

# IMP/Placebo Accountability for Clinical Trial Pharmacy

# Requirements

- Delegated on Delegation Log
  - TRuST training completed – this presentation
  - TRuST log-in
  - Printer
- 
- For the GREAT-2 trial, the clinical trial pharmacy team are **unblinded** to treatment allocation.

# TRuST Randomisation & Drug Accountability System

- Recording drugs received
  - Dispensing/releasing drugs
  - Recording drug returns
  - Recording drugs disposal
  - Recording damaged drugs
  - Recording expired drugs
  - Quarantining drugs
  - Drug accountability
- 
- TRuST can be accessed directly: <https://hicservices.dundee.ac.uk/TRuST> or from the GREAT-2 website <https://sites.dundee.ac.uk/great-2/>
  - 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

- Login 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

If you have multiple projects using TRuST you will need to select the GREAT-2 trial from the dropdown menu.



# Main Menu



Project: GREAT-2 Test

## TEST SITE

Site: Tayside

### PHARMACY

- Scan in Drugs
- Release Drugs
- Drug Returns
- Drugs Disposal
- Drug Accountability
- Drugs on Shelf
- Damaged Drugs
- Discontinued Study Drugs
- Expired Drugs
- Quarantine

# Recording drugs received (1)

## Acknowledgement of Receipt of Clinical Trial Material

Study Name	GREAT-2 Test		
EudraCT	2022-003215-28	CTA	IRAS 1005993
Delivered to:	01 - Tayside		

Email a copy of the form within 7 working days to Tricia Mepham/tricia.mepham@sharpclinical.com

Please find enclosed the following supplies. Please check the quantity and condition of the supplies, complete the last 2 columns in the table below, sign and date to acknowledge receipt.

Please remember to scan in the individual pack IDs on the TRuST system within the next 7 days

Pack ID(s)	Batch	Expiry	Received (√ or x)	Comment? (e.g. item damaged/missing)
0200	321	01/04/2025		
0201	321	01/04/2025		
0202	321	01/04/2025		
0249	321	01/04/2025		
Total Quantity	50			

Packed By:		Date:	
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Received By:		Date:	
Designation:			

SHARP CLINICAL, Unit 28, Heol Klockner, Heads of the Valley Ind. Estate, Rhymney, Tredegar, NP22 5RL, United Kingdom

To be completed by SHARP Clinical Services Ltd:  
Acknowledgement of receipt signed, dated and returned. Filed in Clinical Trial Folder.

- Acknowledgement of Receipt of Clinical Trial Material Form
  - Confirm receipt on form: complete “Received” column by placing a tick in each box.
  - If any packs are missing or damaged, documented under “Comments” column
  - Sign and date form under “Received By” (see next slide)
  - Email signed form to SHARP: [tricia.mepham@sharpclinical.com](mailto:tricia.mepham@sharpclinical.com) & file in PSF

## Recording drugs received (2) Scan in drugs



### DRUG MANAGEMENT - SCAN IN PACK ID'S

0228  
0229  
0230  
0231  
0232  
0233  
0234  
0235  
0236  
0237  
0238  
0239  
0240  
0241  
0242  
0243  
0244  
0245  
0246  
0247  
0248  
0249

Ensure a space is entered after the last pack ID

Invalid Pack ID Count: 1

Valid Pack ID Count: 50

Check Valid

Return to Main Menu



### DRUG MANAGEMENT - SCAN IN PACK ID'S

0200  
0201  
0202  
0203  
0204  
0205  
0206  
0207  
0208  
0209  
0210  
0211  
0212  
0213  
0214  
0215  
0216  
0217  
0218  
0219  
0220  
0221  
0222

Invalid Pack ID Count: 0

Valid Pack ID Count: 50

Check Valid

Save

Return to Main Menu

- Click “Scan in Drugs” from main Menu
- Enter pack IDs manually – one per line
- Ensure there is a space entered after the last pack ID
- Click “Check Valid”
- Remove any invalid bottle IDs added accidentally
- When all pack IDs are valid, click “Save”
- Drug Accountability and Drugs on Shelf will be updated

## Dispensing/Releasing drugs (1)



RELEASE DRUGS - SCAN PACK ID'S

Select Participant: 0110

Confirm Participant ID

Confirm Participant ID: 0110

Return to Main Menu



RELEASE DRUGS - SCAN PACK ID'S

Participant: 0110

Release Drugs	Please Scan Drugs
0103	0103
0104	0104
0106	
0107	
0109	
0110	
0112	
0113	

Check Valid

Release Drugs

Return to Main Menu

You will receive a hard copy of the Clinical Trial Request Form from the Research Nurse

- Click “Release Drugs” on Main Menu
- Select participant ID from the Clinical Trial Request Form
- Tick “Confirm Participant ID”
- Check pack IDs listed on TRuST match the pack IDs listed on the Clinical Trial Request Form
- Enter pack IDs listed on the Request Form in the “Please Scan Drugs” box - one pack ID per line, ensure there is a space entered after the last pack ID
- Click “Check Valid”
- If all pack IDs entered as valid, the Release Drugs button will appear
- Click “Release Drugs” to generate the Clinical Trial Release Form
- Print Clinical Trial Release Form
- Dug Accountability will be updated



# Dispensing/Releasing drugs (1) Clinical Trial Release Form Page 1

GREAT-2: A phase 2 trial of Gremubamab compared to placebo in participants with bronchiectasis and chronic Pseudomonas aeruginosa infection

## CLINICAL TRIAL RELEASE FORM

EudraCT	2022-003215-28	Sponsor	University of Dundee and NHS Tayside
CTA		Protocol No.	1-023-22
IRAS	1005993	Local CTP ID	

Chief Investigator	Prof James Chalmers	Tel No	01382 386131
Principal Investigator	Prof James Chalmers	Tel No	01382 386131

Participant ID:	0105
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Randomised to	Placebo
Total volume to be infused	250 ml
Rate of infusion	62.5 ml/hour
Please Supply	
Sodium chloride 0.9% (250ml/500ml)	1 bag
Gremubamab 200mg/Placebo 4ml	8 vials
Water for injection	0 ml

Please Supply	Gremubamab 1500mg/Gremubamab 500mg/Placebo					
Dose	200mg for Gremubamab per pack/4ml for Placebo per pack					
Expiry	13/02/2024					
Quantity	1 vial per pack					
Pack ID						
0054	0057	0072	0075	0102	0105	0108
0111						

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

FOR TRuST Validation:			
Barcodes			
0054	0057	0072	0075
0102	0105	0108	0111

Ensure that the Clinical Trial Release Form is printed on 2 separate pages.

Important: page 1 of the Clinical Trial Release Form contains unblinded information.

Page 1:

- Signed by the person releasing the pack
- Checked & signed by another member of the pharmacy team
- Signed by the person collecting the packs

# Dispensing/Releasing drugs (2) Clinical Trial Release Form Page 2



GREAT-2: A phase 2 trial of Gremubamab compared to placebo in participants with bronchiectasis and chronic Pseudomonas aeruginosa infection

**This sheet ONLY to be given with IMP infusion to blinded Research Nurse**

EudraCT	2022-003215-28	Sponsor	University of Dundee and NHS Tayside
CTA		Protocol No.	1-023-22
IRAS	1005993	Local CTP ID	

Chief Investigator	Prof James Chalmers	Tel No	01382 386131
Principal Investigator	Prof James Chalmers	Tel No	01382 386131

Participant ID:	0105		
Participant Name:			
Date of Birth:	14/09/1955	Hospital Number/CHI:	
Visit Number:	2	Visit Date:	17/03/2023

Randomised to	Gremubamab 1500mg or Gremubamab 500 mg or placebo
Total volume to be infused	250 ml
Rate of infusion	62.5 ml/hour
Infusion made up by (signature)	
Date	
Time	
Print name	
Checked by (signature)	
Print name	
Infusion given by (signature)	
Date	
Start time	
Print name	
Checked by (signature)	
Print name	

- Unblinded team member to prepare the IV infusion according to the IMP Management Plan
- IV infusion should be prepared as close as possible to when the treatment will be given.

Page 2:

- Sign “Infusion made by”
- Add date and time of infusion preparation
- Checked & signed by another member of the pharmacy team
- **Only** Page 2 to be given to the blinded team member and record of administration of infusion completed
- To be filed in ISF

## Recording Drug Returns

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**DRUGS RETURNED**

Participant: 0131

Packs Returned:

0016  Sealed  Opened

0017  Sealed  Opened

0014  Sealed  Opened

**Record Drugs Returned**

Return to Main Menu

↓

**DRUGS RETURNED**

Participant: 0131

Packs recorded as returned

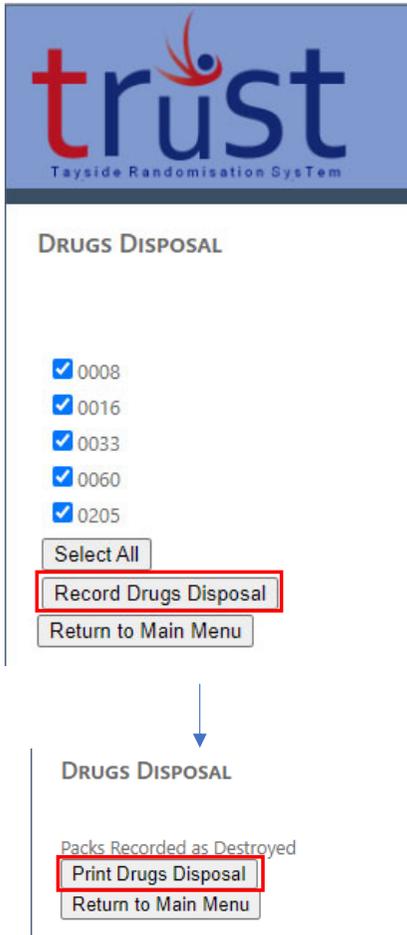
Return to Main Menu

- Click “Drug Returns” on Main Menu
- Select and confirm the participant ID which the pack is allocated to
- Tick pack IDs which are being returned
- Select “Sealed” or “Opened”
- In the textbox, if you have selected “opened” enter the number of vials (e.g. “1”)
- Click “Record Drugs Returned”
- Drug Accountability will be updated

Clinical trial pharmacy should not record drug returns on TRuST for the ½ unused vial that will be remaining from each infusion. This should be documented locally as per local procedure.

Drug returns should only be recorded where a vial is not used due to other circumstances and the whole vial is unused.

# Recording Drugs Disposal (1)



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DRUGS DISPOSAL

- 0008
- 0016
- 0033
- 0060
- 0205

Select All

**Record Drugs Disposal**

Return to Main Menu

↓

DRUGS DISPOSAL

Packs Recorded as Destroyed

**Print Drugs Disposal**

Return to Main Menu

All drug returns may be disposed of immediately, there is no need to request permission from Trial Manger

At the end of the trial, wait until CTP have been requested by Trial Manager to dispose of any remaining drugs

- Click “Drug Disposal” on Main Menu
- This will list all of the pack IDs that have been marked as returned
- Tick the appropriate pack IDs
- Click “Record Drug Disposal”
- Print Clinical Trial Disposal Form
- Dug Accountability will be updated

## Recording Drugs Disposal (2)



GREAT-2: A phase 2 trial of Gremubamab compared to placebo in participants with bronchiectasis and chronic Pseudomonas aeruginosa infection

### CLINICAL TRIAL DISPOSAL FORM

EudraCT	2022-003215-28	Sponsor	University of Dundee and NHS Tayside
CTA		Protocol No.	1-023-22
IRAS	1005993	Local CTP ID	

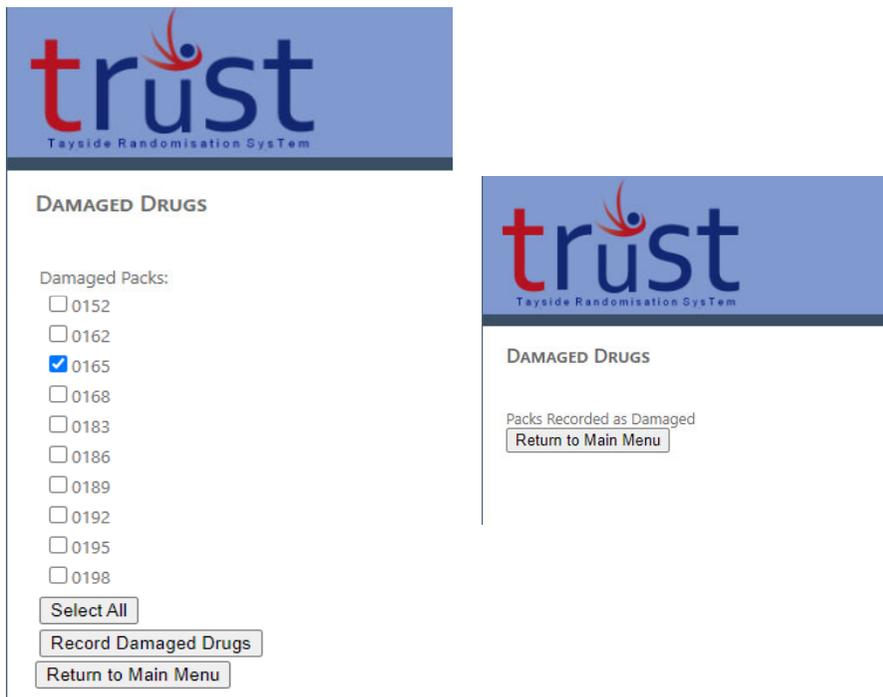
Chief Investigator	Prof James Chalmers	Tel No	01382 386131
Principal Investigator	Prof James Chalmers	Tel No	01382 386131

FOR PHARMACY USE:	
Pack ID:	Quantity of Unused (vial per pack)
0008	1
0016	1
0033	1
0060	1
0205	1

Disposed as CTP Policy by	
Date of Disposal	

- Dispose of drugs as per local procedure
- Complete Clinical Trial Disposal Form
- File in PSF

## Recording Damaged Drugs



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**DAMAGED DRUGS**

Damaged Packs:

- 0152
- 0162
- 0165
- 0168
- 0183
- 0186
- 0189
- 0192
- 0195
- 0198

[Select All](#)

[Record Damaged Drugs](#)

[Return to Main Menu](#)

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Tayside Randomisation SysTem

**DAMAGED DRUGS**

Packs Recorded as Damaged

[Return to Main Menu](#)

Should be completed if drugs are damaged on receipt or become damaged during the course of the trial

- Click “Damaged Drugs” on main menu
- Tick any pack IDs that are damaged
- Click “Record Damaged”
- Drug Accountability will be updated
- Inform Trial Manager to arrange replacements
- Do not dispose of damaged drugs until confirmation to dispose received from Trial Manager

# Recording Expired Drugs

- Click “Expired Drugs” on Main Menu
- Tick the appropriate pack IDs
- Click “Record Drugs Expired”
- Drug Accountability will be updated



## EXPIRED DRUGS

Expired Packs:

- 0136
- 0137
- 0139
- 0140
- 0142
- 0143
- 0145
- 0146
- 0148
- 0149
- 0151

Select All

Record Drugs Expired

Return to Main Menu

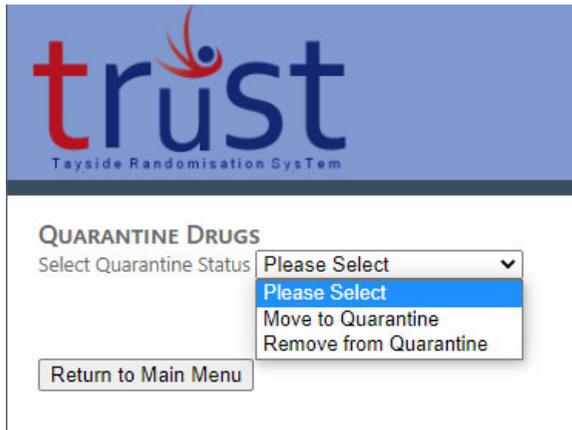


## EXPIRED DRUGS

Packs Recorded as Expired

Return to Main Menu

## Quarantine Drugs (1)

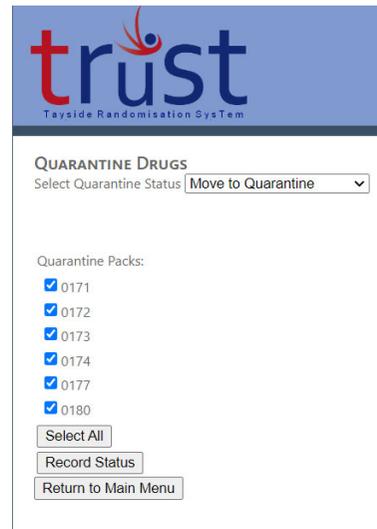


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Tayside Randomisation SysTem

QUARANTINE DRUGS  
Select Quarantine Status: Please Select

- Please Select
- Move to Quarantine
- Remove from Quarantine

Return to Main Menu



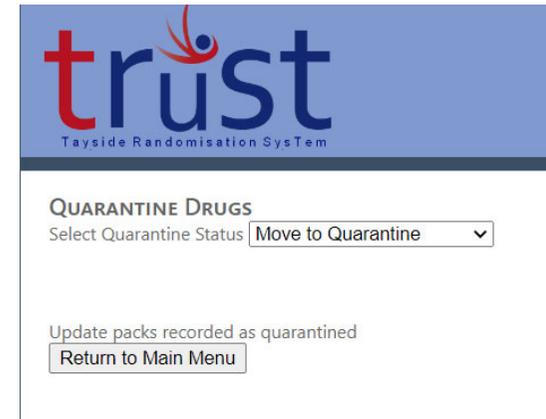
trust  
Tayside Randomisation SysTem

QUARANTINE DRUGS  
Select Quarantine Status: Move to Quarantine

Quarantine Packs:

- 0171
- 0172
- 0173
- 0174
- 0177
- 0180

Select All  
Record Status  
Return to Main Menu



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Tayside Randomisation SysTem

QUARANTINE DRUGS  
Select Quarantine Status: Move to Quarantine

Update packs recorded as quarantined

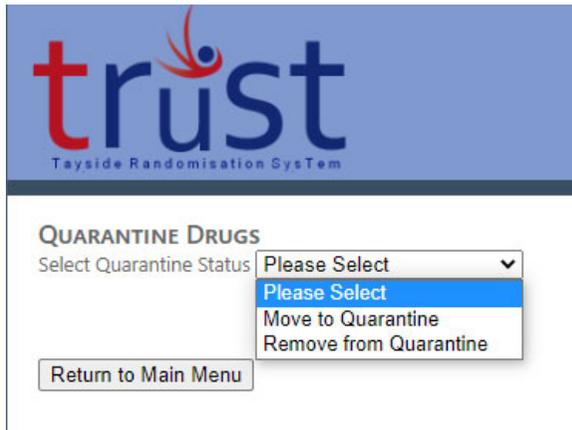
Return to Main Menu

Trial Manager will inform CTP if any drugs are to be placed into quarantine

Report to the Trial Manager if CTP require drugs to be quarantined e.g. temperature excursion

- Click “Quarantine” on Main Menu
- Select Quarantine Status “Move to Quarantine”
- Tick pack IDs to be quarantined
- Drug Accountability will be updated
- Drugs should be held in quarantine at usual temperature until CTP is informed to “Remove From Quarantine”

## Quarantine Drugs (2)

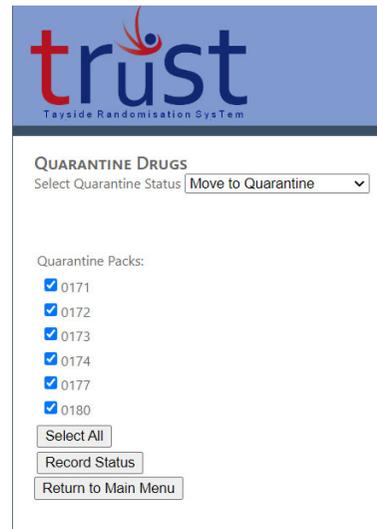


trust  
Tayside Randomisation System

QUARANTINE DRUGS  
Select Quarantine Status: Please Select

- Please Select
- Move to Quarantine
- Remove from Quarantine

Return to Main Menu



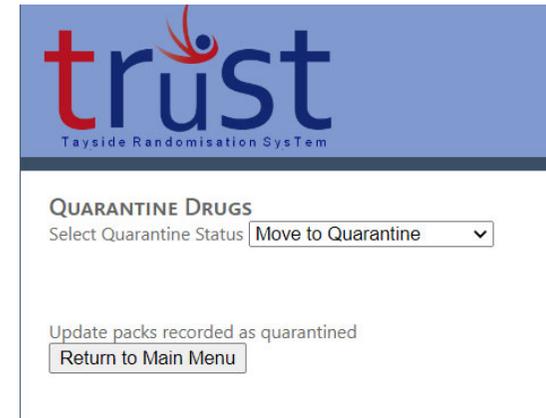
trust  
Tayside Randomisation System

QUARANTINE DRUGS  
Select Quarantine Status: Move to Quarantine

Quarantine Packs:

- 0171
- 0172
- 0173
- 0174
- 0177
- 0180

Select All  
Record Status  
Return to Main Menu



trust  
Tayside Randomisation System

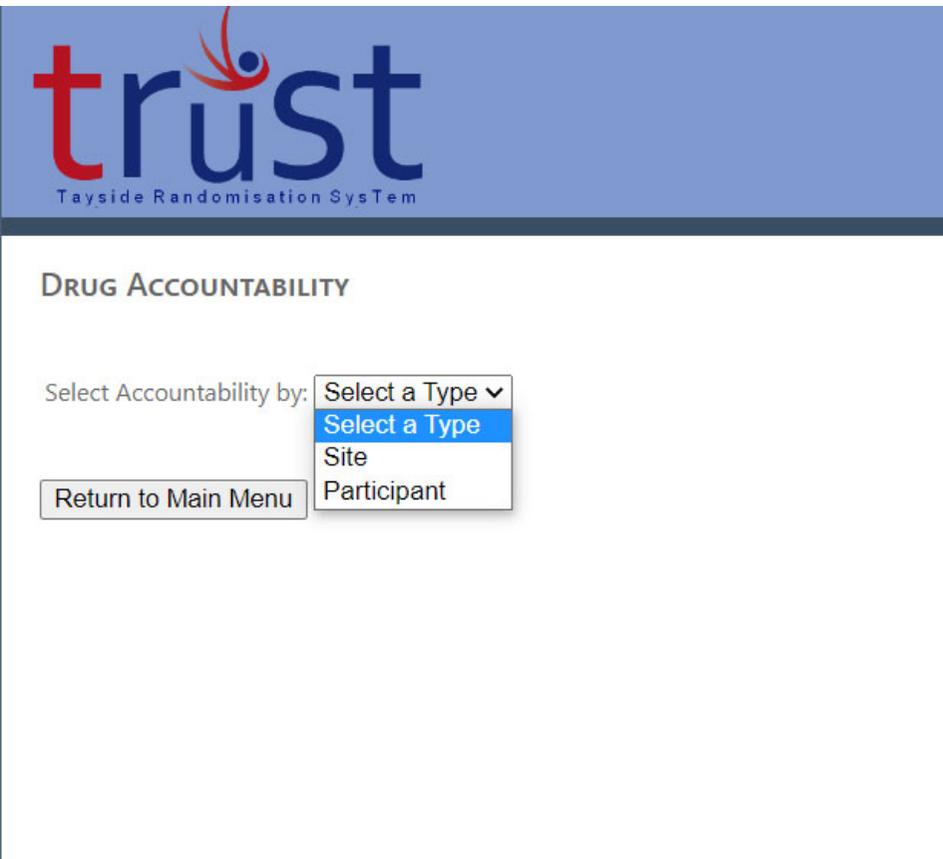
QUARANTINE DRUGS  
Select Quarantine Status: Move to Quarantine

Update packs recorded as quarantined  
Return to Main Menu

Trial Manager will inform CTP when quarantined drugs are to be replaced on shelf or disposed of.

- Click “Quarantine” on Main Menu
- Select Quarantine Status “Remove from Quarantine”
- Tick pack IDs to be removed from quarantine
- Drug Accountability will be updated
- If drugs are to be disposed of, Disposing Drugs should be followed

## Drug Accountability (1)



The screenshot shows the 'trust' logo at the top left, with 'Tayside Randomisation System' underneath. Below the logo is the heading 'DRUG ACCOUNTABILITY'. Underneath the heading is the text 'Select Accountability by:' followed by a dropdown menu. The dropdown menu is open, showing three options: 'Select a Type', 'Site', and 'Participant'. To the left of the dropdown menu is a button labeled 'Return to Main Menu'.

- Drug Accountability can be viewed as either a whole site or for individual participants.
- Drug accountability displays pack IDs and does not display which treatment each participant has been allocated to.
- Click “Drug Accountability” on Main Menu
- Select type of accountability to view

# Drug Accountability (2) By Site



DRUG ACCOUNTABILITY

Select Accountability by:

Treatment: Gremubamab 1500mg Gremubamab 500mg Placebo

Pack ID	Expiry	Batch	Quantity (vial per pack)	Dose	Received	Received By	Released	Participant ID	Released By	Returned	Returned By	Return Quantity	Destroyed	Destroyed By
0021	13/02/2024	123	1	200mg/4ml	23/02/2023	great2pharma				24/02/2023	great2pharma	Damaged	01/03/2023	great2pharma
0022	13/02/2024	123	1	200mg/4ml	23/02/2023	great2pharma	01/03/2023	0114	great2pharma					
0023	13/02/2024	123	1	200mg/4ml	23/02/2023	great2pharma				23/02/2023	great2pharma	Damaged	01/03/2023	great2pharma
0024	13/02/2024	123	1	200mg/4ml	24/02/2023	great2pharma				24/02/2023	great2pharma	Damaged		
0030	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0032	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0033	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0034	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0035	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0036	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0037	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0038	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0039	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0040	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma	08/03/2023	0121	great2pharma					
0041	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma	08/03/2023	0121	great2pharma					
0042	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0044	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0045	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0046	13/02/2024	123	1	200mg/4ml	08/03/2023	great2pharma								
0047	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma		0116						
0048	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma	01/03/2023	0115	great2pharma					
0049	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma		0116						
0050	13/02/2024	123	1	200mg/4ml	01/03/2023	great2pharma		0116						
0051	13/02/2024	124	1	200mg/4ml	24/02/2023	great2pharma	01/03/2023	0115	great2pharma	01/03/2023	great2rand	Lost		
0052	13/02/2024	124	1	200mg/4ml	01/03/2023	great2pharma		0116						
0053	13/02/2024	124	1	200mg/4ml	01/03/2023	great2pharma		0116						
0054	13/02/2024	124	1	200mg/4ml	24/02/2023	great2pharma	17/03/2023	0105	great2pharma					
0057	13/02/2024	124	1	200mg/4ml	24/02/2023	great2pharma	17/03/2023	0105	great2pharma					
0060	13/02/2024	124	1	200mg/4ml	24/02/2023	great2pharma				24/02/2023	great2pharma	Damaged		
0063	01/03/2023	125	1	200mg/4ml	01/03/2023	great2pharma								

Official Trial Accountability Log – paper copy not required during trial

- Select Accountability by Site
- At end of trial the Trial Manager will inform CTP to dispose of any remaining drugs
- Drug Accountability Log must be printed after all remaining drugs and drug returns have been recorded and disposed of

# Drug Accountability (3) By Participant



**DRUG ACCOUNTABILITY**

Select Accountability by: Participant

Select Participant: 0110

Confirm Participant ID  
 Confirm Participant ID: 0110

[Return to Main Menu](#)

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**DRUG ACCOUNTABILITY**

Select Accountability by: Participant

Participant ID: 0110  
 Treatment: Gremubamab 1500mg Gremubamab 500mg Placebo

Pack ID	Expiry	Batch	Quantity (vial per pack)	Dose	Received	Received By	Released	Released By	Returned	Returned By	Return	Quantity	Destroyed	Destroyed By
0103	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0104	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0106	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0107	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0109	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0110	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0112	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0113	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma	05/04/2023	great2pharma						
0115	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0116	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0118	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0119	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0121	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0122	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0124	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								
0125	20/03/2024	111	1	200mg/4ml	17/03/2023	great2pharma								

[Print Accountability](#)

- Select Accountability by Participant
- Select participant ID from dropdown menu
- Confirm the participant ID.

# Drug Accountability (4) Current Stock



## CURRENT STOCK

Pack ID	Expiry	Batch	Quantity	Received	Received By
0003	13/02/2024	123	1	12/04/2023	great2pharma
0006	13/02/2024	123	1	12/04/2023	great2pharma
0009	13/02/2024	123	1	12/04/2023	great2pharma
0010	13/02/2024	123	1	12/04/2023	great2pharma
0011	13/02/2024	123	1	12/04/2023	great2pharma
0012	13/02/2024	123	1	12/04/2023	great2pharma
0013	13/02/2024	123	1	12/04/2023	great2pharma
0014	13/02/2024	123	1	12/04/2023	great2pharma
0015	13/02/2024	123	1	12/04/2023	great2pharma
0016	13/02/2024	123	1	12/04/2023	great2pharma
0017	13/02/2024	123	1	12/04/2023	great2pharma
0018	13/02/2024	123	1	12/04/2023	great2pharma
0019	13/02/2024	123	1	12/04/2023	great2pharma
0020	13/02/2024	123	1	12/04/2023	great2pharma
0025	13/02/2024	123	1	12/04/2023	great2pharma
0026	13/02/2024	123	1	12/04/2023	great2pharma
0027	13/02/2024	123	1	12/04/2023	great2pharma
0028	13/02/2024	123	1	12/04/2023	great2pharma

- Displays the current available stock
- Lists pack IDs which have been received on TRuST but have not been allocated to a participant yet.

## Notes

Documents to be filed in PSF:

- Signed Acknowledgement of Receipt of Clinical Trial Material
  - Signed Clinical Trial Request Forms
  - Signed Clinical Trial Release Forms (page 1 only)
  - Signed Drug Disposal Forms
  - Complete Drug Accountability Form – at end of trial only
- 
- Please document this training to your 'Trial Training log' held in the PSF
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- Any questions contact GREAT-2 Clinical Trial Manager  
Gillian Martin [Great-2-TM@dundee.ac.uk](mailto:Great-2-TM@dundee.ac.uk) 01382 381955