



Participant name:

Hospital ID:

CHI/Date of Birth:

GREAT-2 GRemubamab ErAdication Trial

Sponsor University of Dundee-NHS Tayside
 Chief Investigator Professor James Chalmers
 IRAS number 1005993

Principal Investigator

Contact number

Contact email

**Visit 6 – Treatment phase, treatment dose 3
 to be filed in medical notes as source data**

Date of visit: Participant trial ID

Please tick to indicate the following has been completed:

Confirmed participant's identity

Concomitant medications have been reviewed

Adverse events have been reviewed

Exacerbations have been reviewed

NHS samples:

Full blood count

Urea & electrolytes, creatinine

Liver function tests

Urine pregnancy test performed, if applicable

Research samples:

Blood samples pre-infusion

Blood samples post-infusion

Sputum sample

Questionnaires:

Quality of Life-Bronchiectasis Questionnaire

Bronchiectasis Impact Measure Questionnaire

Vital signs pre-infusion, during infusion and post-infusion must be recorded and filed in the medical notes e.g. observation chart.

Participant name:

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Trial medication

Tick to confirm:

Participant was given pre-dose antihistamine prior to trial medication
 Name, dose and time of administration must be documented and filed in the medical notes e.g. prescription chart

Was trial medication given as per protocol? (250 ml over 240 minutes)
 Time of start of infusion must be documented and filed in the medical notes e.g. infusion chart
 If not given as per protocol reason should be documented here.

Spirometry

What method of bronchodilation was used?

| | | | | | |
|----------------------|--------------------------|------|----------------------|-----|--------------------------------------|
| nebulised salbutamol | <input type="checkbox"/> | Dose | <input type="text"/> | mg | Number of puffs <input type="text"/> |
| inhaled salbutamol | <input type="checkbox"/> | Dose | <input type="text"/> | mcg | |

File copy of spirometry results in notes.

The following must be filed in the participant's medical notes:

- Pregnancy test results, if applicable, signed & dated by doctor on delegation log
- Blood results signed and dated by doctor on delegation log
- Vital signs taken pre, during and post-trial medication administration
- Changes to concomitant medications since last visit
- Any adverse events since last visit
- Any pulmonary exacerbations since last visit
- Spirometry results signed and dated by doctor on delegation log
- Any other notable findings and actions taken
- Any paper copies of questionnaires
- If the participant was withdrawn from the trial at this visit, document reason

The visit has been carried out as per protocol.

| | |
|------------|----------------------|
| Signature: | <input type="text"/> |
| Name: | <input type="text"/> |
| Job title: | <input type="text"/> |
| Date: | <input type="text"/> |