



Value of inhaled treatment with
aztreonam lysine in bronchiectasis

TRuST: Pharmacy



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.
- Pharmacists will use TRuST for the following :
 - Stock Control
 - Drug accountability
 - Printing Clinical Trial Release Forms
 - Documenting IMP returns and destruction

TRuST

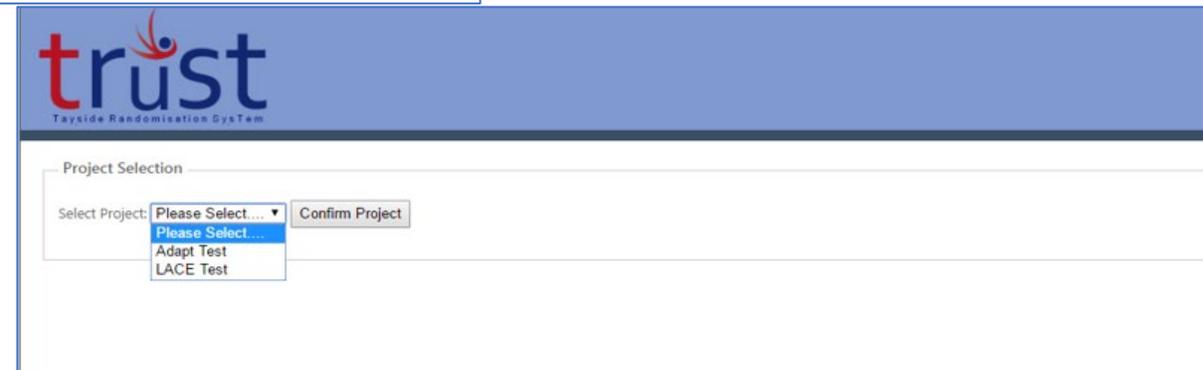
- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST>
- Login details will be sent out after training has taken place. If not received, click on “Forgotten Password” and enter your email as your username.
- For those staff using the generic login you will be required to enter your name before starting any tasks

- 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 button and your new password will be emailed to you

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



TRuST: Menu



Welcome pVitalBE! [[Log Out](#)]
[Change Password](#)

Project: VitalBe

Site: Royal Brompton

PHARMACY

Scan in Drugs

Release Drugs

Drug Returns

Drugs Disposal

Drug Accountability

Drugs on Shelf

Damaged Drugs

Discontinued Study Drugs

Expired Drugs

Quarantine



Scan in drugs

Enter Pack IDs

Click return after each entry, including after the last pack ID

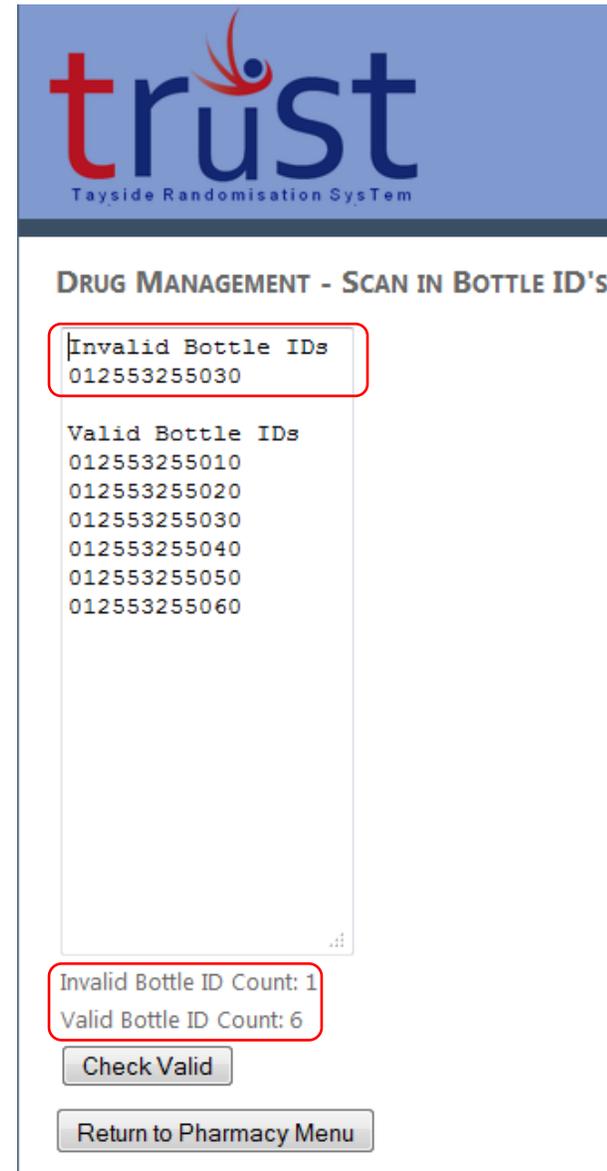
Click on [Check Valid](#)

The screenshot shows the 'trust' logo at the top, with 'Tayside Randomisation SysTem' underneath. Below this is the title 'DRUG MANAGEMENT - SCAN IN BOTTLE ID'S'. A text input field contains the following list of 10 pack IDs: 012553255010, 012553255020, 012553255030, 012553255040, 012553255050, 012553255060, and 012553255030. A vertical cursor is positioned at the end of the last entry. Below the input field are two buttons: 'Check Valid' and 'Return to Pharmacy Menu'.

Scan in drugs

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.



The screenshot shows the 'trust' logo at the top, with 'Tayside Randomisation System' underneath. Below the logo is the title 'DRUG MANAGEMENT - SCAN IN BOTTLE ID'S'. The main content area is divided into two sections: 'Invalid Bottle IDs' and 'Valid Bottle IDs'. The 'Invalid Bottle IDs' section contains a single ID, '012553255030', which is highlighted with a red box. The 'Valid Bottle IDs' section contains six IDs: '012553255010', '012553255020', '012553255030', '012553255040', '012553255050', and '012553255060'. Below these sections, there are two summary lines: 'Invalid Bottle ID Count: 1' and 'Valid Bottle ID Count: 6', both highlighted with red boxes. At the bottom, there are two buttons: 'Check Valid' and 'Return to Pharmacy Menu'.

trust
Tayside Randomisation System

DRUG MANAGEMENT - SCAN IN BOTTLE ID'S

Invalid Bottle IDs
012553255030

Valid Bottle IDs
012553255010
012553255020
012553255030
012553255040
012553255050
012553255060

Invalid Bottle ID Count: 1
Valid Bottle ID Count: 6

Check Valid

Return to Pharmacy Menu

Scan in drugs

Highlight any Invalid Pack IDs and delete

The screenshot shows the 'trust' logo at the top, with 'Tayside Randomisation System' underneath. Below the logo is the title 'DRUG MANAGEMENT - SCAN IN BOTTLE ID'S'. A text area contains two sections: 'Invalid Bottle IDs' with the value '012553255030', and 'Valid Bottle IDs' with a list of six values: '012553255010', '012553255020', '012553255030', '012553255040', '012553255050', and '012553255060'. Below the text area, it displays 'Invalid Bottle ID Count: 1' and 'Valid Bottle ID Count: 6'. At the bottom, there are two buttons: 'Check Valid' and 'Return to Pharmacy Menu'. A blue arrow points from the text 'Highlight any Invalid Pack IDs and delete' to the '012553255030' ID in the 'Invalid Bottle IDs' list. Another blue arrow points from the text 'Click Check Valid' to the 'Check Valid' button.

Scan in drugs

trust
Tayside Randomisation System

DRUG MANAGEMENT - SCAN IN BOTTLE ID'S

012553255010
012553255020
012553255030
012553255040
012553255050
012553255060

Valid Bottle ID Count: 6

Check Valid Save Return to Pharmacy Menu

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

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 pack(s) have been damaged

Click [Record Damaged](#)



The screenshot shows the 'trust' logo at the top, with 'Tayside Randomisation System' underneath. Below this is the heading 'DRUG MANAGEMENT - SCAN IN BOTTLE ID'S' and the sub-heading 'Record Damaged Drugs'. A list of six drug pack IDs is shown, each with a checkbox. The first checkbox is checked and highlighted with a red box. Below the list is a 'Record Damaged' button, also highlighted with a red box, and a 'Return to Pharmacy Menu' button.

Drug Pack ID	Status
<input checked="" type="checkbox"/> 031553255010	Damaged
<input type="checkbox"/> 031553255020	Not Damaged
<input type="checkbox"/> 031553255030	Not Damaged
<input type="checkbox"/> 031553255040	Not Damaged
<input type="checkbox"/> 031553255050	Not Damaged
<input type="checkbox"/> 031553255060	Not Damaged

Dispensing/Releasing Drugs to Participant

Completed clinical Trial Request form received in pharmacy

From the Menu page click [Release Drugs](#).

 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			
URUSOL handsets	1		
Please Supply Cayston three times per day/ Placebo three times per day			
Dose			
Pack ID			
<u>Investigator's</u> or delegate's Signature:		Date:	
May be signed up to 7 days prior to patient visit (except randomisation visit).			
Research Nurse's Signature:		Date:	
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 <u>so</u> please give details (To be signed on day of patient visit.)			
FOR TRUST Validation:			
Barcodes			

VitalBE IMP Request Form - Download Date:



MAIN MENU

[Scan in Drugs](#)
[Release Drugs](#)
[Drug Returns](#)
[Drugs Disposal](#)

[Drug Accountability](#)
[Drugs on Shelf](#)
[Damaged Drugs](#)
[Discontinued Study Drugs](#)
[Expired Drugs](#)
[Quarantine](#)

Dispensing/Releasing Drugs to Participant



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

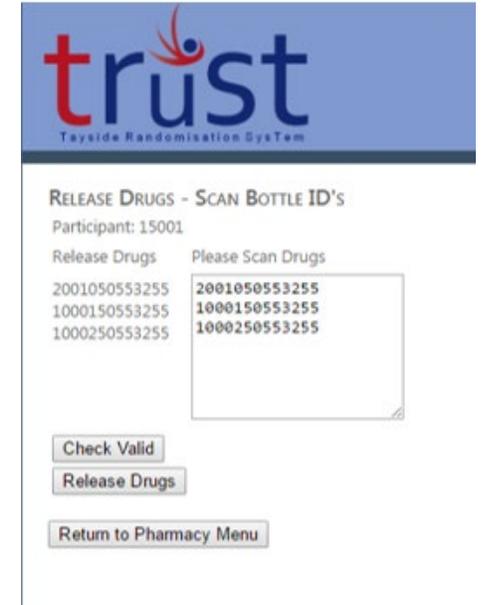


Tick box to **Confirm Participant ID**

Ensure cursor is flashing in the **Scan in Drug ID** box

Enter each pack ID to be released

The packs entered should match the request form. Select enter again when last pack ID entered.



Click on **Check Valid**

Click on **release drugs**

Dispensing/Releasing Drugs to Participant

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 collecting 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

Drugs on shelf



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.

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](#)

Drug Accountability - Recording Drug Returns

From the Menu click [Drug Returns](#)



From the drop down menu [Select Participant ID](#)

Tick box to [Confirm Participant ID](#)

Tick boxes to select pack ID

If pack is sealed, tick box [Sealed](#)

If pack is opened tick [Opened](#)

If pack is opened enter the total number of unused vials returned

Click [Record Drugs Returned](#)

DRUGS RETURNED

Participant: 01549

Packs Returned:

<input type="checkbox"/> 0049	<input type="radio"/> Sealed	<input type="radio"/> Opened	<input type="text"/>
<input type="checkbox"/> 0051	<input type="radio"/> Sealed	<input type="radio"/> Opened	<input type="text"/>

[Record Drugs Returned](#)

[Return to Main Menu](#)

Drug Accountability - Recording Expired Drugs

If recruitment is exceptionally slower than anticipated the site will 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



Drug Accountability - Putting Drugs into Quarantine

Drugs should be placed in quarantine when:

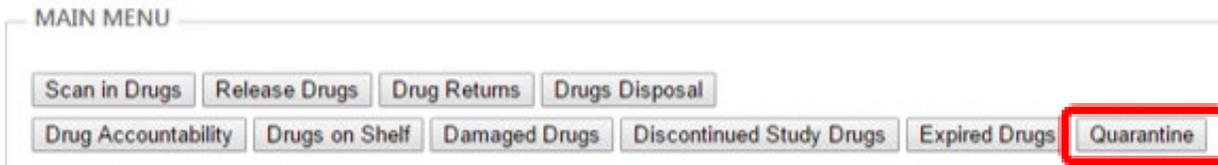
- The storage temperature is out with the limits described in the IMP management plan.
- Pharmacist to notify Trial Management team to advise which packs need to be quarantined
- HIC trigger action notifying pharmacist which packs to then move to quarantine
- Pharmacist can action quarantine on TRuST
- Trial manager 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

Drug Accountability - Putting Drugs into Quarantine

- You have been alerted by email from HIC to quarantine the drugs



From the Menu click [Quarantine](#)



Select the packs which have to be put into quarantine.

Click [Quarantine Drugs](#).

Drug Accountability - Disposing of Drugs

Before disposing of 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](#)



Drug Accountability - Disposing of Drugs

Print the clinical trial disposal form, and sign and date to confirm disposal of trial drug as per local SOP

File the completed clinical trial disposal form in the Pharmacy Site File (PSF)

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

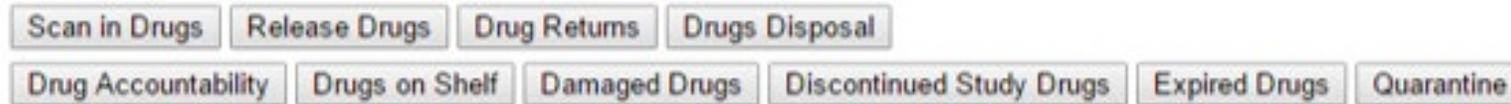
FOR PHARMACY USE:	
Pack ID:	Quantity of Unused (vials)
0061	28

Disposed as CTP Policy by	
Date of Disposal	

Drug Accountability



MAIN MENU



From the menu click [Drug Accountability](#)

By participant- from drop-down menu select by [Participant](#)

By site – from drop-down menu select by [Site](#).

Drug Accountability - by participant

- Select participant ID
- Click “Confirm Participant ID”

 Welcome CJTP! [Log Out]
Change Password

DRUG ACCOUNTABILITY

Select Accountability by: **Participant** ▼

Participant ID: 15001

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					

Bottle ID	Expiry	Batch	Quantity	Received	Received By	Released	Released By	Returned	Returned By	Return Quantity	Destroyed	Destroyed By
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					

Drug Accountability - by site

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

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

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

