



Value of inhaled treatment with  
aztreonam lysine in bronchiectasis

# Randomisation



# TRuST – Tayside Randomisation System

- Web-based randomisation system used by Research Nurses and Clinical Trial Pharmacy Staff
- Trial Manager and trial monitors have access to TRuST to enable them to check randomisation and drug accountability remotely.
- Research Nurses will use TRuST for the following :
  - Randomisation of participants
  - Printing of Participant Appointment and Nurse Appointment sheets
  - Printing Clinical Trial Request Forms to request IMP from the Clinical Trial Pharmacy
  - Re-ordering IMP lost by participant
  - Recording that a participant has stopped their trial medication

# Randomisation: Requirement

- Delegated to randomise on Delegation Log
- **Unblinded** member of staff
- Randomisation training completed: this presentation and TRuST User Guide
- Medical Record signed by PI/delegate confirming eligibility
- Internet access
- TRuST log-in
- Participant ID
- Printer

# Randomisation: TRuST System

- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST>
- Login details will be sent out after training has taken place. If not received, click on “Forgotten Password” and enter your email as your username.

- Log in with your details; on first login you will be asked to change your password

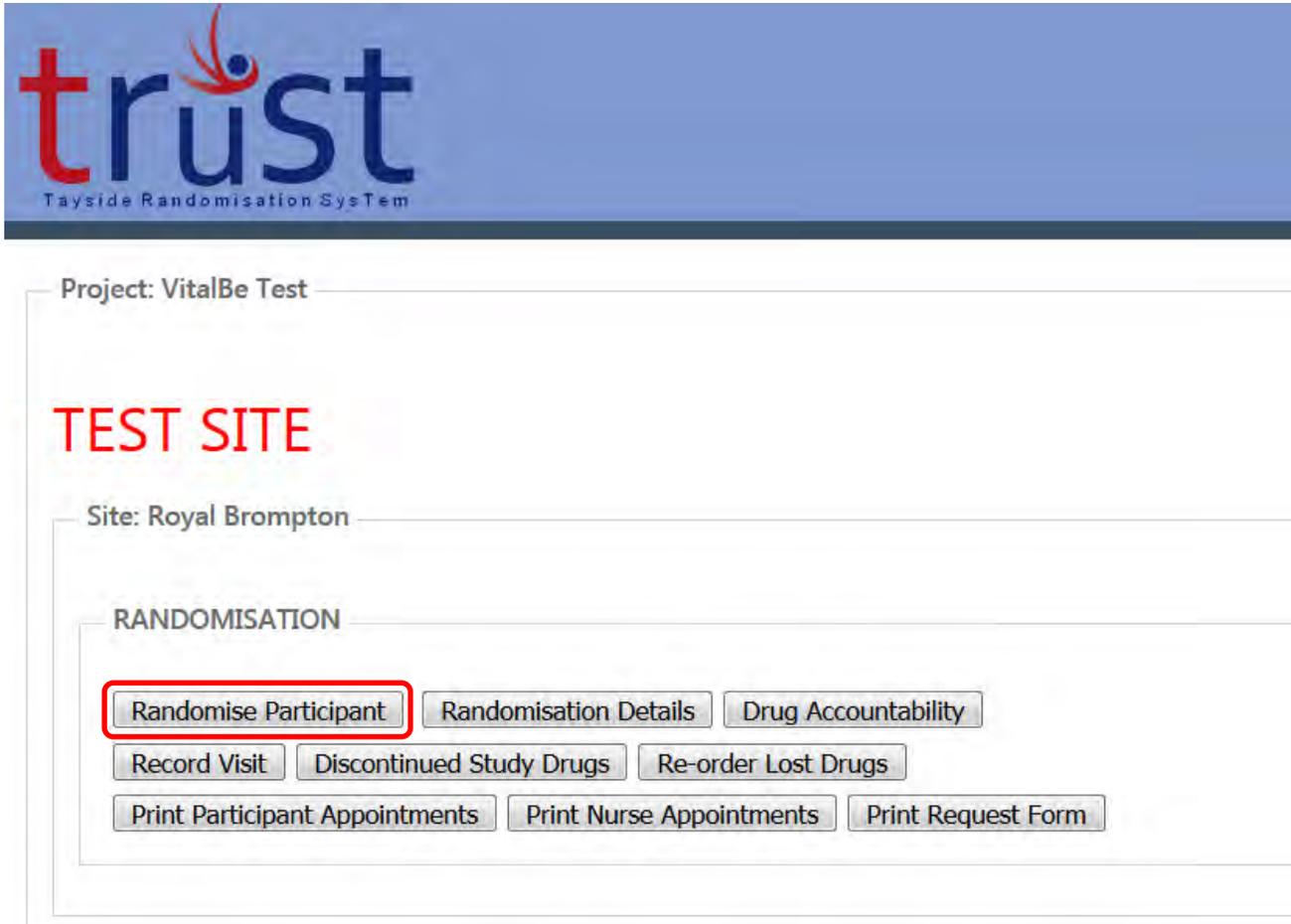


If you forget your password click the forgotten password link and your new password will be emailed to you

For staff with multiple projects on TRuST select the VitalBE trial from the dropdown menu.



# Randomising a participant



Project: VitalBe Test

**TEST SITE**

Site: Royal Brompton

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

- Main menu.
- Click randomise participant.

# Randomising a participant

**RANDOMISE PARTICIPANT**

**Participant Identifiers**

Initials:    
**First and last initial should be entered**

Date of Birth:

Gender:  Male  Female

**Eligibility Criteria**

Has the participant had a CT scan of the chest demonstrating bronchiectasis in 1 or more lobes in the past?  Yes  No

Does the participant have a history of at least 3 exacerbations in the past 12 months?  Yes  No

Has Pseudomonas aeruginosa or other 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 positive for P. aeruginosa or other Gram-negative respiratory pathogens (must be within 28 days)

Bronchiectasis severity index at screening

FEV1 % predicted at screening visit

eGFR at screening visit

[Return to Main Menu](#) [Next](#)

- Enter participant identifiers
- Complete eligibility criteria questions
- Click next

# Randomising a participant

**RANDOMISE PARTICIPANT**

Site: Royal Brompton

Participant ID: 01

Was Pseudomonas aeruginosa present in sputum at screening?:  Yes  No

Is the participant on macrolide treatment?:  Yes  No

Has the CI/PI signed CRF to confirm eligibility of participant?  Yes  No

Does the participant meet eligibility criteria?  Yes  No

[Return to Main Menu](#)

- 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
- **It is an MHRA and GCP requirement that a medical doctor confirms eligibility prior to randomisation.**
- If all questions are completed the randomise button will appear. Click to randomise.

# Randomising a participant

## RANDOMISE PARTICIPANT

Site: Royal Brompton

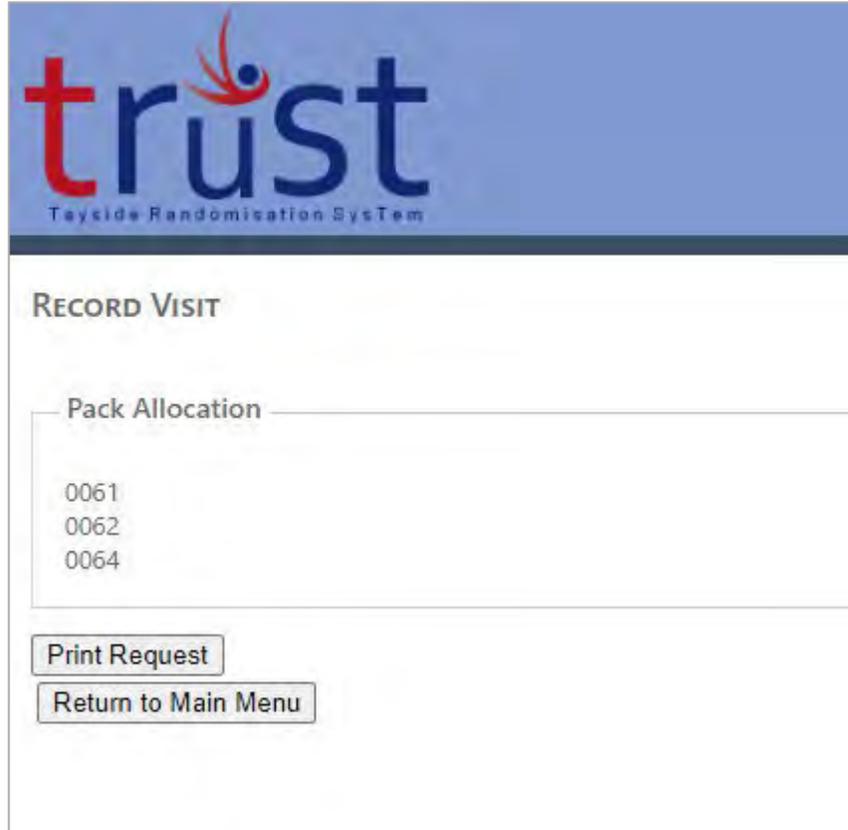
Subject Identifier: 01793

Randomisation Allocation: Participant Successfully Randomised

Record Visit

- Randomisation notification will be displayed
- You will receive an email confirmation of this randomisation
- Click “Record Visit” to display the pack ID allocation.

# IMP pack allocation



The screenshot shows the 'trust' logo at the top left, with 'Tayside Randomisation System' written below it. The main heading is 'RECORD VISIT'. Below this is a section titled 'Pack Allocation' which contains a list of three items: '0061', '0062', and '0064'. At the bottom of the form are two buttons: 'Print Request' and 'Return to Main Menu'.

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.

# Clinical Trial Request Form

**VitalBE**  
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	EDCTP 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	
<del>Wet wipes</del> 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	

WARE 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 participant's visit to confirm that it is still appropriate for the participant to receive the IMP

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).



# Recording Subsequent Visits

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

For all visits following randomisation click on “Record Visit” button from the main menu

trust  
Tayside Randomisation System

RECORD VISIT

Participant Selection

Select Participant: **Select a Participant ID**

Return to Main Menu

From the drop down menu select participant ID

trust  
Tayside Randomisation System

RECORD VISIT

Participant Selection

Select Participant: 15001

Confirm Participant ID  Confirm Participant ID: 15001

Return to Main Menu

Confirm Participant ID

RECORD VISIT

Participant ID: 01738  
Visit 3

**Record Visit**

Return to Main Menu

Click on “record visit”

RECORD VISIT

Participant ID: 01738  
Visit 3

Record Visit

Pack Allocation

0039  
0041  
0043

Print Request

Return to Main Menu

Pack allocation is displayed

Click on “Print Request”

Print and complete the form as for randomisation visit

# Recording IMP as lost & allocating replacement pack IDs

In cases where pack IDs are lost this must be recorded on TRuST to allocate replacement pack IDs

From “Main Menu”, click on the “Re-order Lost Drugs”.

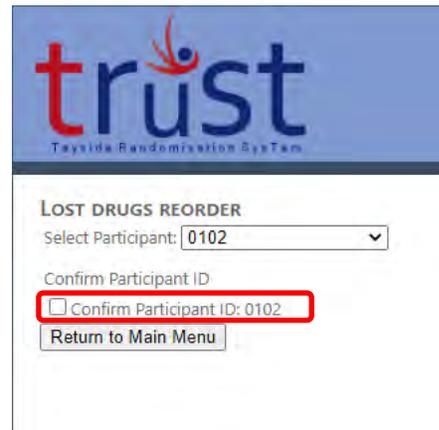
- Select participant ID
- Tick “Confirm Participant ID”.

The Participant ID and pack list will be displayed

- Select the pack ID(s) that have been lost
- Click “Record Lost Drugs”

TRuST will re-allocate new pack IDs to that visit

- Click “Print Request” and take the new request form to pharmacy



trust  
Tayside Randomisation System

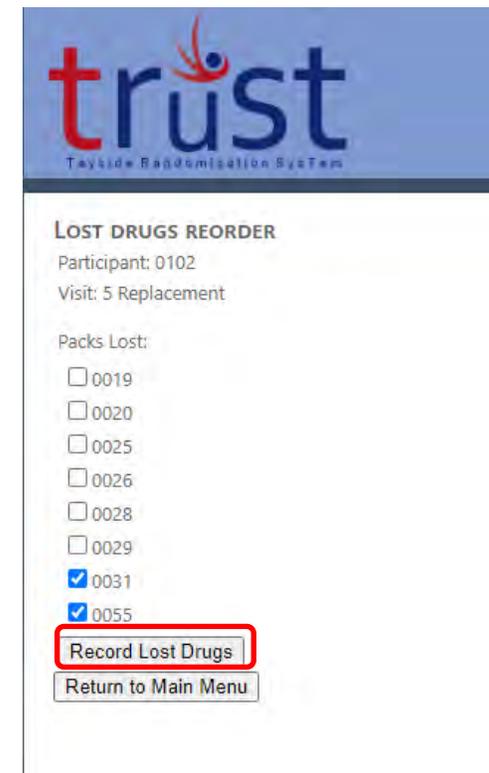
LOST DRUGS REORDER

Select Participant: 0102

Confirm Participant ID

Confirm Participant ID: 0102

Return to Main Menu



trust  
Tayside Randomisation System

LOST DRUGS REORDER

Participant: 0102

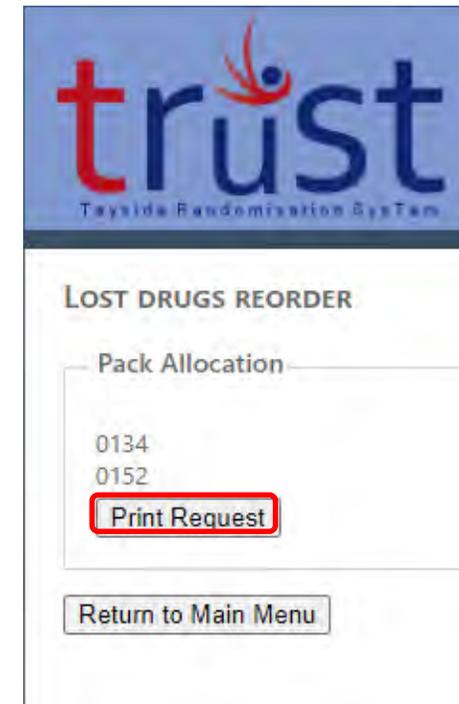
Visit: 5 Replacement

Packs Lost:

- 0019
- 0020
- 0025
- 0026
- 0028
- 0029
- 0031
- 0055

Record Lost Drugs

Return to Main Menu



trust  
Tayside Randomisation System

LOST DRUGS REORDER

Pack Allocation

- 0134
- 0152

Print Request

Return to Main Menu

# Recording IMP as Discontinued

If a participant discontinues treatment, you must record this on TRuST

- From the main menu, click “Discontinued Study Drugs”.
- Select the participant ID from a dropdown menu.
- Tick “Confirm Participant ID”
- Click “Discontinued study drugs”



trust  
Tayside Randomisation System

DISCONTINUED STUDY DRUGS

Select Participant:



trust  
Tayside Randomisation System

DISCONTINUED STUDY DRUGS

Select Participant:

Confirm Participant ID

Confirm Participant ID: 0110



trust  
Tayside Randomisation System

DISCONTINUED STUDY DRUGS

Participant: 0110



trust  
Tayside Randomisation System

DISCONTINUED STUDY DRUGS

Participant: 0110 - discontinued study drugs

## Site Randomisation Details

- To check the randomisation details go back to main menu and click the Randomisation Details button.



The screenshot shows the VitalBE Randomisation System interface. At the top left is the 'trust' logo with the text 'Tayside Randomisation System' below it. Below the logo, the 'Project' is identified as 'VitalBE' and the 'Site' as 'Tayside'. A section titled 'RANDOMISATION' contains several buttons: 'Randomise Participant', 'Randomisation Details' (highlighted with a red box), 'Drug Accountability', 'Record Visit', 'Discontinued Study Drugs', 'Re-order Lost Drugs', 'Print Participant Appointments', 'Print Nurse Appointments', and 'Print Request Form'.

- Details of all participants randomised at site will be shown

# Drug Accountability

The screenshot shows the VitalBE Randomisation System interface. At the top, the 'trust' logo is visible with the text 'Tayside Randomisation System' below it. The main content area is titled 'Project: VitalBE' and 'Site: Tayside'. Under the 'RANDOMISATION' section, there are several buttons: 'Randomise Participant', 'Randomisation Details', 'Drug Accountability' (highlighted with a red box), 'Record Visit', 'Discontinued Study Drugs', 'Re-order Lost Drugs', 'Print Participant Appointments', 'Print Nurse Appointments', and 'Print Request Form'.

- To check Drug Accountability for participants at site go back to main menu and click the “Drug Accountability” button.
- This displays pack IDs and does not display treatment allocation.

- Drug accountability can be checked for site or individual participant

For site IMP accountability, select “Site” from the dropdown menu

Details of Pack ID for all drug allocated at site will be listed with participant ID

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

**IMP ACCOUNTABILITY FORM FOR PHARMACY - AZTREONAM LYSINE (CAYSTON) FOR INHALATION 75MG THREE TIMES PER DAY MATCHED PLACEBO THREE TIMES PER DAY**

EudraCT	<b>2018-001590-24</b>	CTA Number	<b>21726/0289/001-0001</b>	IRAS	<b>252929</b>	Local CTP ID	
Chief Investigator	<b>Prof James Chalmers</b>	Tel No	<b>01382 386131</b>	Principal Investigator	<b>James Chalmers</b>	Tel No	<b>01382 386131</b>

PACKS					RECEIVED		RELEASED			RETURNED			DISPOSED OF	
PACK ID	Expiry	Batch no	Quantity (vials)	Dose	Date	User Login	Date	Participant ID	User Login	Date	User Login	Quantity	Date	User Login
0001	10/11/2022	3344	28	75mg	10/11/2022	pvb2				01/02/2023	pvb2	Expired	01/02/2023	pvb2
0002	10/11/2022	3344	28	75mg	10/11/2022	pvb2				01/02/2023	pvb2	Expired	01/02/2023	pvb2
0003	10/11/2022	3344	28	75mg	10/11/2022	pvb2				01/02/2023	pvb2	Expired	01/02/2023	pvb2
0004	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0005	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0006	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0007	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0008	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0009	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0010	10/11/2022	3344	28	75mg	10/11/2022	pvb2				16/02/2023	pvb2	Damaged		
0031	01/11/2024	2233	28	75mg	09/11/2022	pvb2				09/11/2022	pvb2	Damaged	09/11/2022	pvb2
0032	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09003	pvb2					
0033	01/11/2024	2233	28	75mg	09/11/2022	pvb2	09/11/2022	09004	pvb2	10/11/2022	pvb2	28	10/11/2022	pvb2
0034	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09003	pvb2					
0035	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09003	pvb2					
0036	01/11/2024	2233	28	75mg	09/11/2022	pvb2				09/11/2022	pvb2	Damaged	10/11/2022	pvb2
0037	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09006	pvb2	10/11/2022	pvb2	12	01/02/2023	pvb2
0038	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09006	pvb2	10/11/2022	pvb2	3	10/11/2022	pvb2
0039	01/11/2024	2233	28	75mg	09/11/2022	pvb2	09/11/2022	09004	pvb2	10/11/2022	pvb2	14	10/11/2022	pvb2
0040	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09006	pvb2					
0041	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09007	pvb2	16/02/2023	pvb2	28		
0042	01/11/2024	2233	28	75mg	09/11/2022	pvb2	09/11/2022	09004	pvb2	16/02/2023	pvb2	28		
0043	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09007	pvb2	16/02/2023	pvb2	28		
0044	01/11/2024	2233	28	75mg	09/11/2022	pvb2	10/11/2022	09007	pvb2	16/02/2023	pvb2	28		

VitalBE IMP Accountability form Per Site V1.0 30-07-2019 Download Date: 16/02/2023 09:58:55

- To check drug accountability for an individual participant select Participant from the dropdown menu
- Select participant ID
- Click “Confirm Participant ID”

The screenshot shows the 'TRUST Tayside Pharmacy System' interface. At the top right, it says 'Welcome CJTP! [ Log Out ] [ Change Password ]'. The main section is titled 'DRUG ACCOUNTABILITY'. Below this, there is a dropdown menu 'Select Accountability by:' with 'Participant' selected. Underneath, it says 'Participant ID: 15001'. There are two tables displaying drug accountability data. The first table has one row with the following data: Bottle ID: 2001050553255, Expiry: 17/05/2017, Batch: 1234, Quantity: 30, Received: 23/05/2016, Received By: CJTP, Released: 23/05/2016, Released By: CJTP. The second table has two rows: the first row has Bottle ID: 1000150553255, Expiry: 23/05/2018, Batch: 1234, Quantity: 400, Received: 23/05/2016, Received By: CJTP, Released: 23/05/2016, Released By: CJTP; the second row has Bottle ID: 1000250553255, Expiry: 23/05/2018, Batch: 1234, Quantity: 400, Received: 23/05/2016, Received By: CJTP, Released: 23/05/2016, Released By: CJTP. At the bottom left of the interface, there are two buttons: 'Print Drug Accountability' and 'Return to Pharmacy Menu'.

Bottle ID	Expiry	Batch	Quantity	Received	Received By	Released	Released By	Returned	Returned By	Return Quantity	Destroyed	Destroyed By
2001050553255	17/05/2017	1234	30	23/05/2016	CJTP	23/05/2016	CJTP					
1000150553255	23/05/2018	1234	400	23/05/2016	CJTP	23/05/2016	CJTP					
1000250553255	23/05/2018	1234	400	23/05/2016	CJTP	23/05/2016	CJTP					

- Please contact the trial management team if you have any questions or issues: [respiratorytrials@dundee.ac.uk](mailto:respiratorytrials@dundee.ac.uk)

