



# Randomisation & Requesting IMP



## TRuST – Tayside Randomisation System

- Web-based randomisation system used by Research Nurses
- TRuST for AIR-NET will be used for randomisation only. Clinical trial pharmacy will perform IMP accountability, this will not be documented on TRuST.
- AIR-NET is unblinded, team members delegated randomisation and clinical trial pharmacy will receive the participant randomisation allocation
- The participant will also be made aware of their treatment allocation

## Randomisation Requirements

- Delegated to randomise on Delegation Log
- Randomisation training completed – this presentation documented on Training Log
- Eligibility Form reviewed & signed by PI/delegate
- Internet access
- TRuST log-in
- Participant ID
- Printer

# Completion of Eligibility Form

Complete the paper eligibility form to determine which arm(s) the participant is eligible to be randomised to.

This must be reviewed & signed by a delegated doctor **before** randomisation takes place

Participant ID

Date of Visit \_\_\_/\_\_\_/\_\_\_

Visit 1 - Screening - Inclusion Criteria

Number	Question	Answers
9.1	Age 18 or over	<input type="radio"/> Yes <input type="radio"/> No
9.2	Able to and provided informed consent	<input type="radio"/> Yes <input type="radio"/> No
9.3	Capable of complying with all trial procedures and of completing the trial, in the opinion of the investigator	<input type="radio"/> Yes <input type="radio"/> No
9.4	Bronchiectasis, confirmed by computed tomography (CT), showing bronchiectasis in 1 or more lobes	<input type="radio"/> Yes <input type="radio"/> No
9.5	Normally produces sputum on a daily basis	
9.6	Able to provide a sputum sample at the screening visit	
9.7	Active neutrophilic inflammation at screening indicated by a positive NEATstik (Neutrophil Elastase Airways Test) result (b)	

(b) A positive NEATstik test is equivalent to a positive Proaxis active NE immunoassay. If NEATstik sample will be shipped to the central laboratory performed and used to confirm eligibility.

Participant ID

Visit 2 - Baseline and randomisation – Confirmation of eligibility

Number	Question	Answers
25.37	Eligible for Arm 1: Standard care?	<input type="radio"/> Yes <input type="radio"/> No
25.38	Eligible for Arm 2: Disulfiram?	<input type="radio"/> Yes <input type="radio"/> No
25.39	Eligible for Arm 3: Dipyridamole?	<input type="radio"/> Yes <input type="radio"/> No
25.40	Eligible for Arm 4: Doxycycline?	<input type="radio"/> Yes <input type="radio"/> No

Eligibility review completed by (*must be a Dr on delegation log*):

Signature:

Name:

Date:

## TRuST Access

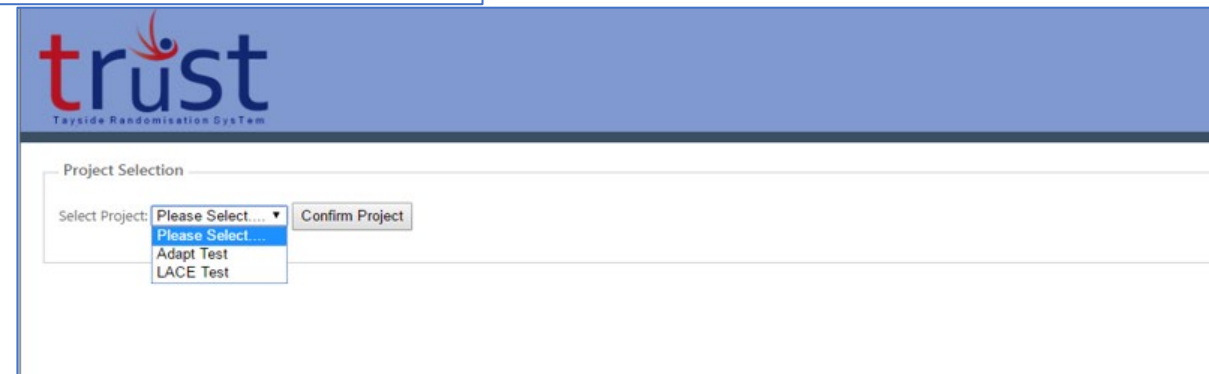
- TRuST can be accessed directly: <https://trust.hicservices.dundee.ac.uk/Account/Login> or from the AIR-NET website
- Login details for TRuST will be sent out after training has taken place. If not received, click on “Forgotten Password” and enter your email as your username.

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



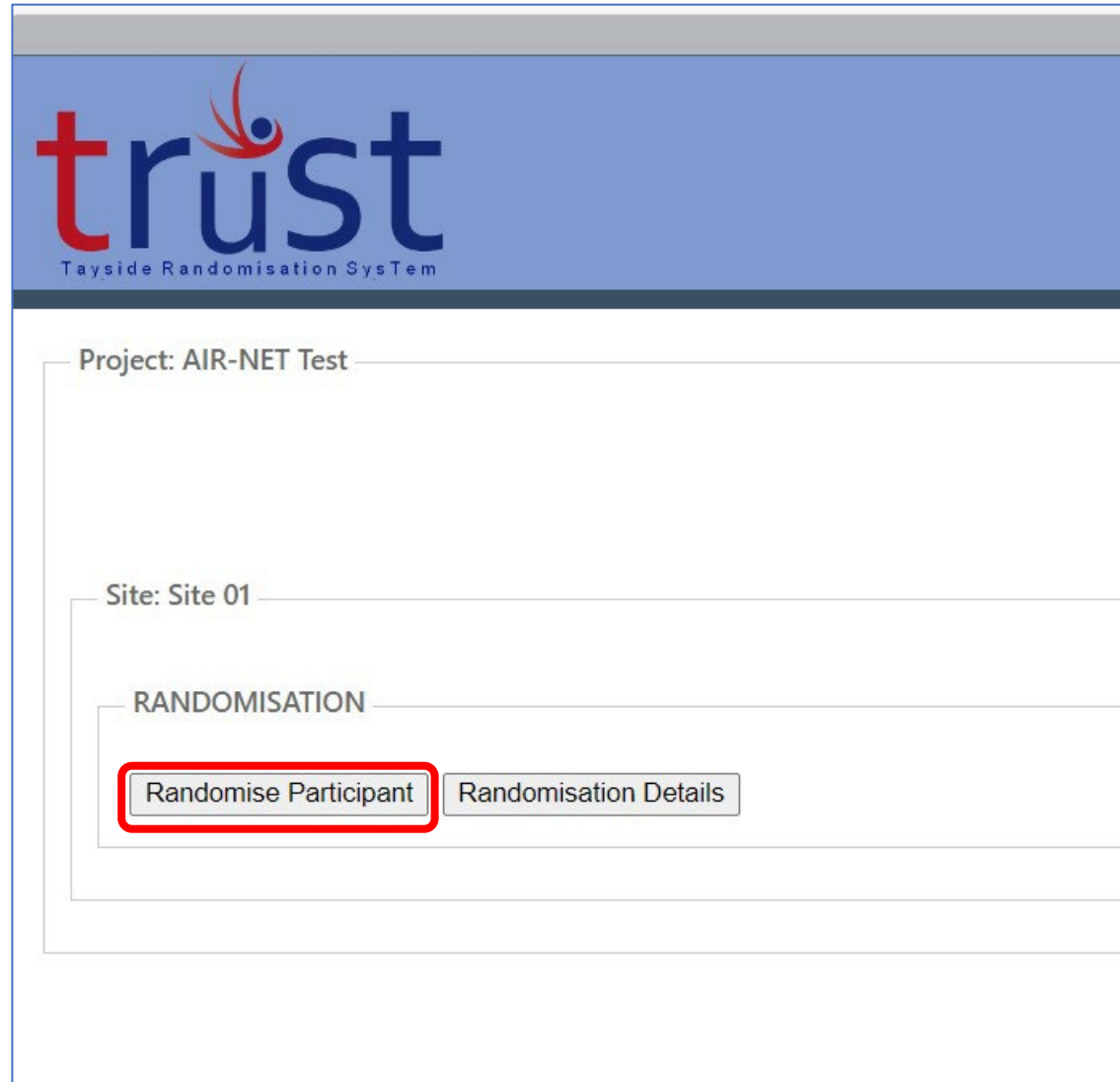
If you forget your password, click the forgotten password link and your new password will be emailed to you

For staff with multiple projects on TRuST select the AIR-NET trial from the dropdown menu.



## Randomising a participant

Click “Randomise Participant” button



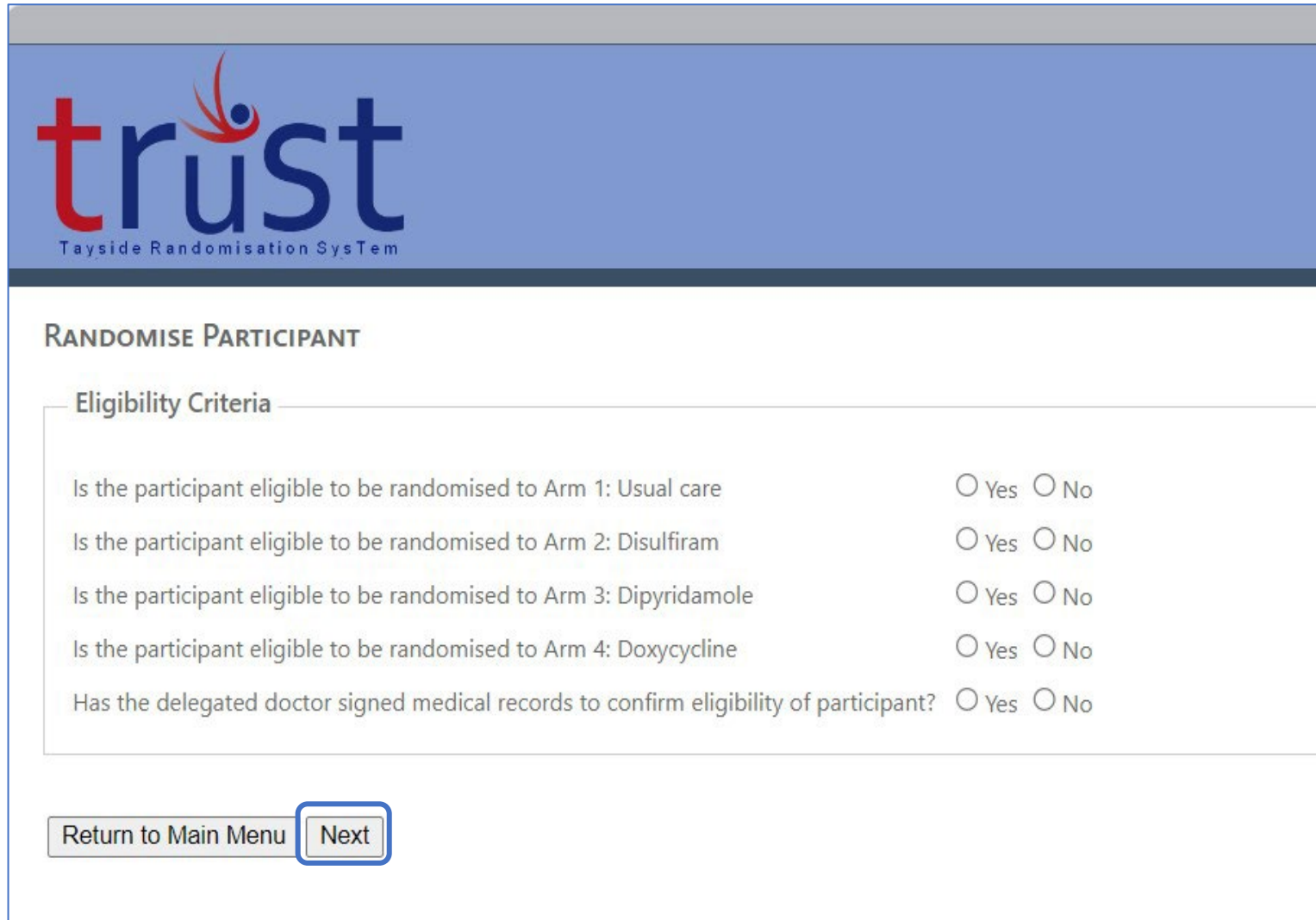
The screenshot displays the Trust Tayside Randomisation System interface. At the top, the logo for 'trust' is shown in red and blue, with 'Tayside Randomisation System' written below it. The main content area is divided into sections: 'Project: AIR-NET Test', 'Site: Site 01', and 'RANDOMISATION'. Under the 'RANDOMISATION' section, there are two buttons: 'Randomise Participant' and 'Randomisation Details'. The 'Randomise Participant' button is highlighted with a red rectangular border.



# Randomising a participant

Complete eligibility criteria questions from the paper Eligibility Form, and confirm this has been signed by a DR on the delegation log

Click on “Next” button



The screenshot shows the 'trust' (Tayside Randomisation System) interface. The main heading is 'RANDOMISE PARTICIPANT'. Below this is a section titled 'Eligibility Criteria' containing five questions, each with 'Yes' and 'No' radio button options:

- Is the participant eligible to be randomised to Arm 1: Usual care  Yes  No
- Is the participant eligible to be randomised to Arm 2: Disulfiram  Yes  No
- Is the participant eligible to be randomised to Arm 3: Dipyridamole  Yes  No
- Is the participant eligible to be randomised to Arm 4: Doxycycline  Yes  No
- Has the delegated doctor signed medical records to confirm eligibility of participant?  Yes  No

At the bottom of the form, there are two buttons: 'Return to Main Menu' and 'Next'. The 'Next' button is highlighted with a blue border.





# Randomising a participant

- Add participant ID (site ID is prepopulated)
- Complete stratification questions
- Completed consent must be “Yes”
- Eligibility must be “Yes”

The screenshot shows the 'RANDOMISE PARTICIPANT' interface. At the top is the 'trust' logo with 'Tayside Randomisation System' below it. The main content area is titled 'RANDOMISE PARTICIPANT' and contains the following elements:

- 'Site: Site 01' (prepopulated)
- 'Participant ID: 01' followed by three empty input boxes.
- 'Pseudomonas aeruginosa infection recorded in the last 2 years:  Yes  No'
- 'Long-term use of macrolides:  Yes  No'
- 'Has participant completed informed consent?  Yes  No'
- 'Does the participant meet eligibility criteria?  Yes  No'
- 'Return to Main Menu' button.

Red arrows from the list on the left point to the 'Participant ID' field, the stratification questions, the 'Has participant completed informed consent?' question, and the 'Does the participant meet eligibility criteria?' question.

## Randomising a participant

When both consent form and eligibility criteria have been completed as “Yes” the “Randomise” button will appear.



### RANDOMISE PARTICIPANT

Site: Site 01

Participant ID: 01

Pseudomonas aeruginosa infection recorded in the last 2 years:  Yes  No

Long-term use of macrolides:  Yes  No

Has participant completed informed consent?  Yes  No

Does the participant meet eligibility criteria?  Yes  No

**Randomise**

Return to Main Menu

Click on “Randomise” button



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## Randomising a participant

The screen will now display the randomisation allocation.



The screenshot displays the 'trust' logo (Tayside Randomisation System) at the top. Below the header, the text 'RANDOMISE PARTICIPANT' is centered. The main content area shows the following information: 'Site: Site 01', 'Subject Identifier: 01123', and 'Randomisation Allocation: Doxycycline 100mg, one capsule once daily'. A button labeled 'Return to Main Menu' is located at the bottom of the content area. A red arrow points from the text 'The screen will now display the randomisation allocation.' to the 'Randomisation Allocation' text.



# IMP Request/Release Form for Pharmacy


*This form is not generated by TRuST*

This form should be completed manually after a randomisation takes place. This is not required where a participant has been allocated to “usual care”

Research team to complete:

- PI details
- Participant & visit details
- Randomisation allocation
- PI/delegated doctor to confirm, sign & date

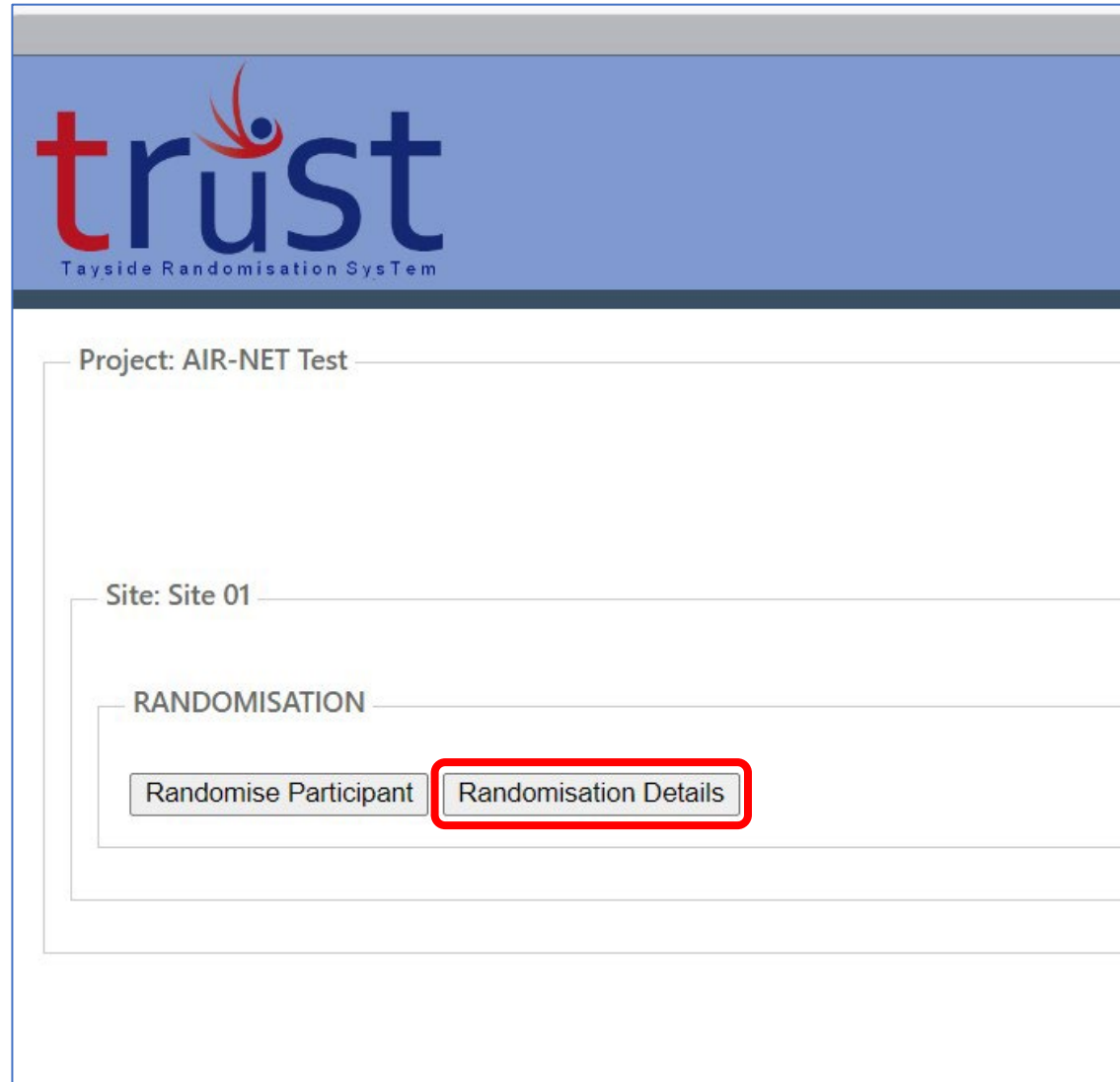
Provide this form to clinical trial pharmacy for dispensing  
Document the research team member who collects the trial medication from pharmacy

 AIR-NET Trial: Testing anti-inflammatories for the treatment of bronchiectasis			
<b>CLINICAL TRIAL REQUEST &amp; RELEASE FORM</b>			
Sponsor:	University of Dundee and NHS Tayside		
IRAS	1010124	CTP No.	
Chief Investigator:	Prof James Chalmers	Tel No: 01382 386131	
Principal Investigator:		Tel No:	
Participant ID:			
Participant Name:			
Date of Birth:		Hospital Number/CHI Number	
Visit Number:		Visit Date:	
Participant has been randomised to the following:			
<input type="checkbox"/> Disulfiram 200mg tablets 2 tablets 1 daily for 28 days			
<input type="checkbox"/> Dipyridamole 200mg capsules 1 capsule twice daily for 28 days			
<input type="checkbox"/> Doxycycline 100mg capsules 1 capsule once daily for 28 days			
Investigator or delegate Signature:		Date:	
Clinical Trial Pharmacy: Please supply the following:			
<input type="checkbox"/> Disulfiram 200mg x 60 tablets			
<input type="checkbox"/> Dipyridamole 200mg x 60 MR capsules.			
<input type="checkbox"/> Doxycycline 100mg x 30 capsules			
<input type="checkbox"/> PIL issued with trial medication			
Dispensed By:		Date:	
Checked By:		Date:	
Collected by:		Date:	
<small>AIR-NET IMP Request Release Form V1 18-11-2024</small>			

# Randomisation Details

Main menu:

Click “Randomisation Details” button



# Randomisation Details



Welcome **airnetrandomise!** [ [Log Out](#) ]  
[Change Password](#)

## RANDOMISATION DETAILS

Participant ID	Treatment Allocated	Randomised Date	Randomised By
01123	Doxycycline 100mg, one capsule once daily	15/11/2024	aimetrandomise
01777	Usual Care	22/11/2024	aimetrandomise

Total Randomised: 2

[Return to Main Menu](#)



## RANDOMISATION DETAILS

Participant ID	Treatment Allocated
01123	Doxycycline 100mg, one capsule once daily
01777	Usual Care

Total Randomised: 2

[Return to Main Menu](#)



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AIR-NET Trial Management Team: [AIRNET-TM@dundee.ac.uk](mailto:AIRNET-TM@dundee.ac.uk)  
01382 383830

TRuST hicservices-support: [hicsupport@dundee.ac.uk](mailto:hicsupport@dundee.ac.uk)



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