AIR-NET

Trial Visits

All visits

- **Participant Payment**

Participants are eligible for a payment of £100.00 per visit. (Maximum 6 visits)

- **Participant Identity**

Participant identity should be checked at each visit. Some examples of identification are listed below:

- Passport
- Driving licence
- Current matriculation card
- Young person's or senior citizen's railcard
- Proof of Address
- National Insurance Card
- CHI Number/Medical Card

All visits

Participant trial ID

- All participants consented to the trial should be allocated a participant ID number.
- Participant ID numbers are made up of five numbers:
- First two numbers to indicate the site and
- Last three indicate the participant number at that site.
- E.g. 01001 is the first participant at site one.
- Use participant ID numbers in order
- Ensure site ID is correct for your site.
- If participant fails screening, and does not go on to randomisation, their participant ID number should not be re-used.

Worksheets

- Worksheets are available to facilitate data collection
- Their use is not mandatory
- If worksheets are used to record source data, they must be filed in the medical notes.

Visit 1 Screening (-35 days to day 0)

- Informed Consent
- Eligibility check
- Demographics
- Medical history
- Con meds
- Physical Exam
- Height & weight
- Vital signs
- ECG
- Full blood count & research bloods.
- Sputum sample for eligibility & research
- Research blood sample
- Research sputum sample
- Post bronchodilation spirometry
- Pregnancy test if applicable
- Questionnaires

Visit 1: BEST diary

Completion of BEST Diary

Participants have 3 options (discuss their preference and record this at visit 1 on the eCRF):

Complete the diary on the paper form
Complete the diary through Castor Connect App
Complete the diary online using a web browser
(participants will receive a daily email reminder via a weblink)

The diary is completed every day from day 0 (visit 2) to day 28 (visit 5)

Important points:
If the participant chooses to complete the diary online (either app or browser, you must collect their email address and add this to Castor **during visit 1**

You must enter visit 2 data (at a minimum the visit date) **on the day of the visit**
This is to allow the email notifications to be set up for the following day (day 1)

Visit 2 Baseline & Randomisation

- Continued Consent
- Eligibility check
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- 6-minute walk test
- Research blood sample
- Research sputum sample
- Nasal sample
- Pregnancy test if applicable
- Questionnaires
- Randomisation
- Dispensing trial drugs

Visit 3 (day 7)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Research blood sample
- Research sputum sample
- Pregnancy test if applicable
- Questionnaires

Visit 4 (day 14)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Pregnancy test if applicable
- Questionnaires

Visit 5 (day 28)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- 6-minute walk test
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Nasal sample
- Pregnancy test if applicable
- Questionnaires
- Drug accountability

Visit 6 (day 56)

- Continued Consent
- Record Con meds
- Record AEs
- Record any exacerbations
- Vital signs
- Post bronchodilation spirometry
- Full blood count, urea and electrolytes, liver function test
- Research blood sample
- Research sputum sample
- Questionnaires

Safety Visits (as required)

Participants will be requested to attend an unscheduled safety visit if they experience a bronchiectasis exacerbation or any other safety concern

- Concomitant medications check
- Review/recording of adverse events
- Review/recording of exacerbations
- Vital signs
- Post bronchodilation spirometry
- Safety bloods
- Research bloods, as per lab manual
- Research sputum sample collection

Visit windows

Missed trial assessments or trial medication, or visits completed outside the visit window, will not be reported as breaches, where this is due to participant choice or a clinical decision.

Visits 2,3 and 4 should be every 7 days, and visit 5 14 days after visit 4. If a participant is unable to attend on the scheduled visit day, then a delay of up to 2 days is acceptable, after which it becomes a missed visit.