

Initials [ \_ ] [ \_ ] [ \_ ]



# GREAT-2 Worksheet - Visit 2 Baseline & Randomisation

## 16. Date of Visit 2

16.1	Date of Visit 2				(dd-m	ım-yyyy)
Visit 2	must be within 35 days of visit 1.	L	<u></u>			
17.	Pregnancy Test - Serum					
	Tick NA for male participants an or post-menopausal	nd female p	participants	s who are pe	erma	nently sterile
17.1	Has serum pregnancy test be at screening?	en perform	ned	⊖Yes	0	No ONA
	Female participants who are not per pregnancy test	rmanently st	erile or post-	menopausal	shoul	d have a
	17.3.1 Date of Pregnancy Tes	st			(dd-	mm-yyyy)
	17.3.3 Result of Pregnancy Te	est		○ Posi	tive	○ Negative
18.	Pregnancy Test – Urine					
18.1	Has urine pregnancy test been on day of visit? Female participants who are not per pregnancy test			⊖ Yes menopausal		No ONA d have a
	18.3.1 Result of Pregnancy Te	est		○ Posi	tive	O Negative
	If <b>positive</b> - Pregnancy is an exclus please withdraw the participant	sion criteria,				
19.	Sputum sample for <i>P.aerug</i>	<i>inosa</i> test	ing			
19.1	Result of sputum sample for F	P. aerugino	osa	○ Posi	tive	ONegative
	taken during screening period If Negative - Participant not eligible		in the trial			U U



Deutieinent ID	r ı	r 1	г	1 F	1
Participant ID					

Initials [ \_ ] [ \_ ] [ \_ ]

## 20. Blood Tests Reviewed

20.1	Have blood tests taken at screening been reviewed	OYes	○ No
	by a doctor? (Must be YES before continuing)		
21.	Inclusion Criteria		
21.1	Age 18-85	O Yes	O No
21.2	Clinical diagnosis of Bronchiectasis	○ Yes	○ No
21.3	Able to and provided informed consent	○ Yes	○ No
21.4	Previous computerised tomography (CT) scan of the chest demonstrating bronchiectasis in 1 or more lobes	O Yes	○ No
21.5	A sputum sample that is culture or PCR positive for <i>P. aeruginosa</i> sent at the screening visit, within 35 days of randomisation*† (If No - Participant not eligible to take part in the trial)	⊖ Yes	○ No
21.6	<i>P. aeruginosa</i> in sputum, bronchoalveolar lavage or another airway sample at least once in the 24 months prior to screening* (If <b>No</b> see Q21.6.1)	⊖ Yes	○ No
	21.6.1 Has a further sample, positive for <i>P. aeruginosa</i> , been obtained during the 35-day screening period? There must be at least 21 days between this sample and the sample obtained at the screening visit.	⊖Yes	⊖ No

\*a participant who does not have a previous positive sample for *P. aeruginosa* may submit two samples, at least 21 days apart, during the 35-day screening period. If these samples are both positive for *P. aeruginosa* then inclusion criteria 5 and 6 will be deemed met and the participant may be enrolled.

† repeat sputum samples may be provided during the screening period, if the sample taken during the screening visit is negative for P. aeruginosa

Participant ID [\_][\_][\_][\_] Initials [\_][\_][\_]



#### **Exclusion Criteria** 22.

22.1	Known hypersensitivity to Gremubamab or any excipient of the investigational product	○ Yes	○ No
22.2	Known clinical diagnosis of Cystic fibrosis	○ Yes	$\bigcirc$ No
22.3	Immunodeficiency requiring replacement immunoglobulin	⊖ Yes	⊖ No
22.4	Active tuberculosis or nontuberculous mycobacterial infection (currently undertreatment, or requiring treatment in the opinion of the investigator).	⊖ Yes	○ No
22.5	Active allergic bronchopulmonary aspergillosis (receiving treatment with corticosteroids and/or antifungal medication)	⊖ Yes	⊖ No
22.6	Recent significant haemoptysis (a volume requiring clinical intervention, within the previous 4 weeks prior to screening)	⊖ Yes	○ No
22.7	Treatment with long term inhaled, systemic or nebulized anti- pseudomonal antibiotics which are newly initiated within the previous 3 months prior to screening (a)	⊖ Yes	⊖ No
22.8	Chronic treatment with cyclical doses of inhaled or nebulized antibiotics e.g. 28 days on and 28 days off at the time of screening	⊖Yes	⊖ No
22.9	Receipt of antipseudomonal antibiotics for an exacerbation during the screening period (b)	⊖Yes	⊖ No
22.10	Treatment with immunosuppressives within previous 6 months prior to screening	○Yes	⊖ No
22.11	Participants with a primary diagnosis of Chronic obstructive pulmonary disease (COPD) associated with >10 pack years smoking history (c)	⊖Yes	⊖ No
22.12	Participants with a primary diagnosis of asthma or asthma which is considered to be poorly controlled at screening (c)	⊖Yes	○ No
22.13	Participants with FEV1 <25% predicted value at screening	OYes	ONo

		COG	RFAT-	2
Partici	pant ID [ _ ] [ _ ] [ _ ] Initials [ _ ] [ _ ] [ _ ]	GRemu	ibamab ErAdication	Trial
22.14	Glomerular filtration rate (eGFR) below 25ml/min/1.73m2 or requiring dialysis. This will be determined at screening (If Yes - Participant not eligible to take part in the trial)	⊖ Yes	○ No	
22.15	Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer	○Yes	ONo	
22.16	Unstable co-morbidities (e.g. cardiovascular disease, active malignancy) which in the opinion of the investigator would make participation in the trial not in the participant's best interest	⊖ Yes	○ No	
22.17	Pregnant or lactating females	○Yes	⊖ No	
22.18	Women of child baring age or male partners of women of child baring age and not practicing a method of acceptable birth control (d)	⊖Yes	○ No	
(a)	Participants who are receiving stable chronic inhaled/nebulized and planned changes to treatment during the trial are eligible. Treatmer macrolide or other oral prophylactic antibiotics are allowed, providir initiation of treatment at least 3 months prior to screening and main trial.	nt with system	ic se, and	
(b)	Participant receiving antipseudomonal antibiotics during the screer prolong the screening period to a maximum of 60 days and may be provided they have a positive sputum sample for <i>P. aeruginosa</i> foll antibiotic therapy. All eligibility criteria must be met prior to randomi procedures to assess eligibility may be required.	e randomized owing cessati	on of	
(c)	Asthma and COPD are common co-diagnoses in participants with Where a participant has a diagnosis of bronchiectasis plus either a may be enrolled in the trial if the clinician performing the screening determines that bronchiectasis is the primary clinical diagnosis, i.e. participant's symptoms and exacerbations are primarily due to bron opinion of the investigator.	sthma or COF assessment where the	PD, they	
(d)	Women of childbearing potential must be willing to have pregnancy entry and prior to each administration of trial medication dose.	testing prior t	o trial	



22.19 Has a doctor on the Delegation Log confirmed all OYes ONO inclusion and exclusion criteria and documented this in the participant's medical notes? (If No - the doctor confirming inclusion and exclusion criteria must document this in the participant's medical notes prior to randomisation)

22.19.1 Date of Signing

(dd-mm-yyyy)

### 23. Concomitant Medications

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

- 23.1 Review Concomitant Medications: Respiratory Medication
- 23.2 Review Concomitant Medications: Other Concomitant Medication

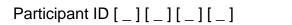
#### 24. Adverse Events since last visit

Complete Adverse Event Log for each Adverse Event since last visit

#### 25. Exacerbation recording

25.1 Has the participant experienced any symptoms OYes ONo of Exacerbation since last visit?

If Yes - complete Exacerbating Form

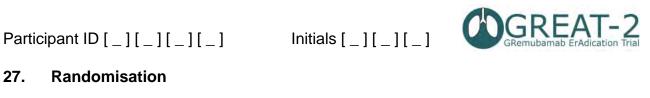


Initials [ \_ ] [ \_ ] [ \_ ]



# 26. Vital Signs

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

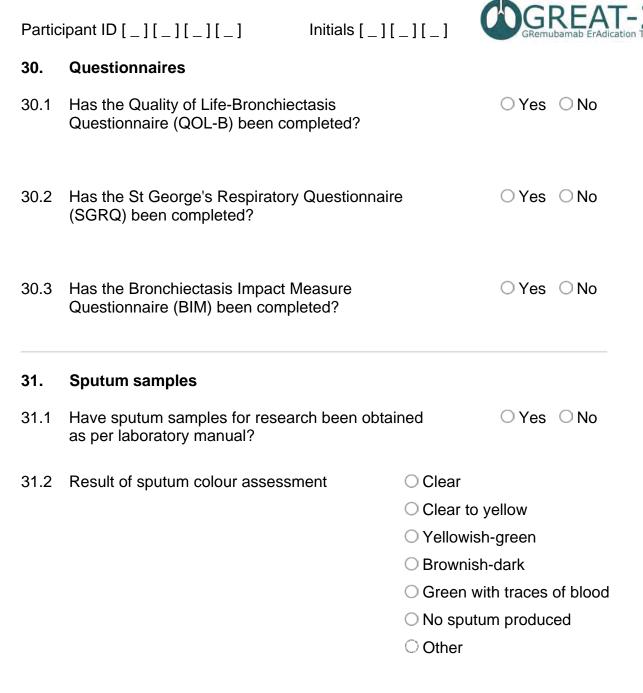


27.1	Has the participant been randomised?			Yes	○ No
27.2	Date of Randomisation		(c	dd-mm-y	уууу)
28.	Blood Samples				
28.1	Have pre-infusion research blood sam obtained as per laboratory manual?	nples been	С	Yes	○ No
28.2	Have post-infusion research blood sar obtained as per laboratory manual?	mples been	С	Yes	○ No
29.	Administration of Trial Medication				
29.1	Was treatment given		С	Yes	○ No
	29.1.1 If No – Reason not given	(p	Previous reactile lease ensure thi corded on the A	is has b	
		0	Other clinical d	ecision	
			Participant's de	ecision	
	29.2.1 If Other – give reason		Other		
	29.1.2 If Yes – Was trial medication given or	n date of visit?	C	Yes	○ No
	29.1.2.1 If 29.1.2 No – Date Medication given	n		C	ld/mm/yyyy
	29.1.2.2 If 29.1.2 No -Reason trial medication	n	O Previou	us react	ion/toxicity
	not given on date of visit		◯ Other o ◯ Particip ◯ Other		decision ecision
	29.3.1 If Other – please give reason				

27.

Randomisation

Participant ID [ _ ] [ _ ] [ _ ] [ _ ] Initials [ _ ]	[_][_]
29.1.3 <b>If 29.1 is Yes</b> - Was IV antihistamine given pr to trial medication infusion?	ior OYes ONo
29.1.3.1 If No – Reason not given	<ul> <li>On regular oral antihistamine</li> <li>Other</li> </ul>
29.1.3.1.1 If Other –please give reason	
29.1.4 If 29.1.2 is Yes - Was trial medication given a (250ml over 240 minutes)	s per protocol? O Yes O No
29.1.4.1 If No - Was infusion slowed or temporarily st	opped? OYes ONo
29.1.4.1.1 <b>If Yes</b> - Reason infusion was slowed or temporarily stopped	<ul> <li>Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)</li> </ul>
	<ul> <li>Other clinical decision</li> <li>Participant's decision</li> </ul>
	<ul> <li>Other (an AE may need to be recorded)</li> </ul>
29.4.1 If Other – please give reason	
29.1.4.2 If 29.1.4 No - Was full volume (250mL) of infusion received?	○ Yes ○ No
29.1.4.2.1 <b>If No</b> - Total volume of infusion rec (NB Total volume of infusion should not be be or be above 249 ml)	
29.1.4.2.2 <b>If No</b> - Reason total volume of infusion not received	<ul> <li>Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)</li> </ul>
	O Other clinical decision
	O Participant's decision
	<ul> <li>Other (an AE may need to be recorded)</li> </ul>
29.5.1 If Other – Please give reason	



31.2.1 If Other - please provide details