

Participant name:   
 Hospital ID/CHI:   
 Date of Birth:

**Value of inhaled treatment with Aztreonam lysine in bronchiectasis- VITAL- BE**

Sponsor University of Dundee-NHS Tayside  
 Chief Investigator Professor James Chalmers  
 IRAS number 252929

Principal Investigator   
 Contact number   
 Contact email

**Visit 1 - Screening**

Date of visit:

The above participant has agreed to take part in the VitalBE clinical trial and has attended for their first visit.

Please tick to indicate the following has been completed:

Confirmed participant has had the Participant Information Sheet for at least 24 hours   
 Confirmed participant's identity

Method used to confirm participant's identity.....

Participant has signed the Informed Consent Form   
 Blood samples taken – Full blood count, U&Es (Sodium, Potassium, Urea, Creatinine, eGFR), LFTs (albumin, bilirubin, Alkaline phosphatase, Alanine transaminase (ALT))   
 Visit has been carried out as per protocol

**Vital signs**

Please enter the results of the following assessments:

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"/>	%	Tympanic temperature	<input type="text"/>	C

***\*Please ensure the height and weight entered into the spirometer is the height and weight recorded at the visit and not historical values.***

**Pregnancy test**

Is the participant a woman of child-bearing potential? yes  no

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

Post-menopausal  If less than 55 years old, date of last period   
 permanent sterilisation

If female and of childbearing potential:

has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method?

result of pregnancy test: negative  positive

**Spirometry**

What method of bronchodilation was used?

nebulised salbutamol  Dose  mg  
 inhaled salbutamol  Dose  mcg Number of puffs

Results of spirometry must be documented in notes.

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**ECG**

Please tick:

Normal

Abnormal, not clinically significant

Abnormal clinical significant

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

Name of doctor making assessment

**Physical examination**

Please tick:

Normal

Abnormal, not clinically significant

Abnormal clinical significant

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

Name of doctor making assessment

**Sputum sample**

Spontaneous sputum sample obtained?

yes  no

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. Cross off any medications not currently taking, sign and date it. Keep in medical notes as evidence of current medications.
- History of bronchiectasis
- Medical history
- Smoking history (*document figures used for calculation in pack years calculator in medical notes*)
- Bronchiectasis severity index
- Any notable findings and actions taken
- Eligibility criteria

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Any further information of note:

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 which the participant consented to
- Copy of GP letter informing GP of participation
- ECG signed and dated by doctor on delegation log
- Blood results signed and dated by doctor on delegation log
- Sputum results signed and dated by doctor on delegation log
- Spirometry results and how bronchodilation was achieved. Spirometry results should be signed and dated on day of visit by doctor on the delegation log. Note that thermal Spirometry printouts fade with time. Please photocopy these and attach the thermal and photocopy together. To be stored in medical notes with Pt ID and visit number on them.

If the participant was withdrawn from the trial at this visit state reason:

Signature:	
Name:	
Job title:	
Date:	