GREAT-2 Worksheet – Visit 5 Treatment Phase

47. Date of Visit 5

47.1 Date of Visit 5 [ ] [ ] [ ] (dd-mm-yyyy)

48. Pregnancy Test – Urine

Tick NA for male participants and female participants who are permanently sterile or post-menopausal

48.1 Has pregnancy test been performed on day of visit? ○ Yes ○ No ○ NA

48.3.1 Result of Pregnancy Test ○ Positive ○ Negative

If positive - Stop trial medication & complete Pregnancy Notification Form

49. Concomitant Medications

Review each medication and check it is still ongoing at each visit

49.1 Review Concomitant Medications: Respiratory Medication

49.2 Review Concomitant Medications: Other Concomitant Medication

50. Adverse Events since last visit

Complete **Adverse Event Log** for each Adverse Event since last visit

51. Exacerbation recording

51.1 Has the participant experienced any symptoms of Exacerbation since last visit? ○ Yes ○ No

If Yes – complete Exacerbation Form

52. Vital Signs

Blood pressure – Systolic		mm Hg
Blood pressure – Diastolic		mm Hg
Pulse rate		beats/min
Temperature		°C
Oxygen saturation		%

53. Blood Samples

53.1 Have pre-infusion research blood samples been obtained as per laboratory manual? ○ Yes ○ No

53.2 Have post-infusion research blood samples been obtained as per laboratory manual? ○ Yes ○ No

53.3 Have NHS samples been taken? ○ Yes ○ No
NHS blood samples are mandatory

53.3.1 If **YES**

Date of sample [ ] [ ] [ ] (dd-mm-yyyy)

Haemoglobin unit ○ g/L ○ g/dL

Haemoglobin [ ]

White cell count [ ] x10^9/L

Neutrophil count [ ] x10^9/L

Eosinophil count [ ] x10^9/L

Platelets [ ] x10^9/L

Click NEXT to go to UEC

Form Urea and Electrolytes, Creatinine (UEC)

Sodium	mmol/L		
Potassium			mmol/L
Creatinine			mmol/L
Urea			mmol/L
eGFR			ml/min

Click NEXT to go to LFT

Form Liver Function Test (LFT)

Albumin		g/L
Bilirubin		umol/L
Alkaline Phosphatase		U/L
Alanine Aminotransferase		U/L

54. Administration of Trial Medication

54.1 Was treatment given ○ Yes ○ No

54.1.1 **If No** – Reason not given
- ○ Previous reaction/toxicity (please ensure this has been recorded on the AE Log)
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other

54.2.1 **If Other** – give reason)

54.1.2 **If Yes** – Was trial medication given on date of visit? ○ Yes ○ No

54.1.2.1 **If 54.1.2 No** – Date Medication given dd/mm/yyyy

54.1.2.2 **If 54.1.2 No** –Reason trial medication not given on date of visit
- ○ Previous reaction/toxicity
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other

54.3.1 **If Other** – please give reason

54.1.3 **If 54.1 is Yes** - Was IV antihistamine given prior to trial medication infusion? ○ Yes ○ No

54.1.3.1 **If No** –Reason not given
- ○ On regular oral antihistamine
- ○ Other

54.1.3.1.1 **If Other** –please give reason

54.1.4 **If 54.1.2 is Yes** - Was trial medication given as per protocol? (250ml over 240 minutes) ○ Yes ○ No

54.1.4.1 **If No** - Was infusion slowed or temporarily stopped? ○ Yes ○ No

54.1.4.1.1 **If Yes** - Reason infusion was slowed or temporarily stopped

- ○ Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other (an AE may need to be recorded)

54.4.1 **If Other** – please give reason

54.1.4.2 **If 54.1.4 No** - Was full volume (250mL) of infusion received? ○ Yes ○ No

54.1.4.2.1 **If No** - Total volume of infusion received? (NB Total volume of infusion should not be below 1 ml or be above 249 ml)

54.1.4.2.2 **If No** - Reason total volume of infusion not received

- ○ Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other (an AE may need to be recorded)

54.5.1 **If Other** – Please give reason

55. Questionnaires

55.1 Has the Quality of Life-Bronchiectasis Questionnaire (QOL-B) been completed? ○ Yes ○ No

55.2 Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed? ○ Yes ○ No

56. Sputum samples

56.1 Have sputum samples for research been obtained as per laboratory manual? ○ Yes ○ No

56.2 Result of sputum colour assessment

- ○ Clear
- ○ Clear to yellow
- ○ Yellowish-green
- ○ Brownish-dark
- ○ Green with traces of blood
- ○ No sputum produced
- ○ Other

56.2.1 **If Other** – please provide details

57. Spirometry

Bronchodilation given (as per WPG) ○ Yes ○ No

If **YES**

FEV1 Base
(to 2 decimal places) L

FVC Base
(to 2 decimal places) L

FEV1 % of predicted values
(to 2 decimal places) %

FVC % of predicted values
(to 2 decimal places) %

FEF 25-75% of predicted values
(to 2 decimal places) %