Tayside Randomisation and Stock Control System (TRuST)
Pharmacy Users Guide

Contents

1. Introduction to TRuST

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

Research Nurses:

- randomise participants.
- Printing appointment sheets
- print Clinical Trial Request Forms.
- Stock control (re-order lost drugs)

Pharmacists:

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

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

TRuST is designed to have automatic stock control with stock being delivered to sites as required for new participants and when new supplies are required for existing participants. If recruitment is exceptionally slower than anticipated the site will have IMP due to expire. 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 Clinical Trial Pharmacies on several occasions. The CTP will be informed when:

- Deliveries of IMP are being sent.
- Inconsistency between IMP sent and IMP entered into TRuST.
- Research Nurses have requested replacement supplies for lost drugs.
- Participant has withdrawn.
- IMP has expired and requires disposal.
- Emergency recall of IMP.

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

2. Getting Started

2.1 Logging in

Go to TRuST https://hicservices.dundee.ac.uk/TRuST

Log in using your username and password. If you have multiple projects using TRuST you will need to select VitalBE from the drop-down menu.

For those staff using the generic login you will be required to enter your name before starting any tasks

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

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

2.2 Main menu

All actions can be accessed from the menu of options, return to this page to start each task.

2.3 Logging out

click Log Out when finished.

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

3. IMP Stock Management

3.1 Recording Drugs Received

You will receive an email confirmation of IMP dispatched by Sharp. On receipt of the IMP Sharp Clinical Services should be notified of deliveries received as per IMP Management Plan Section 3. Please see IMP Management Plan for details of quantities and timing of deliveries.

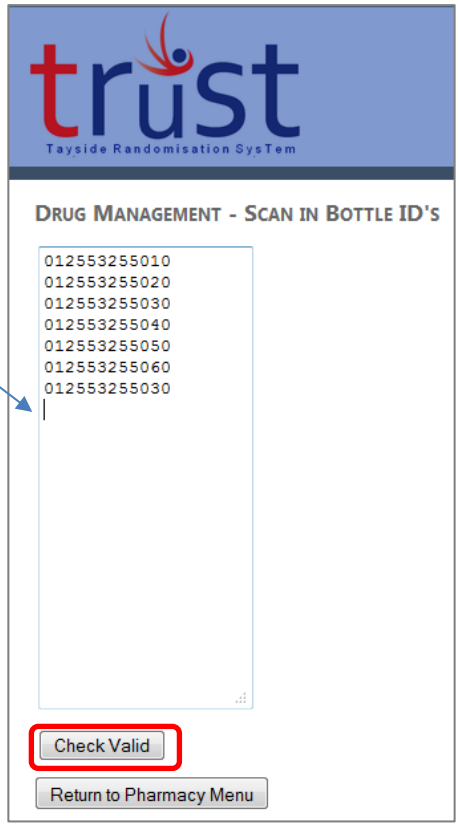
From the Menu page click on Scan in Drugs

Ensure cursor is flashing in the Scan in drug ID box

Enter pack IDs clicking return after each ID

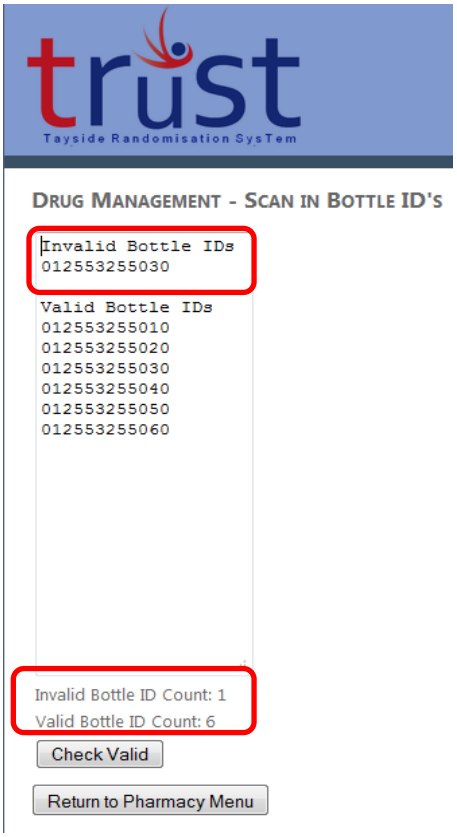
Ensure return is clicked after last pack ID

Click on Check Valid

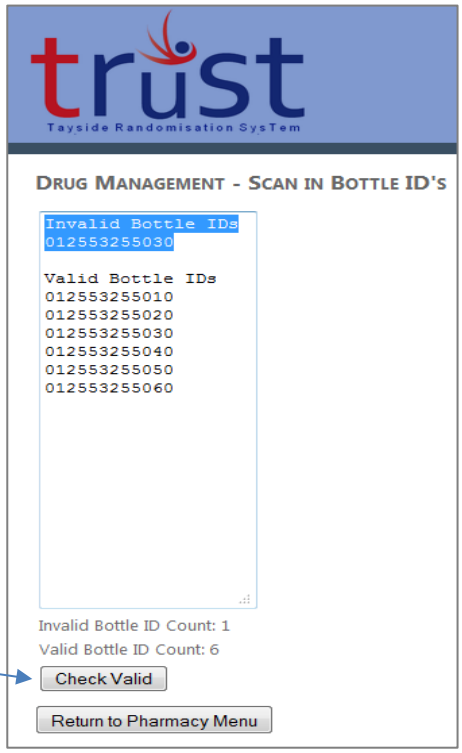


This will check the IDs entered and show if there have been any duplicates or incorrect IDs entered – Invalid Pack IDs.

At the bottom it will show how many Pack IDs are invalid and how many are valid.



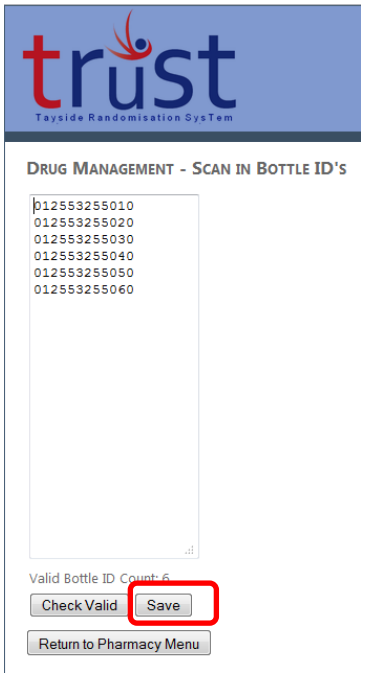
Highlight any Invalid Pack ID(s) and delete.



Click Check Valid

When all Pack IDs are valid and you have checked that all pack IDs are present (if you have entered 6 pack IDs the Valid Pack ID Count should be 6, if not, check which pack IDs are missing and enter these.)

Click Save

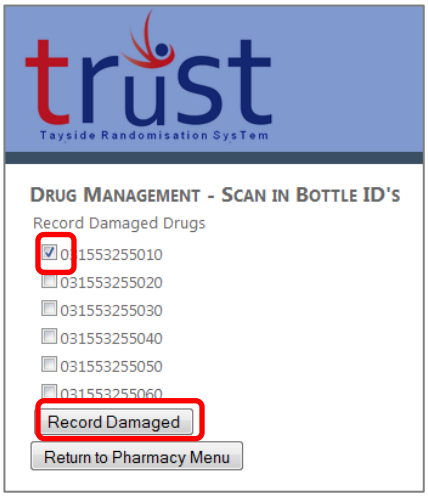


You will receive an email from TRuST alerting you if the pack IDs entered do not match the consignment sent from Sharp Clinical Services.

Record if any of the packs received have been damaged.

3.2 Recording Damaged Drugs

If any drugs are damaged in transit and are unusable they should be recorded as damaged after the whole batch has been entered.



Tick which packs have been damaged.

Click Record Damaged.

If none have been damaged leave blank.

Click Return Pharmacy Menu

Replacement packs will be sent automatically from Sharp Clinical Services once they have been recorded as damaged.

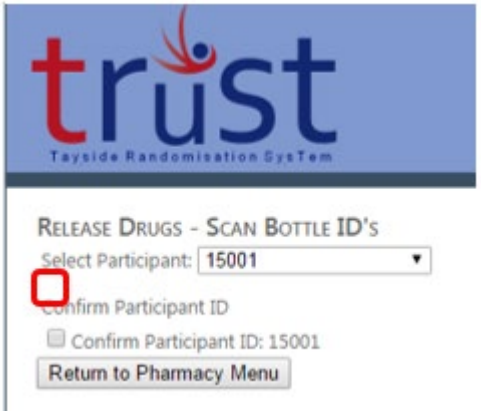
4. Dispensing/Releasing Drugs to Participant

Completed Clinical Trial Request Form received in Pharmacy:

From the Menu page click Release Drugs.

From the drop-down menu select Participant ID

Tick box to Confirm Participant ID



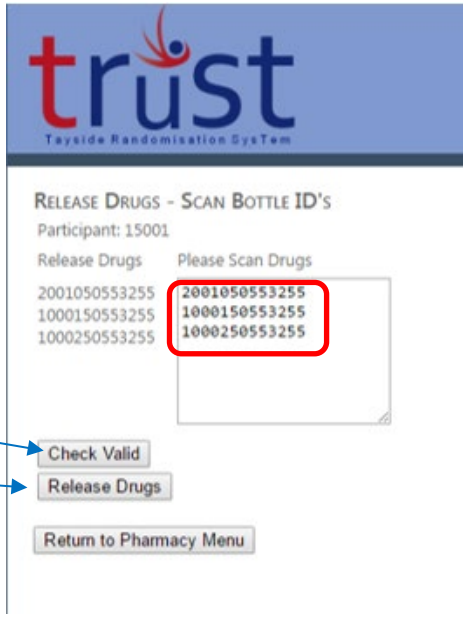
Ensure cursor is flashing in the Scan in drug ID's box

Enter each pack ID to be released.

The packs entered should match the request form. and the packs selected from the shelf. Press enter again when last pack ID scanned

Click on Check Valid

Click on Release Drugs



*If an IMP pack is entered which does not match those allocated to that participant, the release drugs button will not appear and you will not be able to print off the release form. Please check that you have selected the **correct participant** corresponding to the request form and selected the **correct IMP packs** off the shelf to match Clinical Request Form*

Print Clinical Trial Release Form

This should then be signed and dated by CT Pharmacist named on delegation log

The trial drug can then be released to the RN

The Clinical trial release form should be signed and dated by the person collecing the trial drugs

The Clinical Trial Request and Release forms should be filed in the Pharmacy Site File (PSF)

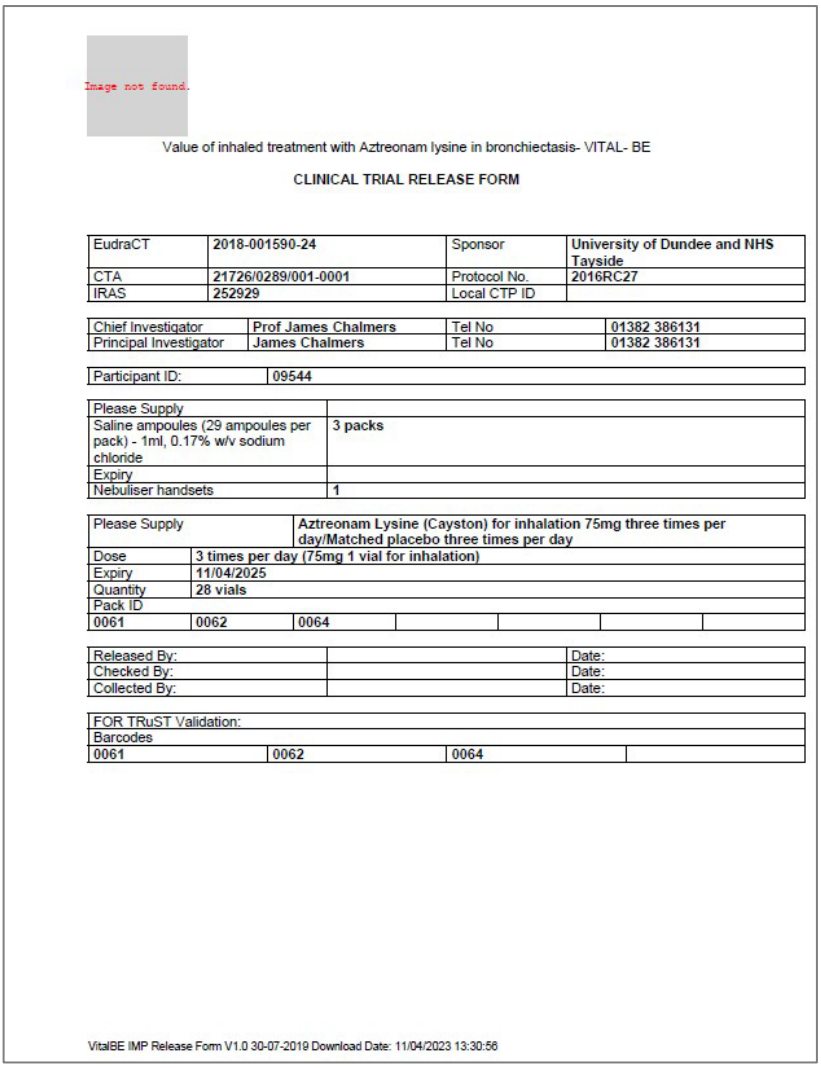


Image not found.

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

CLINICAL TRIAL RELEASE FORM

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 386131
Principal Investigator	James Chalmers	Tel No	01382 386131

Participant ID:	09544

Please Supply	
Saline ampoules (29 ampoules per pack) - 1ml, 0.17% w/v sodium chloride	3 packs
Expiry	
Nebuliser handsets	1

Please Supply	Aztreonam Lysine (Cayston) for inhalation 75mg three times per day/Matched placebo three times per day					
Dose	3 times per day (75mg 1 vial for inhalation)					
Expiry	11/04/2025					
Quantity	28 vials					
Pack ID						
0061	0062	0064				

Released By:		Date:
Checked By:		Date:
Collected By:		Date:

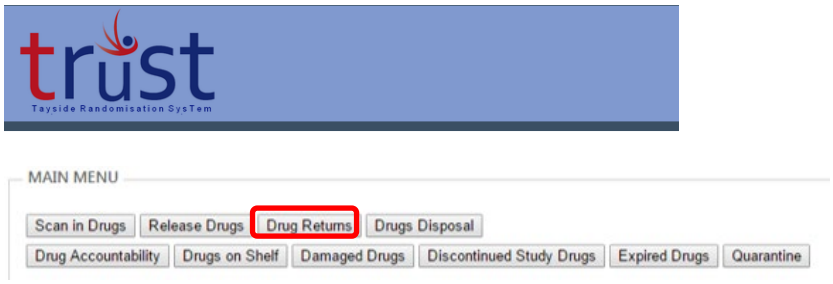
FOR TRuST Validation:			
Barcodes			
0061	0062	0064	

VitalBE IMP Release Form V1.0 30-07-2019 Download Date: 11/04/2023 13:30:56

At visit 5 the participant can be given 3 x treatment supply. Where a participant is not able to take away all packs allocated to them at that time point, record locally what packs were given to the participant on the day and when they subsequently come back to pick up further supplies.

5. Recording Drug Returns

From the Menu click Drug Returns



From drop down menu Select Participant ID

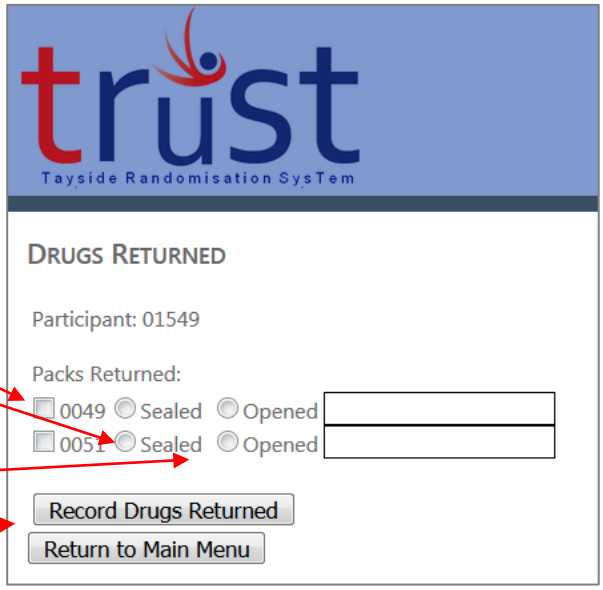
Tick box to Confirm Participant ID.

Tick boxes to Select Pack IDs.

If pack is sealed tick box to confirm this

If pack is opened tick box to confirm this
If pack is opened, enter the total number of unused vials returned.

Click Record Drugs Returned



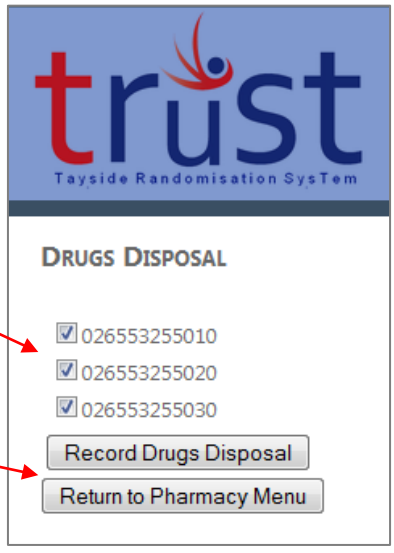
6. Disposing of Drugs

Before disposing any drugs, the drugs must be entered as either returned, expired, or quarantined.

From the Menu click Drug Disposal

Select Pack IDs to be Disposed.

Click Record Drugs Disposal



Click Print Disposal Form

Download the Clinical Trial Disposal Form

Clinical Trial Disposal Form

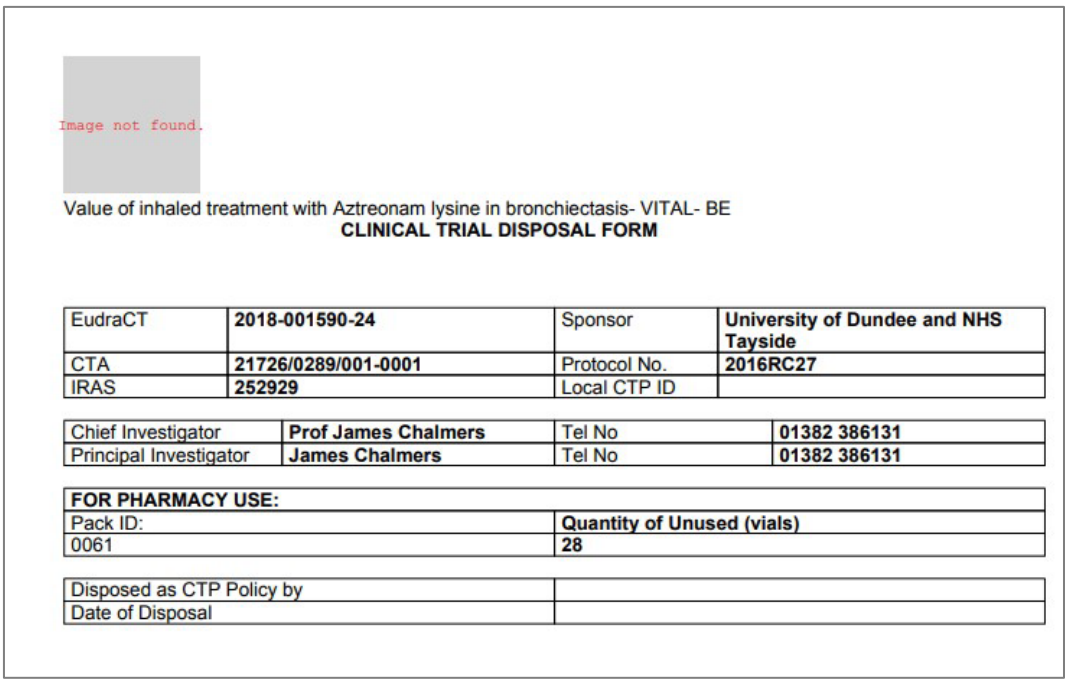


Image not found.

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

CLINICAL TRIAL DISPOSAL FORM

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 386131**
Principal Investigator	**James Chalmers**	Tel No	**01382 386131**

FOR PHARMACY USE:	
Pack ID:	**Quantity of Unused (vials)**
0061	**28**

Disposed as CTP Policy by	
Date of Disposal	

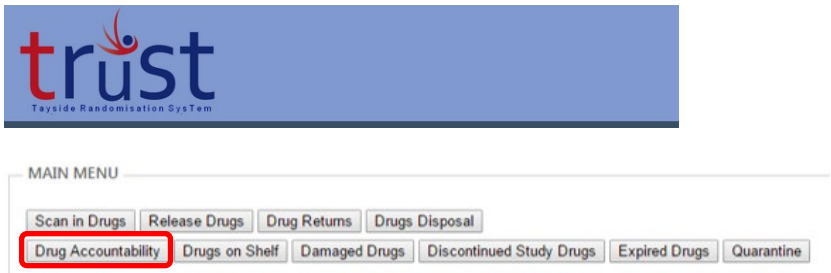
Print this form and sign and date to confirm disposal of trial drugs as per local SOP.

File the completed Clinical Trial Disposal Form in Pharmacy Site File.

7. Checking Drug Accountability

7.1 Accountability by Participant

From the Menu click Drug Accountability.



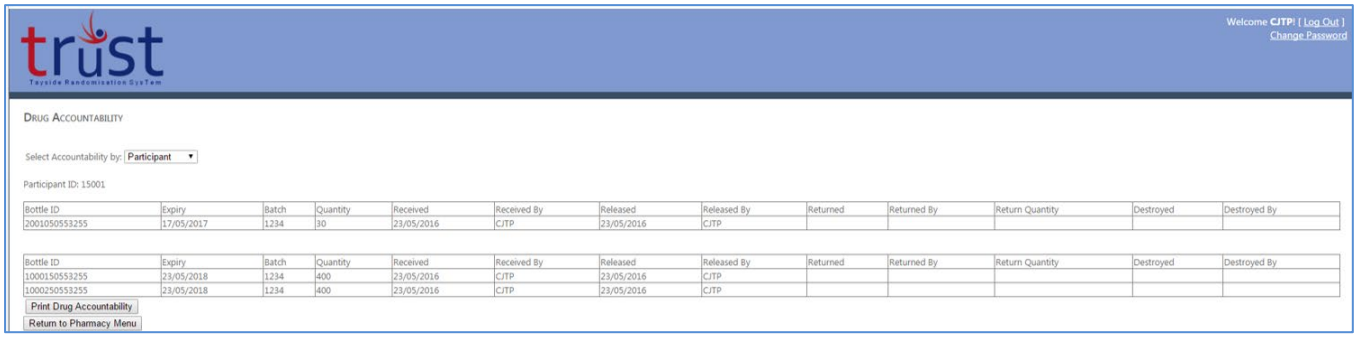
From drop down menu select accountability by Participant

Then Select Participant ID.

Tick box to Confirm Participant ID.

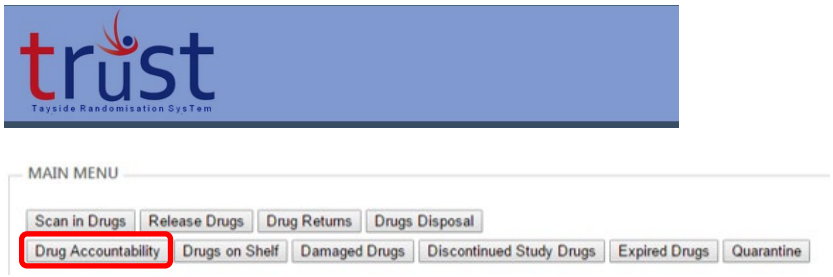
This will show the drug accountability for that participant at that point in the trial.

- This can be printed off, however this is **not** a requirement of the VitalBE Trial Team.
- If required locally, click Print Drug Accountability. This will open the information in a pdf document which can be printed or saved.



7.2 Accountability by Site

From the Menu click Drug Accountability.



From drop down menu select accountability by Site

This will show the drug accountability for all participants at that point in the trial, for this individual site.

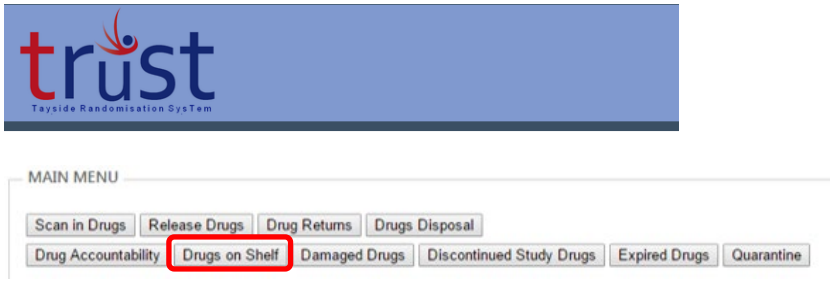
There is no requirement to print this until the end of the trial when all activity at site is completed, with IMP all recorded as disposed of.

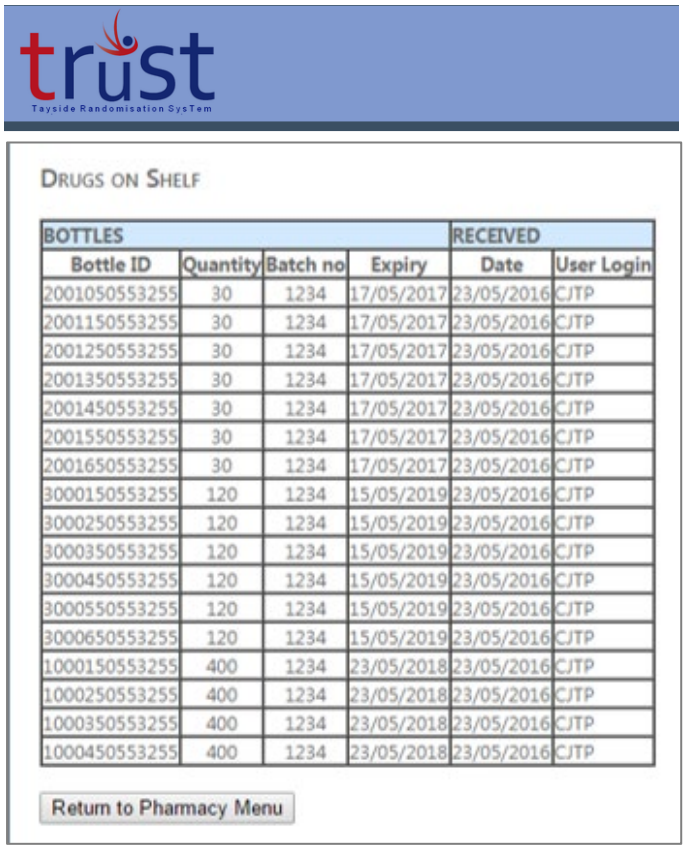
Click Print Drug Accountability. You can then download the pdf, which can either be saved and completed electronically or printed to be completed.

7.3 Checking Stock Levels in Pharmacy

From the Main Menu, click Drugs on Shelf.

This will show which packs are recorded as being on site in your Clinical Trial Pharmacy. i.e they have been received by yourselves but not yet released to a participant.




trust
Tayside Randomisation SysTem

DRUGS ON SHELF

BOTTLES				RECEIVED	
Bottle ID	Quantity	Batch no	Expiry	Date	User Login
2001050553255	30	1234	17/05/2017	23/05/2016	CJTP
2001150553255	30	1234	17/05/2017	23/05/2016	CJTP
2001250553255	30	1234	17/05/2017	23/05/2016	CJTP
2001350553255	30	1234	17/05/2017	23/05/2016	CJTP
2001450553255	30	1234	17/05/2017	23/05/2016	CJTP
2001550553255	30	1234	17/05/2017	23/05/2016	CJTP
2001650553255	30	1234	17/05/2017	23/05/2016	CJTP
3000150553255	120	1234	15/05/2019	23/05/2016	CJTP
3000250553255	120	1234	15/05/2019	23/05/2016	CJTP
3000350553255	120	1234	15/05/2019	23/05/2016	CJTP
3000450553255	120	1234	15/05/2019	23/05/2016	CJTP
3000550553255	120	1234	15/05/2019	23/05/2016	CJTP
3000650553255	120	1234	15/05/2019	23/05/2016	CJTP
1000150553255	400	1234	23/05/2018	23/05/2016	CJTP
1000250553255	400	1234	23/05/2018	23/05/2016	CJTP
1000350553255	400	1234	23/05/2018	23/05/2016	CJTP
1000450553255	400	1234	23/05/2018	23/05/2016	CJTP

Return to Pharmacy Menu

8. Recording that a participant has stopped their trial drugs

If a participant permanently stops taking their trial drugs for whatever reason this should be entered into TRuST by the **Research Nurse**. e.g. participant does not wish to continue on trial drug, participant dies, GP or other doctor stops their trial drug.

You will be alerted by email from TRuST that a participant has stopped their trial drugs.

If a participant stops their trial drugs check whether there are any packs allocated to that participant which have not been collected by participant. DO NOT dispose of these, contact the Clinical Trial Manager. These may be able to go back on shelf if they have not left the CTP fridge.

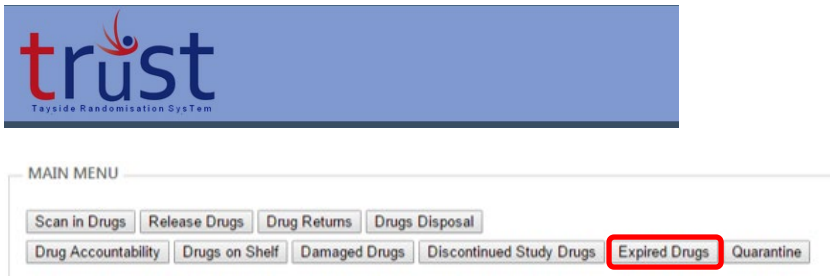
9. Recording Expired Drugs

Only if recruitment is exceptionally slower than anticipated will the site have IMP due to expire.

You will be alerted by email if any drugs on your shelf are due to expire and you will be requested to destroy them.

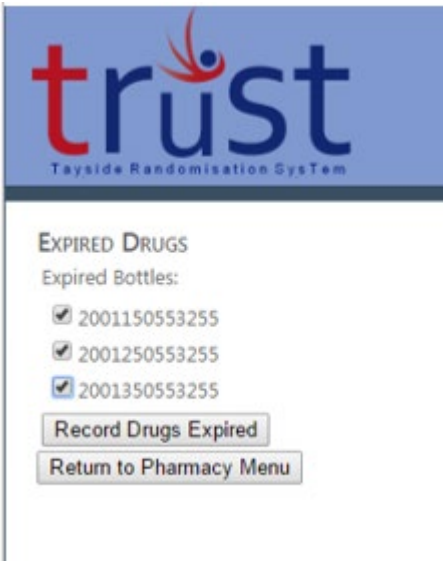
TRuST will alert the IMP supplier to request that they resupply you with drugs to replace expired stock.

From the Menu click Expired Drugs



Select the packs which have expired.

Click Record Drugs Expired



These packs can now be disposed of as per your local policy, and the Drugs Disposal procedure followed as per Section 6.

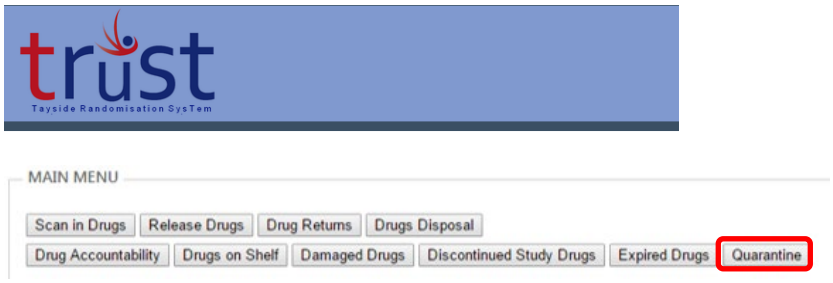
10. Putting drugs into Quarantine

Drugs should be placed in quarantine when:

- The storage temperature is out with the limits described in the IMP management plan.
- You have been alerted by email to quarantine the drugs e.g. for drug recall.

- Pharmacist to advise trial management team with pack IDs and reason for quarantine
- Trial Manager to contact HIC with pack numbers that need to be quarantined
- HIC will trigger action notifying pharmacist which packs to move to quarantine.
- Pharmacist can action quarantine on TRuST
- Trial Manager will inform HIC whether pack should be destroyed or moved back to the shelf
- HIC triggers notification to Pharmacist
- Pharmacist records as destroyed or moved back to shelf depending on decision

From the Menu click Quarantine



Select the packs which have to be put into quarantine.

Click Quarantine Drugs.

You will be informed by the CTM what action to take with these packs e.g. dispose, return to stock or return to Sharp Clinical Services.

11. Trouble Shooting & Contacts

11.1 Requesting New User Accounts

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, a copy of the Delegation Log and Training Logs updated with the persons details.

11.2 Unable to Access TRuST

If the internet is “down” and CTP staff cannot access TRuST to print release forms, blank copies can be found in the Pharmacy Site File. (Electronic copy)

- Open Clinical Trial Release Form online.
- Completed Clinical Trial Release Form fully using the details provided on the Clinical Trial Request Form.
- Print and sign the Clinical Trial Request Form
- Release drugs.
- Enter a file note in the PSF for each release form completed this way stating why it was not possible to use TRuST.
- Email copy of release form to Clinical Trial Manager who will request that the drug accountability is updated on TRuST by HiC services.

If internet access is possible but the TRuST system is not working please contact the Clinical Trial Manager and the procedure above should be followed.

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.

11.3 Contacts

Clinical Trial Manager:

Fiona McLaren-Neil
respiratorytrialsl@dundee.ac.uk
01382 383830