



Value of inhaled treatment with  
aztreonam lysine in bronchiectasis

## Source Data



## Source data

- All visit data must have back up source data in the participant's medical record
- This allows for Source Data Verification (SDV) of data entered in Data Management System (DMS)
- Allows other healthcare professionals know about the trial and any assessments completed during visits
- Template continuation sheets are provided and can be used if required. These should be filed in the medical notes
- If worksheets are used to record source data, they must be filed in the medical record
- NB: the worksheets do not cover everything which is required to be recorded in the medical notes.

# Source data

## All Visits

- Date of visit
- Confirmation of how participant identity was verified
- Details of any notable findings at the visit and any action taken
- Record of blood, sputum and pregnancy test samples taken
- Copy of blood, sputum and pregnancy test results signed and dated by delegated doctor to be added when obtained
- Changes to con meds (*or state there were no changes*)
- AE's (*or state there were none*)
- Confirmation that the visit was carried out as per protocol
- Name and Signature of Research staff completing the visit

# Source data

## Visit 1

- Front coloured card/sheet/sticker to state they are a research participant
- Copy of signed Informed Consent Form
- Copy of Participant Information Sheet (PIS) participant has consented to
- Copy of GP letter informing GP of participation
- Confirmation that the participant has had the PIS for at least 24 hours

## Eligibility Confirmation Form

- Must be completed before randomisation
- Must be signed and dated by a doctor on a Delegation Log
- Must be filed in the medical record

# Source data

## Assessments

- History of bronchiectasis details, if source data not elsewhere in medical notes
- Medical & smoking history if not elsewhere in medical notes
- Height and weight
- For women who were deemed not WOCBP document how this was confirmed
- Physical exam normal/abnormal and action taken if appropriate
- Evidence for questions asked for Bronchiectasis Severity Index, if not elsewhere in medical notes
- Copy of ECG signed and dated by doctor on Delegation Log. Result of ECG i.e. normal/abnormal and any action taken if appropriate
- Vital signs (as recorded in eCRF)
- Vital signs taken during trial medication administration
- Spirometry results and how bronchodilation was achieved