

# Source Data

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## 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 visits
- Template medical notes 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 record
- NB: the worksheets do not cover everything which is required to be recorded in the medical notes.

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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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## 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 dated and signed by doctor on Delegation Log
- Must be filed in the medical record

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## 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.