

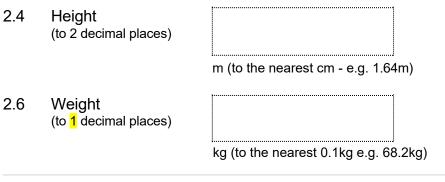
# GREAT-2 Worksheet – Visit 1 Screening

## 1. Informed Consent

1.1	Date of Screening V1				(dd-m	m-yyyy)
1.2	Date of Informed Consent				(dd-m	m-yyyy)
1.4	Has the participant provided consent blood and sputum samples to be sto future research?			0	Yes	⊖ No
1.5	Has the participant provided consent blood samples to be stored for future research?			0	Yes	⊖ No
2. C	Demographics, Height & Weight					
2.1	Age					
2.2	Gender at birth O Male			)		
2.3	Ethnicity					
⊖ Eng ⊖ Irish	glish/Welsh/Scottish/Northern Irish/British					
⊖ Gyp	sy or Irish Traveller	$\bigcirc$	Any other W	/hite ba	ackground	
⊖ Whi	te and Black Caribbean	$\bigcirc$	White and E	Black A	frican	
⊖ Whi	te and Asian	$\bigcirc$	Any other Mi	xed/Mul	tiple ethnic	background
○ India	an	$\bigcirc$	Pakistani			
$\bigcirc$ Ban	gladeshi	$\bigcirc$	Chinese			
⊖Any	other Asian background	$\bigcirc$	African			
⊖ Car	ibbean					
OAny	v other Black/African/Caribbean backgrou	ind				
	0	$\bigcirc$	Any other e	thnic g	roup	
OUnk	nown					
2.3.1	If Ethnicity is Any other ethnic group, then provide details					



# Height & Weight



## 3. Medical History

## Has the participant had any of the following?

Please indicate any history of chronic medical conditions by selecting yes

3.1	Asthma	○Yes ○No
3.2	Nasal polyps	$\bigcirc$ Yes $\bigcirc$ No
3.3	COPD	○Yes ○No
3.4	Rhinosinusitis	$\bigcirc$ Yes $\bigcirc$ No
3.5	Angina	$\bigcirc$ Yes $\bigcirc$ No
3.6	Atrial Fibrillation	$\bigcirc$ Yes $\bigcirc$ No
3.7	Myocardial Infarction	○Yes ○No
3.8	Cardiac Failure	$\bigcirc$ Yes $\bigcirc$ No
3.9	Liver Cirrhosis	⊖Yes ⊖No
3.10	Osteoporosis	○Yes ○No
3.11	Anxiety	$\bigcirc$ Yes $\bigcirc$ No
3.12	Depression	$\bigcirc$ Yes $\bigcirc$ No
3.13	Other relevant medical conditions	$\bigcirc$ Yes $\bigcirc$ No
3.13	.1 If yes, provide details	



Has the participant had any of the following cancers?

3.14 Lung	g Cancer	$\bigcirc$ Yes	$\bigcirc$ No
3.14.1	If YES, currently active?	○ Yes	○ No
3.15 Hae	matological Malignancy	⊖Yes	○No
3.15.1	If YES, currently active?	$\bigcirc$ Yes	○No
3.16 Othe	er Solid Tumours	⊖Yes	○ No
3.16.1	If YES, currently active?	⊖Yes	○No
3.16.2	Details		

# 4. Smoking History 4.1 What is the participant's smoking status? Current ○ Ex ○ Never 4.2 Smoking Status Calculation Pack years can be calculated at

https://www.smokingpackyears.com/

4.2.2	Approximate Pack Years
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## 5. Concomitant Medications

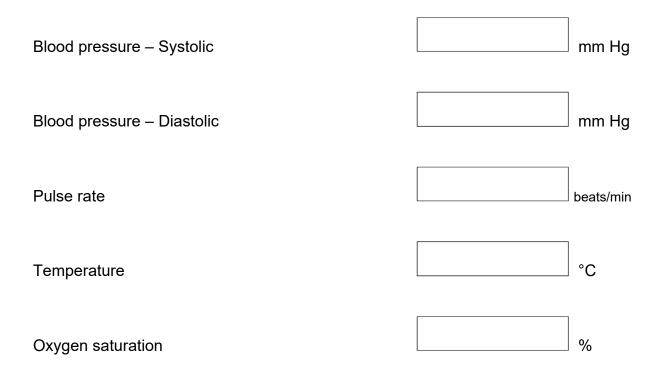
Review participant medications and record on Concomitant Log.

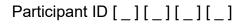
- 5.1 Complete Concomitant Medications: Respiratory Medication
- 5.2 Complete Concomitant Medications: Other Concomitant Medication

Review the Concomitant Medications logs at each visit and ensure that Castor is updated.



# 6. Vital Signs







L

L

%

%

%

## 7. Spirometry

Bronchodilation given (as per WPG)

## ○Yes ○No

.....

.....

## If YES

FEV1 Base (to 2 decimal places)

FVC Base (to 2 decimal places)

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)



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

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

# 8. Bronchiectasis Severity Index

8.1	1.1 Has the participant been hospitalised with a severe exacerbation in the past 2 years?		○ Yes ○ No		
8.2	Number of exacerbations in prev	<b>○</b> 0	○ 1-2	○ 3+	
8.3	MRC Breathlessness Score		○ 1 - Not troubled by breathlessness except on strenuous exercise		
		$\bigcirc$ 2 - Short of brea walking up a slight		n hurryin	g or
		<ul> <li>3- Walks slower</li> <li>on level ground be</li> <li>breathlessness or</li> <li>when walking at ow</li> </ul>	cause ( has to	of stop for	
		◯ 4 - Stops due to walking 100m	breathl	essness	after
		$\bigcirc$ 5 - Housebound breathless on dres			
8.4	Pseudomonas colonisation? Chr defined by the isolation of <i>P. aer</i> culture on 2 or more occasions, a apart in a 1 year period.	<i>ruginosa</i> in sputum		⊖ Yes	○ No
8.5	Colonisation with other organism is defined by the isolation of pote bacteria in sputum culture on 2 c least 3 months apart in 1-year pe	entially pathogenic or more occasions, at	า	⊖ Yes	○ No
8.6	Radiological severity O	Less than 3 lobes invo 3 or more lobes involve			

 $\bigcirc$  Cystic bronchiectasis



Particip	oant ID [ _ ] [ _ ] [ _ ] [ _	GRemubamab ErAdi
9. EC	CG	
9.1 Wa	s ECG performed?	◯Yes ◯No
If YES		
9.1.1	Date ECG was perform	ned (dd-mm-yyyy)
9.1.2	If ECG was performed pl specify result	ease O Normal Abnormal - not clinically significant Abnormal - clinically significant
9.1.3	Was the ECG reviewed	d by a doctor prior to randomisation $\bigcirc$ Yes $\bigcirc$ No
9.1.3.1	Date of review	(dd-mm-yyyy)
ECG m	oust be reviewed prior to	randomisation.
10.	Physical Examination	
	as Physical Examinatior no, Participant not eligible to	
10.1.1	Respiratory	⊖ Normal
		$\bigcirc$ Abnormal - not clinically significant
		○ Abnormal - clinically significant
10.1.1.	1 If abnormal, provide	details



Participant ID	[_]	][_	][_	][_	_ ]
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10.1.2	Cardiovascular	$\bigcirc$ Normal
		$\bigcirc$ Abnormal - not clinically significant
		○ Abnormal - clinically significant

## 10.1.2.1 If abnormal, provide details

I	L		

10.1.3	Abdominal	$\bigcirc$ Normal
		$\bigcirc$ Abnormal - not clinically significant
		○ Abnormal - clinically significant

# 10.1.3.1 If abnormal, provide details

10.1.4	4 Neurological	$\bigcirc$ Normal
		$\bigcirc$ Abnormal - not clinically significant
		$\bigcirc$ Abnormal - clinically significant

## 10.1.4.1 If abnormal, provide details



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

10.1.5 Dermatological O Normal

 $\bigcirc$  Abnormal - not clinically significant

 $\bigcirc$  Abnormal - clinically significant

## 10.1.5.1 If abnormal, provide details

 10.1.6
 Other
 O Abnormal - not clinically significant

 O Abnormal - clinically significant

10.2.1 If 'Other' is 'Abnormal' provide details



Participant ID [	_][_	_][_	_][_	_ ]
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## 11. Inclusion Criteria

11.1	Age 18-85	⊖ Yes	⊖ No
11.2	Clinical diagnosis of Bronchiectasis	⊖Yes	○No
11.3	Able to and provided informed consent	⊖Yes	⊖No
11.4	Previous computerised tomography (CT) scan of the chest demonstrating bronchiectasis in 1 or more lobes	○ Yes	○ No
11,5	<i>P. aeruginosa</i> in sputum, bronchoalveolar lavage or another airway sample at least once in the 24 months prior to screening*	⊖ 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 will be deemed met and the participant may be enrolled.



Participant ID [	_][_	_][_	_][_	_ ]
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## 12. Exclusion Criteria

12.1	Known hypersensitivity to Gremubamab or any excipient of the investigational product	⊖ Yes	○ No
12.2	Known clinical diagnosis of Cystic fibrosis	$\bigcirc$ Yes	$\bigcirc$ No
12.3	Immunodeficiency requiring replacement immunoglobulin	⊖ Yes	○ No
12.4	Active tuberculosis or nontuberculous mycobacterial infection (currently undertreatment, or requiring treatment in the opinion of the investigator).	⊖ Yes	⊖ No
12.5	Active allergic bronchopulmonary aspergillosis (receiving treatment with corticosteroids and/or antifungal medication)	⊖ Yes	○ No
12.6	Recent significant haemoptysis (a volume requiring clinical intervention, within the previous 4 weeks prior to screening)	⊖ Yes	○ No
12.7	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
12.8	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
12.9	Receipt of antipseudomonal antibiotics for an exacerbation during the screening period (b)	⊖Yes	○No
12.10	Treatment with immunosuppressives within previous 6 months prior to screening	⊖ Yes	○ No
12.11	Participants with a primary diagnosis of Chronic obstructive pulmonary disease (COPD) associated with >10 pack years smoking history (c)	⊖Yes	○ No
12.12	Participants with a primary diagnosis of asthma or asthma which is considered to be poorly controlled at screening (c)	⊖ Yes	○ No
12.13	Participants with FEV1 <25% predicted value at screening	⊖Yes	○No



12.14	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	⊖ No
12.15	Unstable co-morbidities (e.g. cardiovascular disease,	⊖Yes	○ No
	active malignancy) which in the opinion of the investigator would make participation in the trial not in the participant's best interest		
12.16	Pregnant or lactating females	$\bigcirc$ Yes	⊖No
12.17	Women of child baring age or male partners of women	⊖Yes	○ No
	of child baring age and not practicing a method of acceptable birth control (d)		
(a)	Participants who are receiving stable chronic inhaled/neb with no planned changes to treatment during the trial are Treatment with systemic macrolide or other oral prophyla are allowed, providing a stable dose, and initiation of trea months prior to screening and maintained throughout the	eligible. ctic antibic itment at le	otics
(b)	Participant receiving antipseudomonal antibiotics during to period may prolong the screening period to a maximum of may be randomized provided they have a positive sputur <i>aeruginosa</i> following cessation of antibiotic therapy. All el must be met prior to randomisation. Re- screening proced eligibility may be required.	of 60 days n sample f igibility crit	and or <i>P.</i> teria
(c)	Asthma and COPD are common co-diagnoses in particip bronchiectasis. Where a participant has a diagnosis of br plus either asthma or COPD, they may be enrolled in the clinician performing the screening assessment determine bronchiectasis is the primary clinical diagnosis, i.e. where symptoms and exacerbations are primarily due to bronch opinion of the investigator.	onchiectas trial if the s that the partic	ipant's
(-1)			1 1

(d) Women of childbearing potential must be willing to have pregnancy testing prior to trial entry and prior to each administration of trial medication dose.

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

## 13. Pregnancy Test - Serum

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

13.1 Has blood been taken for serum pregnancy test?

0.100 0.10	⊖Yes	$\bigcirc$ No	$\bigcirc$ NA
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## 14. Blood Samples

#### Form Full Blood Count

14.1 Have NHS samples been obtained? NHS blood samples are mandatory

## 14.1.1 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

○Yes ○No

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

# 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		
14.2 Have research blood samples been obtained as per laboratory manual?		⊖Yes	○ No	
15. Sputum sample for <i>P. ac</i>	eruginosa testing			
15.1 Has Sputum sample for <i>P. aeruginosa</i> testing been collected?			⊖Yes	○ No