



Source Data



Source data

All Visits

- All data collected must have back up source data in the participant's medical record
 - Allows for Source Data Verification (SDV)
 - Allows other healthcare professionals know about the trial and any assessments completed during the visits
 - Eligibility Form is mandatory, and is source data for participant eligibility and Dr signature.
- Template medical note continuation sheets are provided and can be used if wished. These should be filed in the medical notes.
- If worksheets are used to record source data, they must be filed in the medical notes
- The worksheets do not cover everything which is required to be recorded in the medical notes.

Source Data document to be completed for the Monitoring team

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Visit 1

- Front coloured card/sheet/sticker/pop up 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

Visit 2 Eligibility Confirmation Form

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

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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

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Assessments

- NEATStix test results (visit 1 only)
- History of bronchiectasis details, if source data not elsewhere in medical notes
- Medical 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 a doctor on Delegation Log.
- Result of ECG i.e. normal/abnormal and any action taken if appropriate
- Vital signs results
- Spirometry results and how bronchodilation was achieved
- 6-minute walk test results