AIR-NET

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

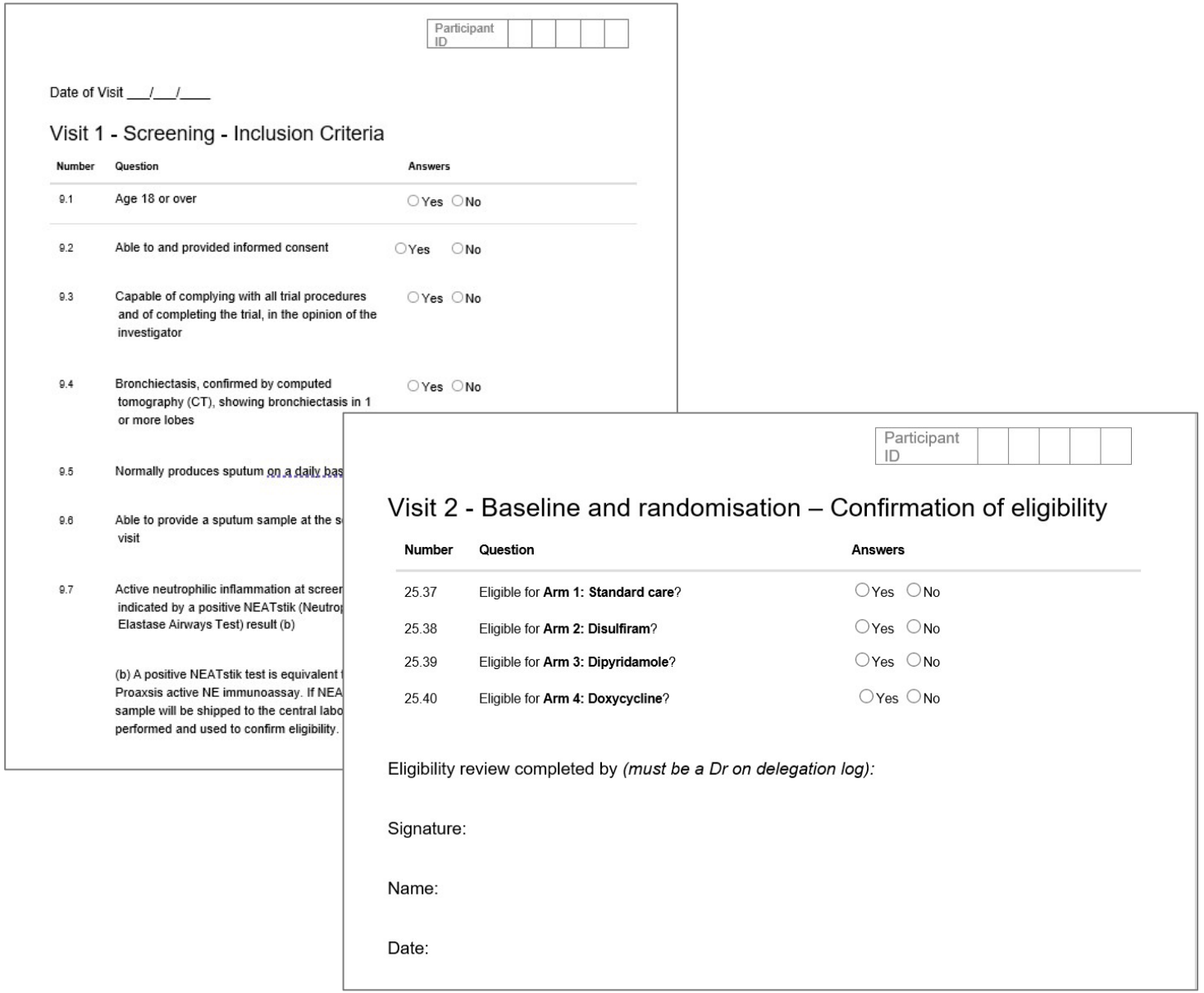
Randomisation Requirements

- 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	○ Yes ○ No
9.2	Able to and provided informed consent	○ Yes ○ No
9.3	Capable of complying with all trial procedures and of completing the trial, in the opinion of the investigator	○ Yes ○ No
9.4	Bronchiectasis, confirmed by computed tomography (CT), showing bronchiectasis in 1 or more lobes	○ Yes ○ No
9.5	Normally produces sputum on a daily bas	
9.6	Able to provide a sputum sample at the s visit	
9.7	Active neutrophilic inflammation at screer indicated by a positive NEATstik (Neutro Elastase Airways Test) result (b)	

(b) A positive NEATstik test is equivalent Proaxsis active NE immunoassay. If NEA sample will be shipped to the central labo 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**?	○ Yes ○ No
25.38	Eligible for **Arm 2: Disulfiram**?	○ Yes ○ No
25.39	Eligible for **Arm 3: Dipyridamole**?	○ Yes ○ No
25.40	Eligible for **Arm 4: Doxycycline**?	○ Yes ○ 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.

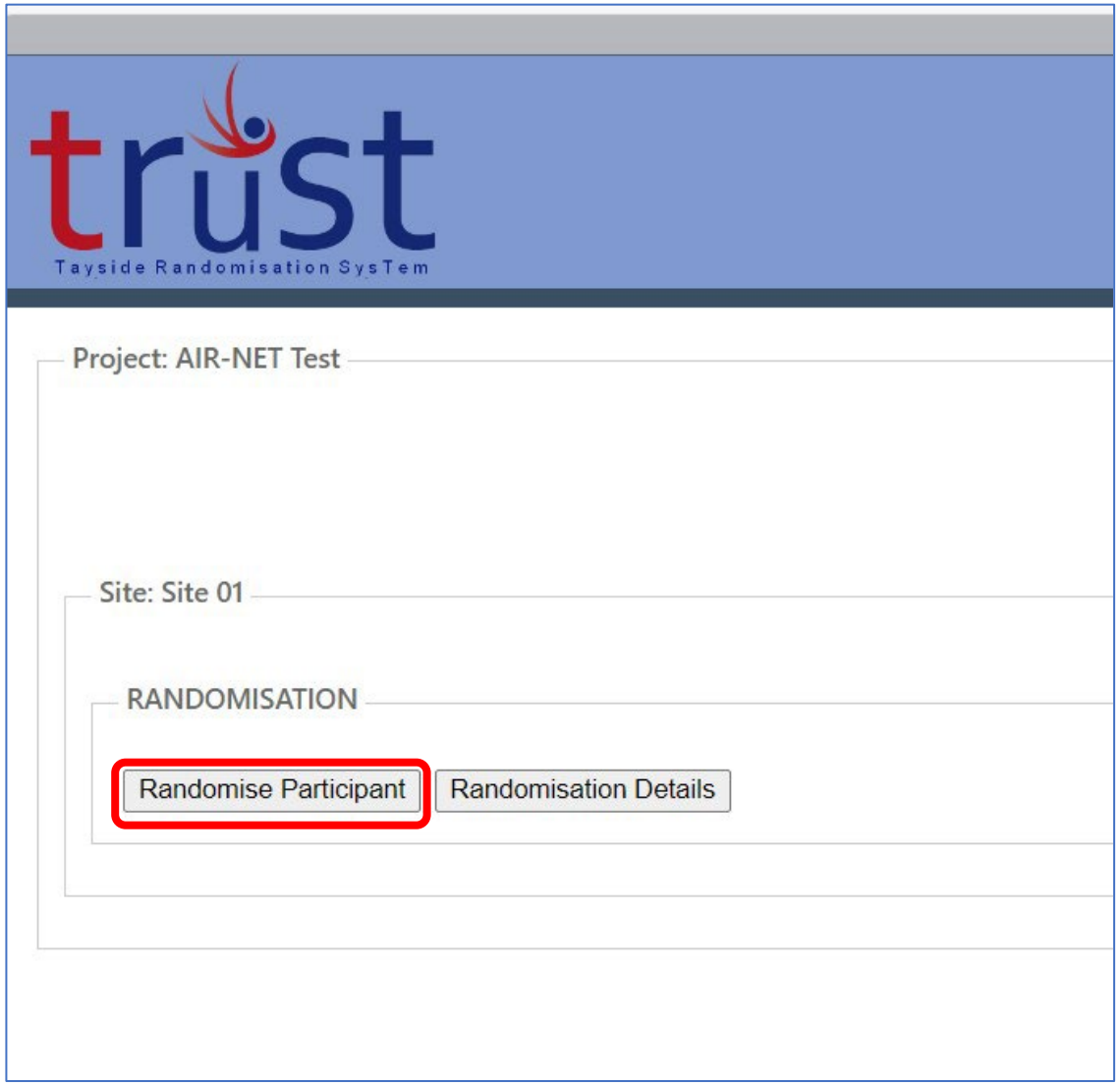
- Log in with your details; on first login you will be asked to change your password

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

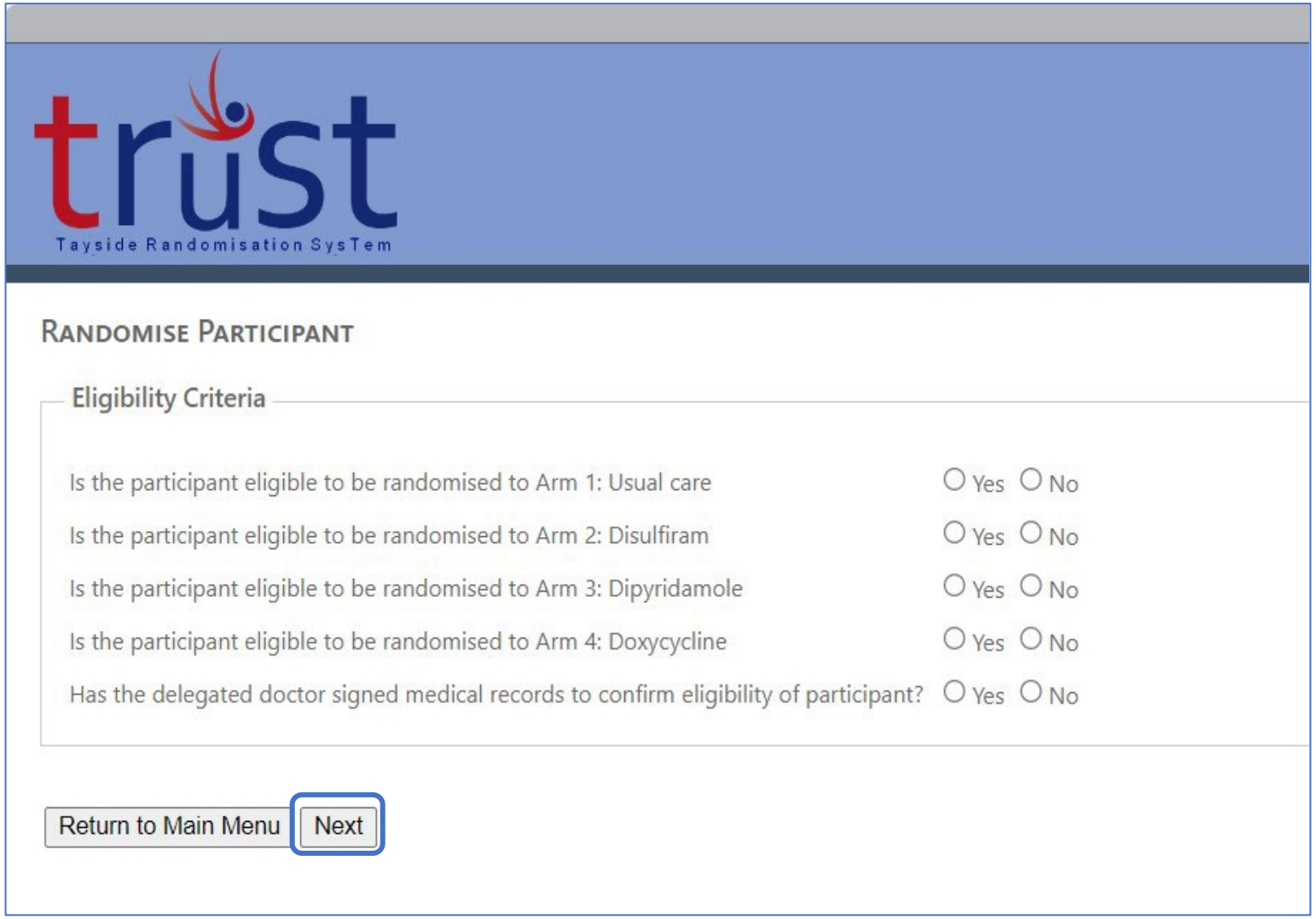
Click “Randomise Participant” button



Randomising a participant

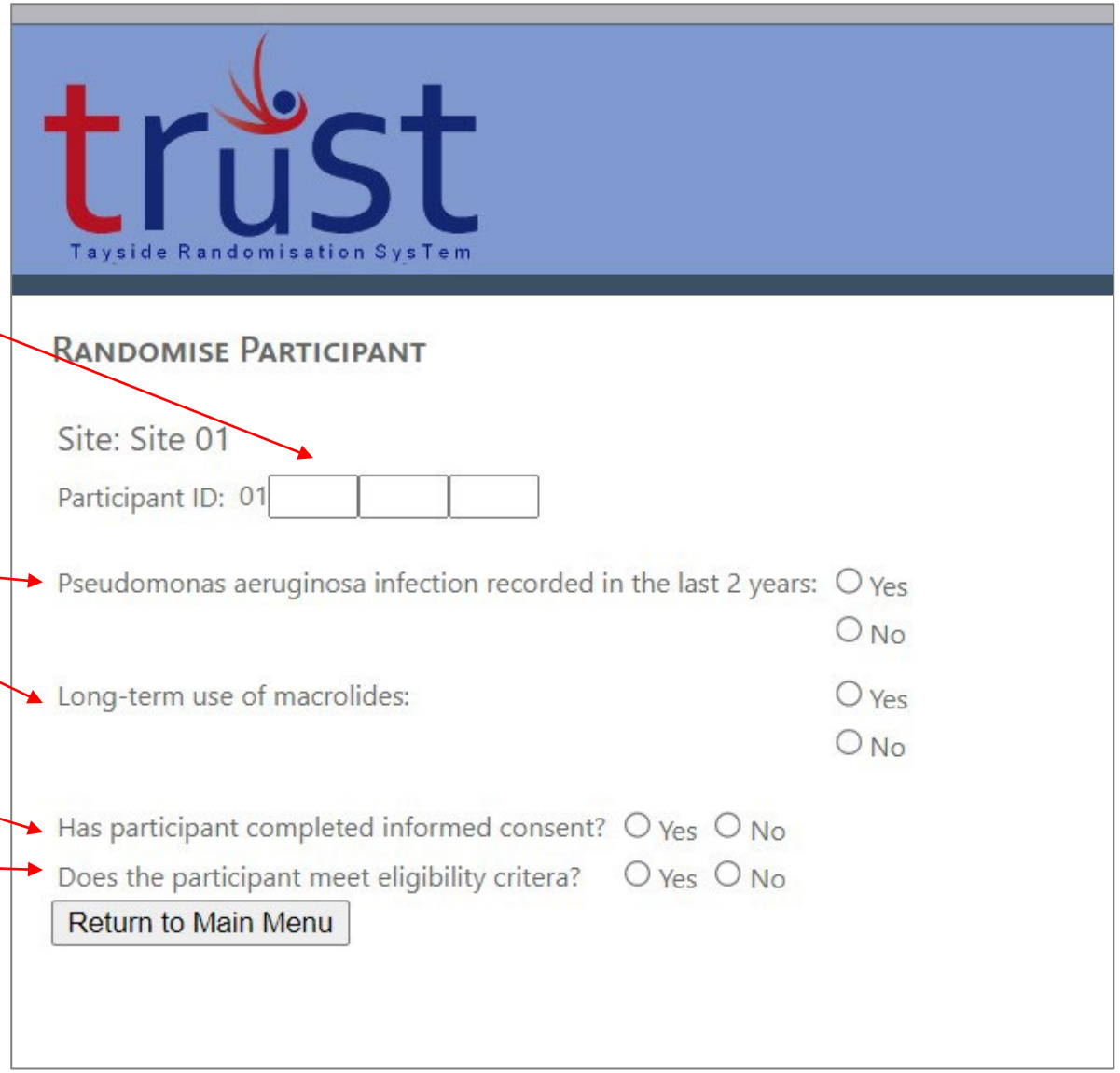
Complete eligibility criteria questions from the paper Eligibility Form, and confirm this has been signed by a DR on the delegation log

Click on “Next” button



Randomising a participant

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



Randomising a participant

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

Click on “Randomise” button

Randomising a participant

The screen will now display the randomisation allocation.

IMP Request/Release Form for Pharmacy

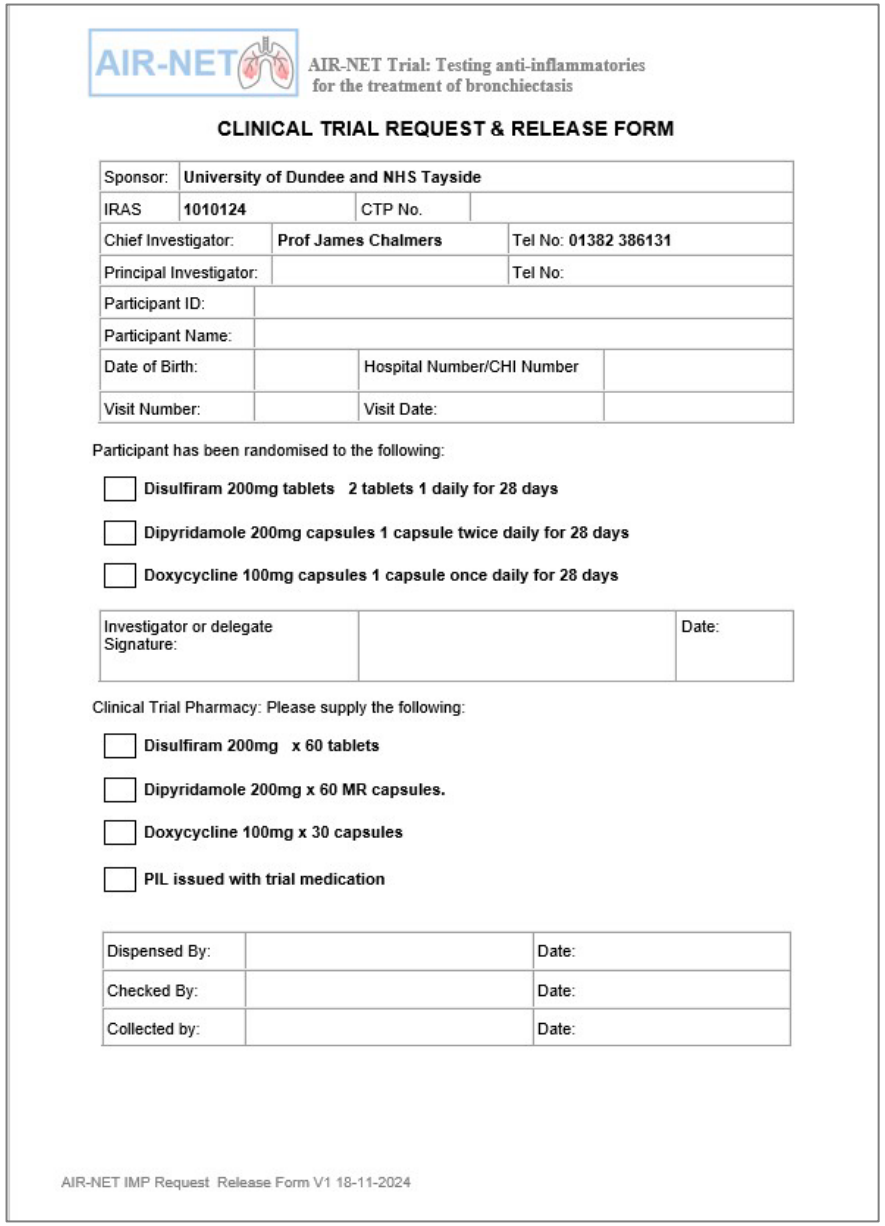
This form is not generated by TRuST

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

AIR-NET Trial: Testing anti-inflammatories for the treatment of bronchiectasis

CLINICAL TRIAL REQUEST & RELEASE FORM

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:

- ☐ Disulfiram 200mg tablets 2 tablets 1 daily for 28 days
- ☐ Dipyridamole 200mg capsules 1 capsule twice daily for 28 days
- ☐ Doxycycline 100mg capsules 1 capsule once daily for 28 days

Investigator or delegate Signature:		Date:

Clinical Trial Pharmacy: Please supply the following:

- ☐ Disulfiram 200mg x 60 tablets
- ☐ Dipyridamole 200mg x 60 MR capsules.
- ☐ Doxycycline 100mg x 30 capsules
- ☐ PIL issued with trial medication

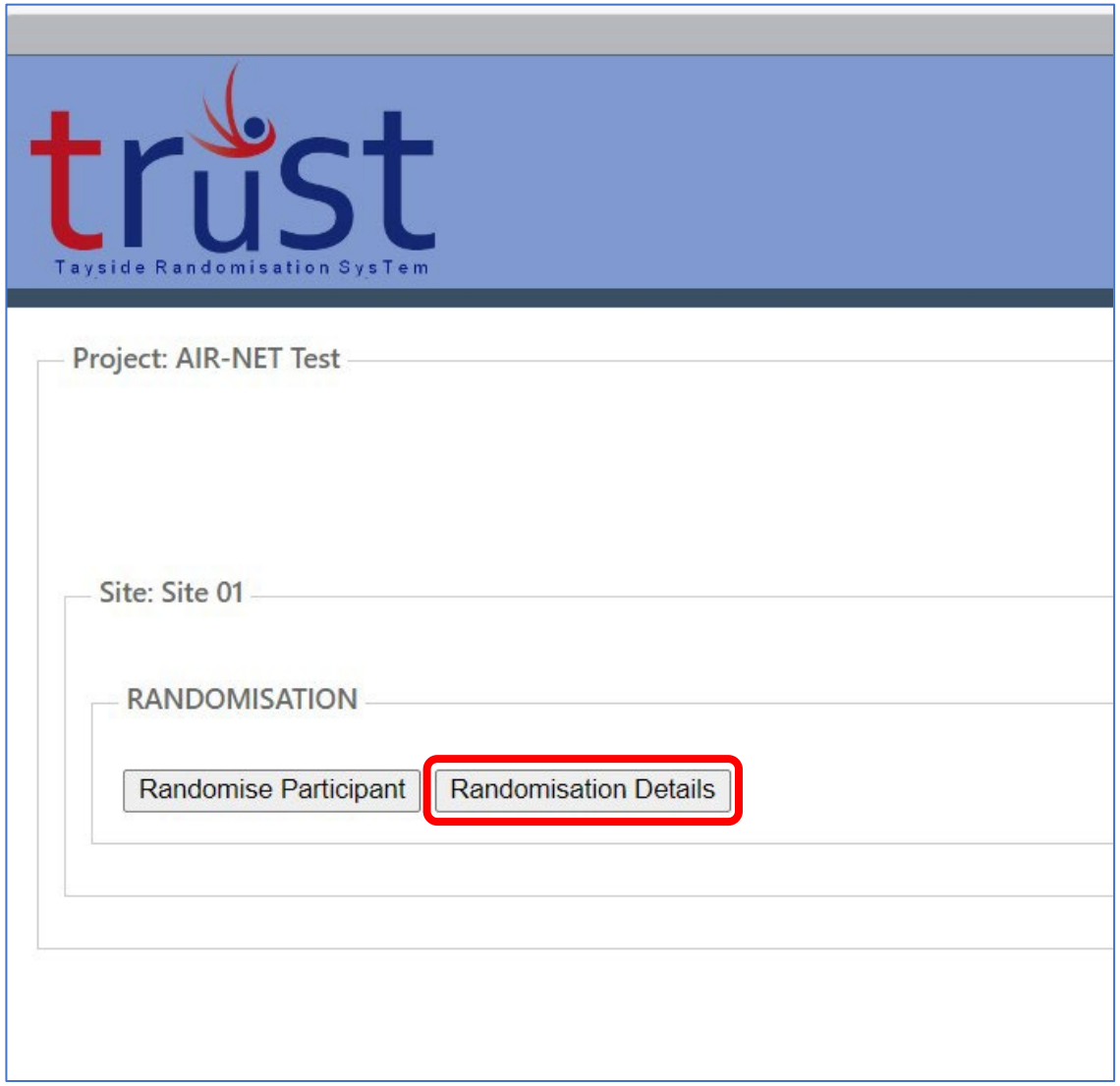
Dispensed By:		Date:
Checked By:		Date:
Collected by:		Date:

AIR-NET IMP Request Release Form V1 18-11-2024

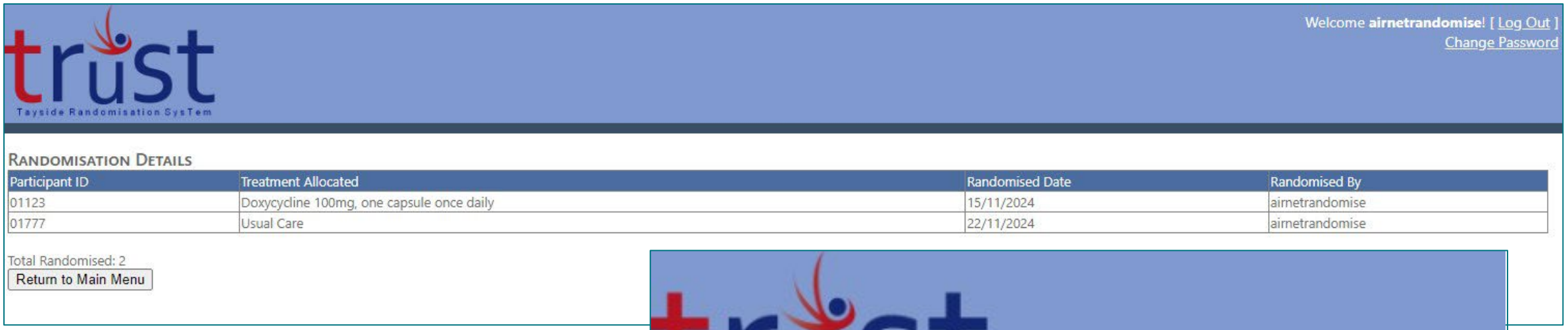
Randomisation Details

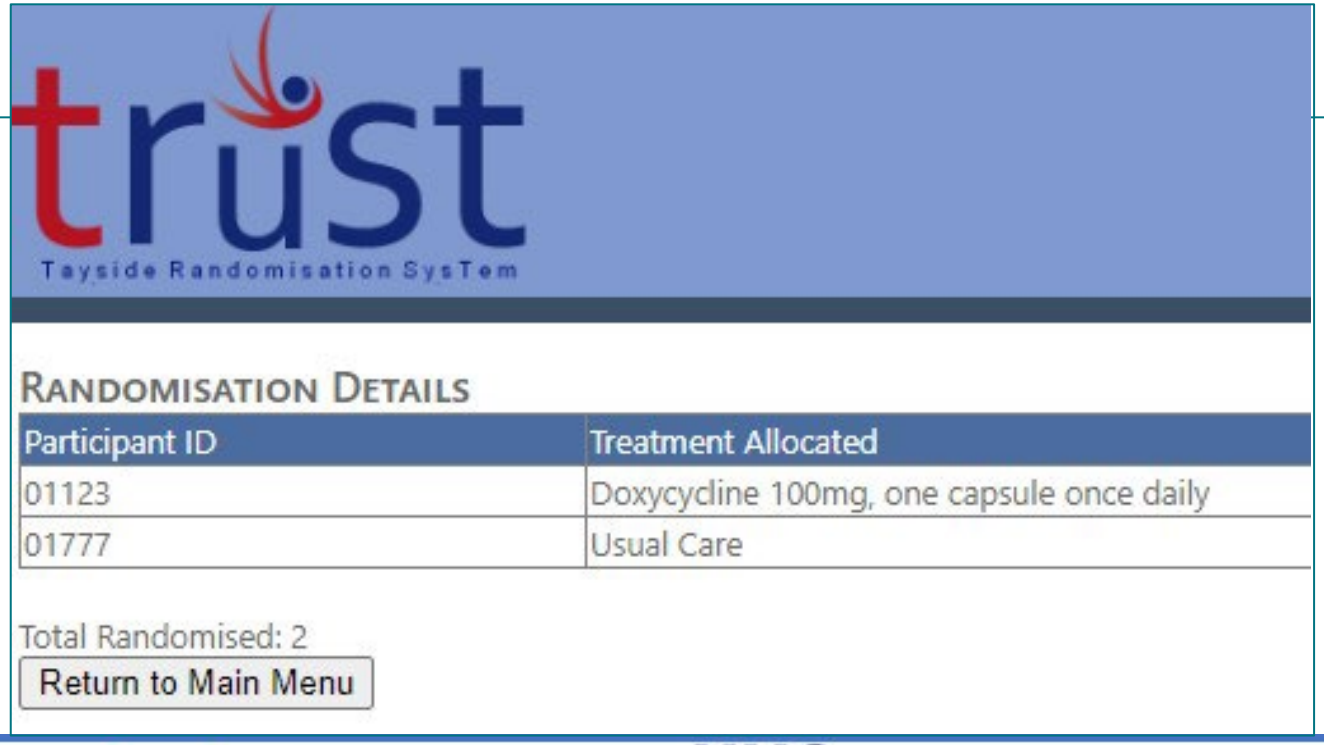
Main menu:

Click “Randomisatin Details” button



Randomisation Details





AIR-NET Trial Management Team: AIRNET-TM@dundee.ac.uk
01382 383830

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