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 5 – Treatment phase, treatment dose 2
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.

GREAT-2
GRemubamab ErAdication Trial

Participant name:	
Hospital ID:	
CHI/Date of Birth:	

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 ☐ Dose _____ mg
inhaled salbutamol ☐ Dose _____ mcg Number of puffs ☐

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- If the participant was withdrawn from the trial at this visit document reason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:	
Name:	
Job title:	
Date:	