant Appointments Print Nurse Appointments Print Request Form

Enter the details to confirm eligibility criteria.

Once complete, click next.

Randomise Participant		
Participant Identifiers		
Initials:		
First and last initial should be entered		
Gender:	◎ Male ◎ Female	
L		
— Eliqibility Criteria		
Has the participant had a CT scan of t	the chest demonstrating bronchiectasis in 1 or more lobes in the past?	© Yes ◎ No
Does the participant have a history of	f at least 3 exacerbations in the past 12 months?	© Yes ◎ No
Has Pseudomonas aeruginosa or othe	er Gram-negative respiratory pathogen been detected in sputum or bronchoalveolar lavage in the past 12 months?	© Yes ◎ No
Has the participant been treated with	anti-biotics within the last 28 days?	© Yes ◎ No
Date of sputum sample that is culture	e positive for P. aeruginosa or other Gram-negative respiratory pathogens (must be within 28 days)	
Bronchiectasis severity index at scree	ning	
FEV1 % predicted at screening visit		
eGFR at screening visit		
Return to Main Menu Next		

The system will then check for blanks and ensure the eligibility criteria fall in the allowed ranges. Prompts will appear in red at the bottom of the page. If the eligibility criteria has not been met the following message will appear 'Values entered are outwith the eligibility criteria'

Ensure all values have been entered correctly, if the values are correct the participant is not eligible and should not be randomised.





If the participant is eligible the following screen will appear:

Randomise Participant	The subject ID is made up of the two-digit
Site: Royal Brompton	site ID (automatically generated by TRuST)
Participant ID: 01	number allocated to participant at site.
Was Pseudomonas aeruginosa present in sputum at screening?: $ {igodot}$ Yes	
© No	This information is required for allocation of
Is the participant on macrolide treatment?:	the IMP, active/placebo groups are matched
O No	on these criteria.
Has the CI/PI signed CRF to confirm eligibility of participant? \bigcirc Yes \bigcirc No \checkmark	
Does the participant meet eligibility critera?	These two questions must be answered
Return to Main Menu	"yes" to allow the participant to be
	randomised.

If all questions are completed, the **randomise** button will appear. Click on this, and it will change to **processing**.

It may take a few minutes to check stock, allocate IMP and send emails.

If you are unsure if randomisation has taken place check the **Randomisation Details** by selection from the main menu to ensure duplicate randomisation does not take place.

RANDOMISATION
Randomise Participant Randomisation Details Drug Accountability
Record Visit Discontinued Study Drugs Re-order Lost Drugs
Print Participant Appointments Print Nurse Appointments Print Request Form

Once the participant has been randomised the following screen will appear:

RANDOMISE PARTICIPANT
Site: Royal Brompton
Subject Identifier: 01793
Randomisation Allocation: Participant Successfully Randomised Record Visit

You should receive a confirmation with the randomisation information.

Click on Record Visit







The screen will now display the pack allocation. Click **Print Request** – this will generate a PDF of the Clinical Trial Request form which you can download and print.

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Add participant name and hospital number/CHI (other fields will be auto filled by TRuST)

The form should be signed and dated by a doctor on the delegation log. For visits 3 onwards this may be done up to 7 days prior to the visit date

The form should be signed and dated by the RN on the day of the participants visit to confirm that it is still appropriate for the participant to receive the IMP

Figure 1

The Request Form should only be signed by those people delegated to this task on the Delegation log.





The completed and signed Request Form should be taken to Clinical Trial Pharmacy and trial drugs collected as per the usual local practice. The Clinical Trial Request Forms will be filed in the Pharmacy Site File (PSF).

Printing Participant and Nurse Appointment Sheets

From the randomisation page it is also possible to **Print Participant Appointment** Sheet for the participant and **Print Nurse Appointment** Sheet if wished. This gives the dates that the participant visits are due and the actual date and time of the participant's next visit can be completed.

The "Print Participant Appointments" and "Print Nurse Appointments" are also available from the main menu page.

RANDOMISATION			
Randomise Participant Randomisation Details Drug Accountability			
Record Visit Discontinued Study Drugs Re-order Lost Drugs			
Print Participant Appointments Print Nurse Appointments Print Request Form			

Value of inhaled treatment wit	VISIT SCHEDULE						
Value of inhaled treatment wit							
	h Aztreonam lysine in bronchie	tasis- VITAL- BE					
I'm cu V Cayst	rrently taking part in the ItalBE Clinical Trial. I am taking either on or Placebo nebulisers						
	www.vitalbe.org.uk		V I CONDL	VIET COU			
Chief Investigator: Pr Local Principal Investigator: Research Nurse: Local Tel: Email:	of James Chaimers		Value of inhaled trea	visit schi	n lysine in bronc	hiectasis- VITAL- E	BE
Participant: Participant ID:							
Visit Name Vi Visit 1 H	sit Type Due Date ospital	Date of Visit Time	Participant: Participant ID:	01001			
Visit 2 H/	ospital		. a. deipune ibi	01001			
0	omplete		Visit Name	Visit Type	Due Date	Date of Visit	Time
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Click "Return to Main Menu to continue in the system or Log out if finished.





Recording Subsequent Visits

For all visits following randomisation click on **Record Visit** button from the main menu.

RANDOMISATION	
Randomise Participant Randomisation Details	5 Drug Accountability
Record Visit Discontinued Study Drugs Re-	-order Lost Drugs
Print Participant Appointments Print Nurse Ap	pointments Print Request Form
From the drop-down menu select Participant ID	trust Tayaide Randomisation System Record Visit
	Participant Selection Select Participant ID
Tayside Randomisation Bystem	Return to Main Menu
Cr Participant Selection Select Participant: 15001 Confirm Participant ID ConfirmParticipant ID: 15001	Record Visit
Return to Main Menu	Participant ID: 01738 Visit 3
Click on Record Visit	Record Visit Return to Main Menu





Once you click **RECORD VISIT** the pack allocation will be displayed.

Click **Print Request** to generate a PDF of the Clinical Trial Request Form. Download and complete the form as detailed in figure 1.

Record Visit
Participant ID: 01738 Visit 3
Record Visit
Pack Allocation
0039
0041 0043
Print Request
Return to Main Menu

Re-order Lost Drugs

PANDOMISATION
Randomise Participant Randomisation Details Drug Accountability
Description Discretioned Charles Description
Record Visit Discontinued Study Drugs Re-order Lost Drugs
Print Participant Appointments Print Nurse Appointments Print Request Form
This raidepart Appointments This raise Appointments

From the drop-down menu select **PARTICIPANT ID**

Tick Confirm Participant ID

The Participant ID and pack list will be displayed.

Select the Pack(s) Lost

Click on Record Lost Drugs

Participant: 01738
Visit: 3 Replacement
Packs Lost:
0039
0041
0043
Record Lost Drugs
Record Lost Drugs Return to Main Menu





A new Pack Allocation will be displayed.	LOST DRUGS REORDER
Click on Print Request	Pack Allocation
This will change to Processing.	0.015
This will generate a PDF to download and complete.	Print Request
Once completed take the Clinical Trial Request Form to	
Pharmacy for replacement drug to be issued.	Return to Main Menu

Recording that a Participant has stopped taking their trial drugs

If a participant stops taking their trial drugs for whatever reason this should be entered into TRuST e.g. participant does not wish to continue on trial drugs, participant dies, GP or other doctor stops their trial drugs. Where possible the participant should always be encouraged to continue with their trial visits.

From main menu click Discontinued Study Drugs

From drop-down Select Participant ID

Tick to Confirm Participant ID

Click Discontinued Study Drugs

Select which drug(s) are to be discontinued.

DISCONTINUED STUDY DRUGS Participant: 01738 Discontinued Study Drugs

Return to Main Menu

A screen appears confirming that the participant has discontinued their trial drugs. An email will be sent to your Clinical Trial Pharmacy. After you have entered a participant as discontinued trial drugs on TRuST the participant **cannot** restart their trial drugs

DISCONTINUED STUDY DRUGS Participant: 01738 - discontinued study drugs

Return to Main Menu





Trouble Shooting & Contacts

Requests for new user accounts should be emailed to the Clinical Trial Manager (see below). Please include the person's full name and email address and role in the trial. Before user accounts will be issued the Clinical Trial Manager will require a copy of the Delegation Log and Training Logs to confirm the person has been delegated the role and has had training in using TRuST.

Please see Operations Manual if unable to access TRuST for the process of randomising participants or requesting new IMP supplies.

If internet access is possible but the TRuST system is not working please contact the Clinical Trial Manager.

For all other activities please wait and complete the tasks when access to TRuST is re-established.

Sites will be informed of any planned downtime for TRuST.

The Clinical Trial Manager will inform sites as soon as they are aware that TRuST is down and will notify them when this is corrected.

Clinical Trial Manager: Fiona McLaren-Neil (t) 01382 383830 email: respiratorytrials@dundee.ac.uk

Clinical Trial Co-ordinator Bakhtawar Abid (t) 01382 388317 email: respiratorytrials@dundee.ac.uk