Tayside Randomisation and Stock Control System (TRuST)

Research Nurse Users Guide

Contents

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

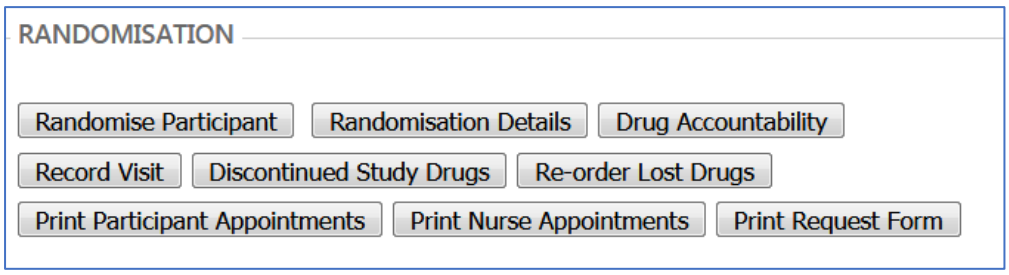
If this is the first time you are logging in to TRuST you will be asked to change your password.

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.

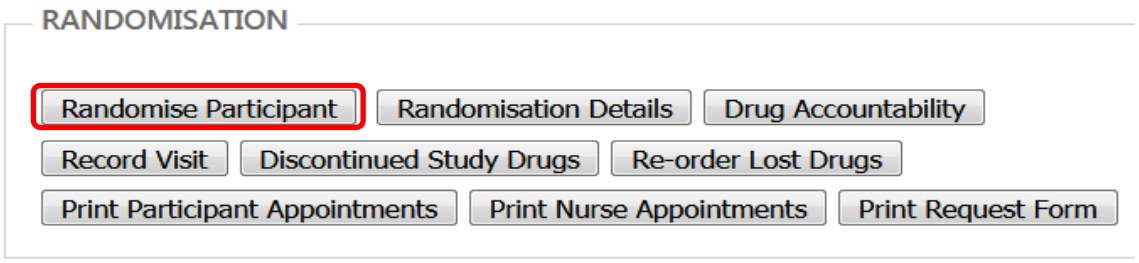


When finished all task click **Log Out**

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

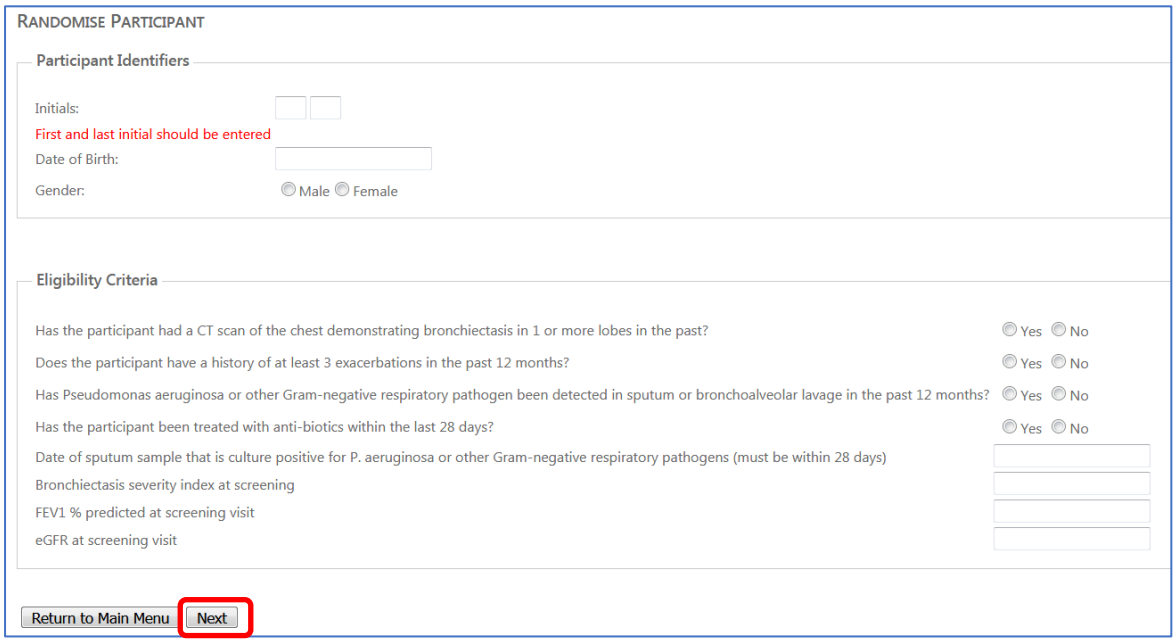
Randomise a Participant

From the main menu select “randomise participant”



Enter the details to confirm eligibility criteria.

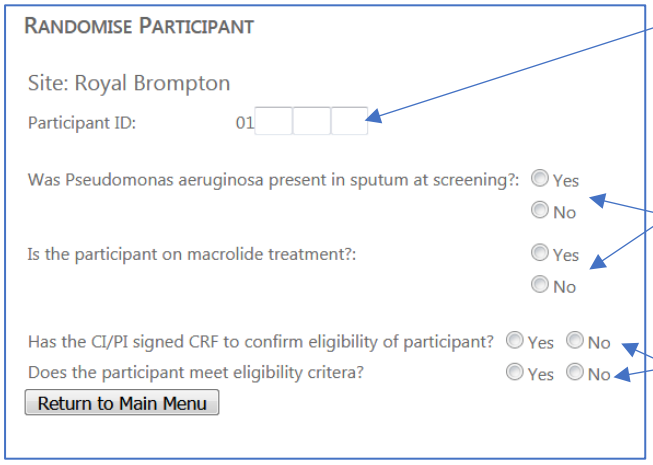
Once complete, click **next.**



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:



The subject ID is made up of the two-digit site ID (automatically generated by TRuST) and the remaining three digits from the ID number allocated to participant at site.

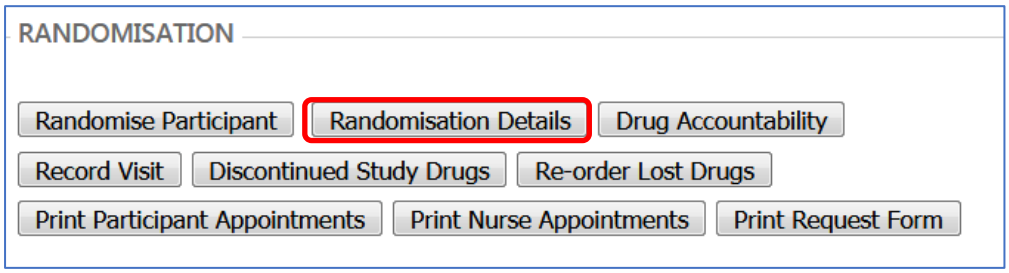
This information is required for allocation of the IMP, active/placebo groups are matched on these criteria.

These two questions must be answered "yes" to allow the participant to be randomised.

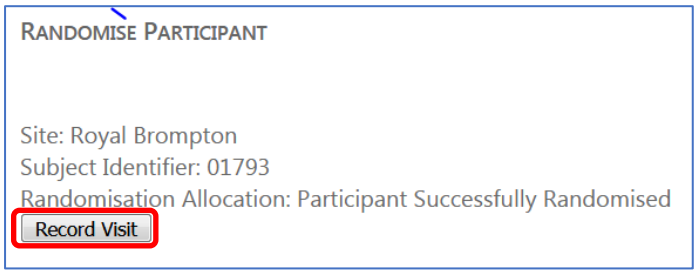
If all questions are completed, the **randomise** button will appear. Click on this, and it will change to **processing**.

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.



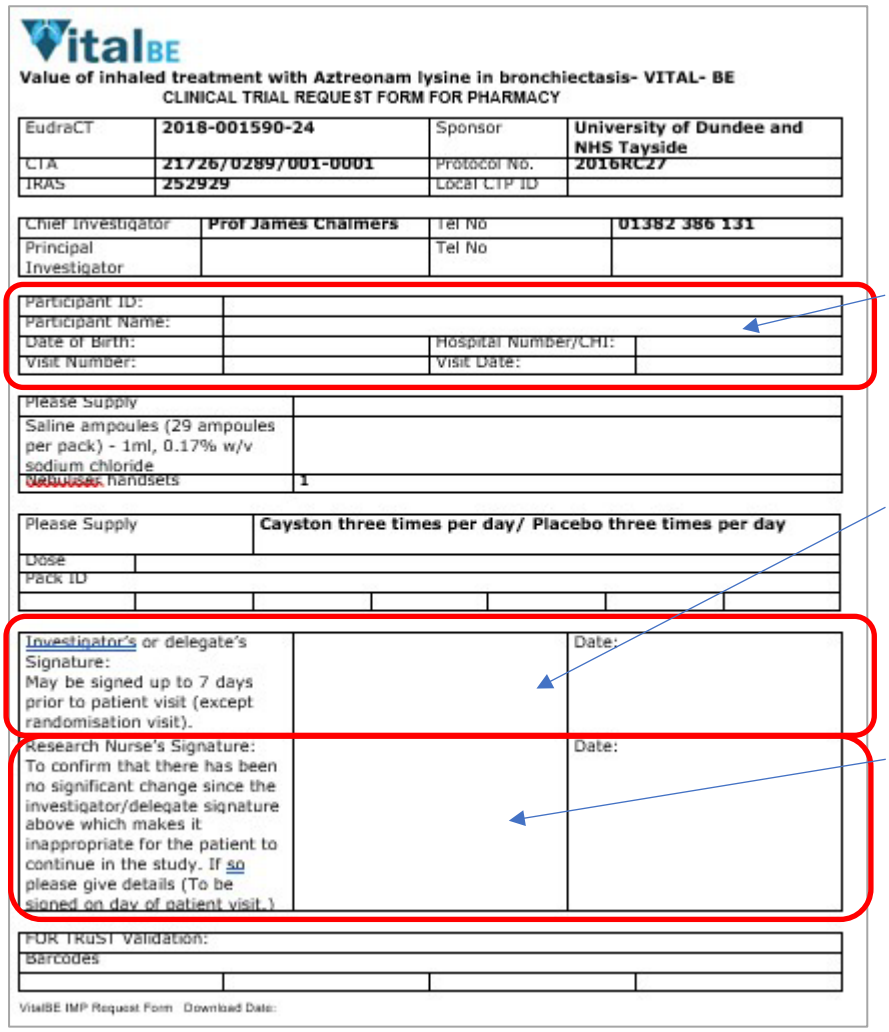
Once the participant has been randomised the following screen will appear:



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.



Value of inhaled treatment with Aztreonam lysine in bronchiectasis- VITAL- BE
CLINICAL TRIAL REQUEST FORM FOR PHARMACY

EudraCT	2018-001590-24	Sponsor	University of Dundee and NHS Tayside
CTA	21726/0289/001-0001	Protocol No.	2016RC27
IRAS	252929	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:	
Visit Number:		Visit Date:	

Please Supply	
Saline ampoules (29 ampoules per pack) - 1ml, 0.17% w/v sodium chloride	
Nebuliser handsets	1

Please Supply	Cayston three times per day/ Placebo three times per day
Dose	
Pack ID	

Investigator's or delegate's Signature: May be signed up to 7 days prior to patient visit (except randomisation visit).		Date:
Research Nurse's Signature: To confirm that there has been no significant change since the investigator/delegate signature above which makes it inappropriate for the patient to continue in the study. If so please give details (To be signed on day of patient visit.)		Date:

FOR TRuST Validation:			
Barcodes			

VitalBE IMP Request Form Download Date:

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

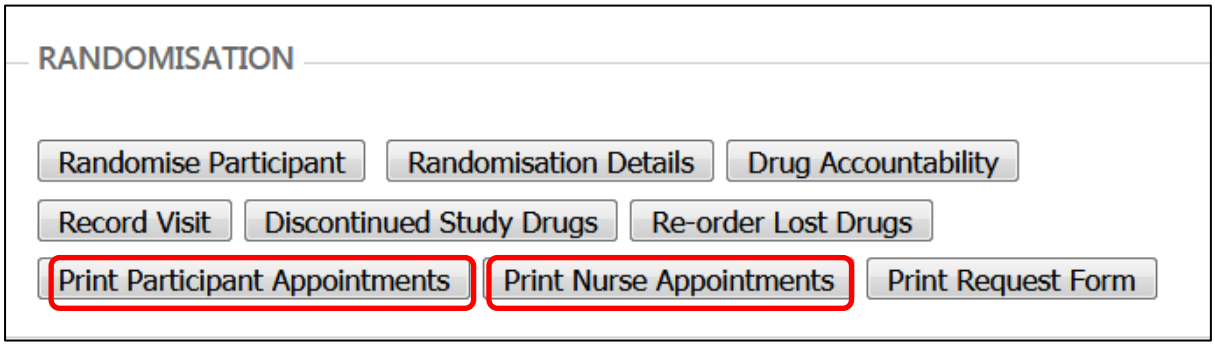
The Request Form should only be signed by those people delegated to this task on the Delegation log.

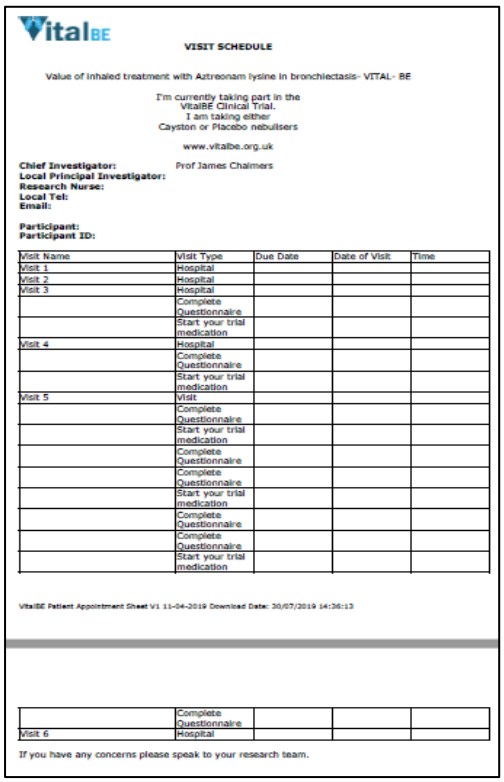
The completed and signed Request Form should be taken to Clinical Trial Pharmacy and trial drugs collected as per the usual local practice. The Clinical Trial Request Forms will be filed in the Pharmacy Site File (PSF).

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.





VitalBE

VISIT SCHEDULE

Value of inhaled treatment with Aztreonam lysine in bronchiectasis- VITAL- BE

I'm currently taking part in the VitalBE Clinical Trial.
I am taking either Cayston or Placebo nebulisers

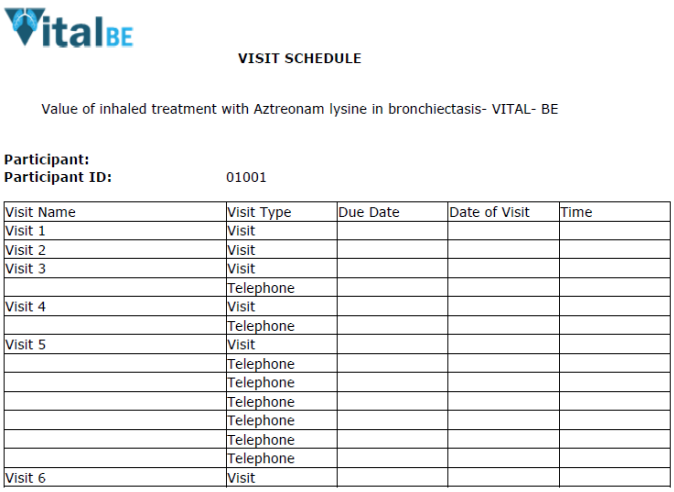
www.vitalbe.org.uk

Chief Investigator: Prof James Chalmers
Local Principal Investigator:
Research Nurse:
Local Tel:
Email:

Participant:
Participant ID:

Visit Name	Visit Type	Due Date	Date of Visit	Time
Visit 1	Hospital			
Visit 2	Hospital			
Visit 3	Hospital			
	Complete Questionnaire			
	Start your trial medication			
Visit 4	Hospital			
	Complete Questionnaire			
	Start your trial medication			
Visit 5	Visit			
	Complete Questionnaire			
	Start your trial medication			
	Complete Questionnaire			
	Complete Questionnaire			
	Start your trial medication			
	Complete Questionnaire			
	Complete Questionnaire			
	Start your trial medication			
	Complete Questionnaire			
Visit 6	Hospital			

If you have any concerns please speak to your research team.



VitalBE

VISIT SCHEDULE

Value of inhaled treatment with Aztreonam lysine in bronchiectasis- VITAL- BE

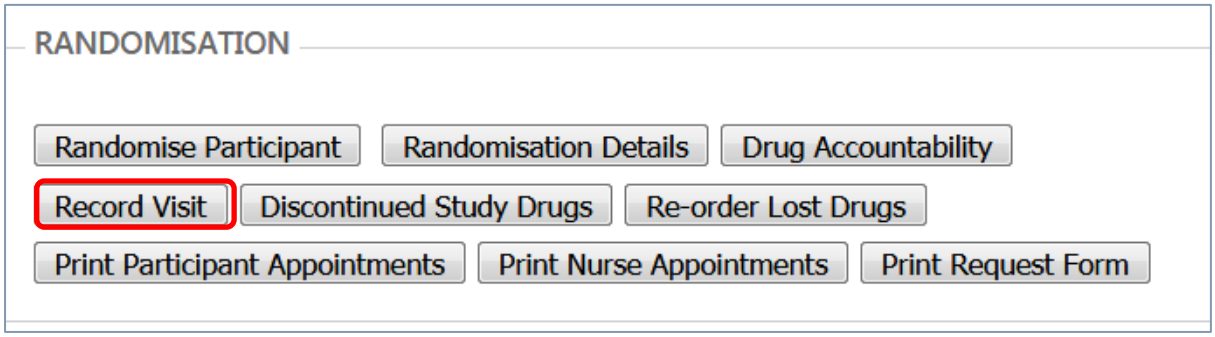
Participant:
Participant ID: 01001

Visit Name	Visit Type	Due Date	Date of Visit	Time
Visit 1	Visit			
Visit 2	Visit			
Visit 3	Visit			
	Telephone			
Visit 4	Visit			
	Telephone			
Visit 5	Visit			
	Telephone			
	Telephone			
	Telephone			
	Telephone			
	Telephone			
	Telephone			
Visit 6	Visit			

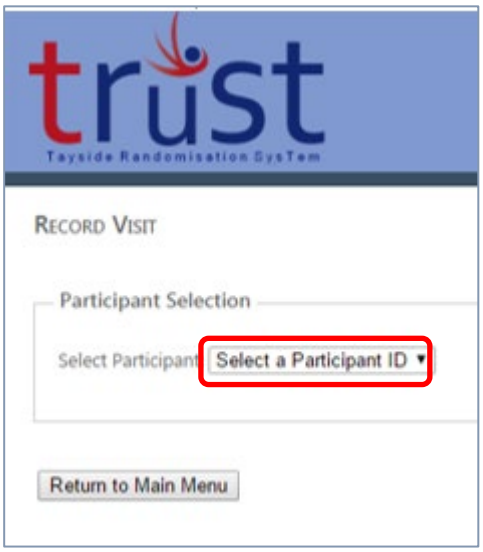
Click "Return to **Main Menu** to continue in the system or **Log out** if finished.

Recording Subsequent Visits

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



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



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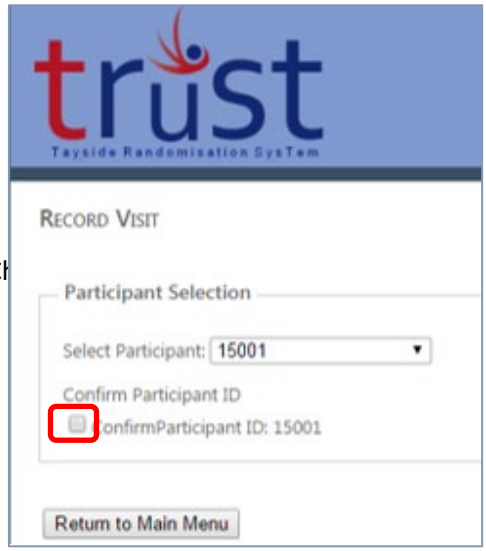
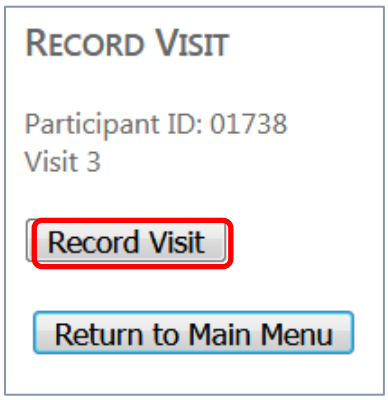
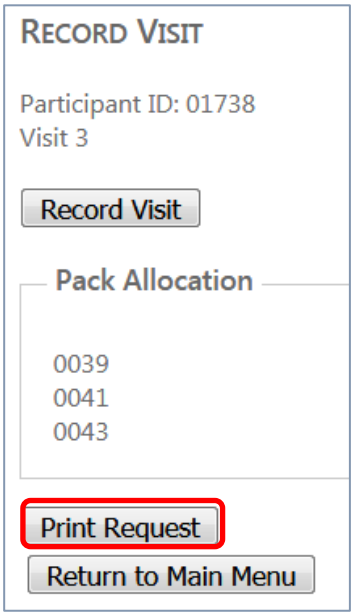


Click on **Record Visit**

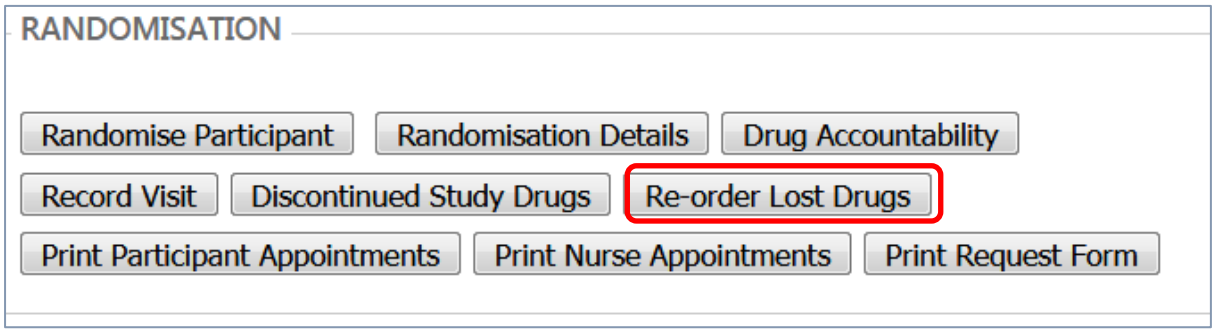


Once you click **RECORD VISIT** the pack allocation will be displayed.

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



Re-order Lost Drugs



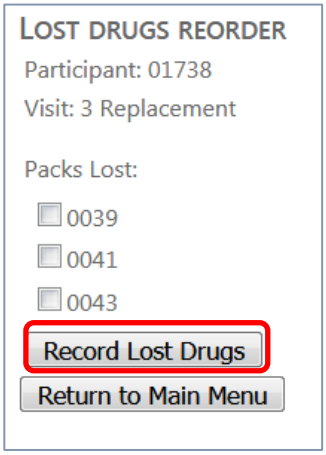
From the drop-down menu select **PARTICIPANT ID**

Tick **Confirm Participant ID**

The Participant ID and pack list will be displayed.

Select the Pack(s) Lost

Click on **Record Lost Drugs**



A new Pack Allocation will be displayed.

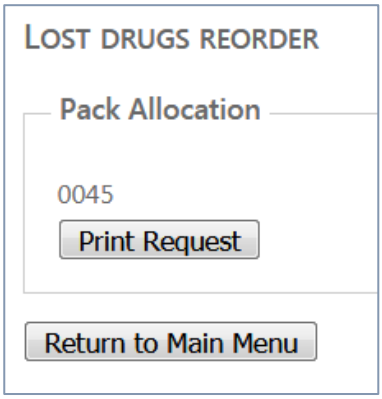
Click on **Print Request**

This will change to **Processing.**

This will generate a PDF to download and complete.

Once completed take the Clinical Trial Request Form to

Pharmacy for replacement drug to be issued.



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.

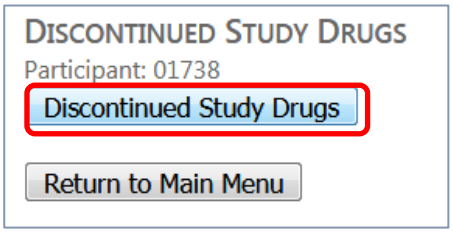
From main menu click **Discontinued Study Drugs**

From drop-down **Select Participant ID**

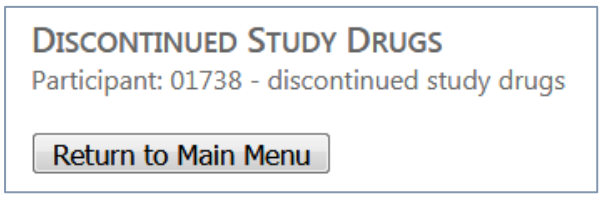
Tick to Confirm **Participant ID**

Click **Discontinued Study Drugs**

Select which drug(s) are to be discontinued.



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



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