



Participant name:
 CHI / Hospital ID:

ESCAPE: Exacerbation and Symptom Control After Pseudomonas Eradication Treatment in Adult Bronchiectasis: a multicentre randomized controlled trial

Sponsor: University of Dundee & NHS Tayside
 Chief Investigator: Professor James Chalmers
 IRAS number: 1011311

Principal Investigator	<input type="text"/>
Contact number	<input type="text"/>
Contact email	<input type="text"/>

Visit 1 – Screening
To be filed in medical notes as source data

Date of visit: Participant trial ID

Please tick to indicate the following trial procedures have been completed:

- Participant has had the Participant Information Sheet for at least 24 hours
- Confirmed participant's identity
- Informed Consent received
- Eligibility checks
- Vital signs

Samples:

- Negative urine pregnancy test, if applicable
- Sputum sample positive for *P. aeruginosa* within previous 6 months
- OR
- Collection of sputum sample for *P. aeruginosa* testing

Pregnancy test:

Is the participant a woman of childbearing potential? Yes No

If female but not of childbearing potential, how has this been confirmed?

Post-menopausal	<input type="checkbox"/>	Date of last period	<input type="text"/>
Permanent sterilisation	<input type="checkbox"/>		



Participant name:
CHI / Hospital ID:

ECG

Please tick:

Normal
Abnormal, not clinically significant
Abnormal, clinically significant

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

Vital signs:

Height	<input type="text"/>	cm	Weight	<input type="text"/>	kg
Blood pressure	<input type="text"/>	mmHg	Pulse	<input type="text"/>	bpm
Oxygen saturation (room air)	<input type="text"/>	%	Temperature	<input type="text"/>	°C

Physical exam

Please tick:

Normal
Abnormal, not clinically significant
Abnormal, clinically significant

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:



Participant name:
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The following must have source data documented in the medical notes. If not documented elsewhere these should be written in the notes.

- Concomitant medications, file a copy of repeat prescription if available, ensure this is accurate for what the participant is taking at the time of visit, update if necessary.
- History of bronchiectasis
- Medical history
- Bronchiectasis severity index
- Any notable findings and actions taken

The following should be filed in the participant’s medical notes:

- Front coloured card/sheet/sticker to state they are a research participant
- Copy of the signed Informed Consent Form
- Copy of the Participant Information Sheet, version which the participant consented to
- Copy of GP letter informing GP of participation
- ECG signed & dated
- Pregnancy test results, if applicable
- Sputum sample results: either a positive sample for *P. aeruginosa* within previous 6 months or results of sample taken at visit 1
- If the participant was withdrawn from the trial at this visit, document reason

Any further information of note:

The visit has been carried out as per protocol.

Signature:	<input type="text"/>
Name:	<input type="text"/>
Job title:	<input type="text"/>
Date:	<input type="text"/>