



GREAT-2 Worksheet - Visit 5 Treatment Phase

47.	Date of Visit 5				
47.1	Date of Visit 5			(dd-m	m-yyyy)
48.	Pregnancy Test – Urine				
Tick N	IA for male participants and female participants who are perr	manen	tly sterile	or po	st-menopausal
48.1	Has pregnancy test been performed on day of visit?		○Yes	\bigcirc N	lo O NA
	48.3.1 Result of Pregnancy Test		○ Pos	itive	○ Negative
	If positive - Stop trial medication & complete Pregnancy Notification Form				
49. Revie	Concomitant Medications ew each medication and check it is still ongoing at	each	visit		
49.1	Review Concomitant Medications: Respiratory M	1edica	ation		
49.2	Review Concomitant Medications: Other Concor	nitant	t Medic	ation	
50	. Adverse Events since last visit				
	Complete Adverse Event Log for each Adverse	Ever	nt since	last v	/isit
51	. Exacerbation recording				
51.1	Has the participant experienced any symptoms of Exacerbation since last visit?			○Ye	s ONo
	If Yes – complete Exacerbation Form				

Participant ID	[]	[]	[]	[]
i aitioipaiti ib				



52. Vital Signs

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

Participant ID	[]	[]	[]	[]
i aitioipaiti ib				

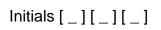
Initials	Γ	1 [11	1
minaid	L —	J L —	. J L .	_ 」



53. Blood Samples

53.1	Have pre-infusion research blood samples been obtained as per laboratory manual?			○ Yes ○ No
53.2	2 Have post-infusion research blood samples been obtained as per laboratory manual?			○ Yes ○ No
53.3	3.3 Have NHS samples been taken? NHS blood samples are mandatory			○ Yes ○ No
53.3.′	I If YES			
Date	of sample			(dd-mm-yyyy)
Haem	noglobin unit	○ g/L	○ g/dL	
Haem	noglobin			
White	cell count		x10	^9/L
Neutr	ophil count		x10	^9/L
Eosin	ophil count		x10	^9/L
Platel	ets		x10	^9/L

Click NEXT to go to UEC





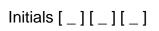
Form Urea and Electr	olytes, Creatin	nine (UEC)
Sodium	mmol/L	
Potassium		mmol/L
Creatinine		mmol/L
Urea		mmol/L
eGFR		ml/min
Click NEXT to go to LFT		
Form Liver Function	Test (LFT)	
Albumin		g/L
Bilirubin		umol/L
Alkaline Phosphatase		U/L
Alanine Aminotransferase		U/L

Initials	Γ	1 [11	1
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54. Administration of Trial Medication

54.1	Was treatment given	○ Yes ○ No
	54.1.1 If No – Reason not given	O Previous reaction/toxicity (please ensure this has been recorded on the AE Log)
		Other clinical decision
		O Participant's decision
		Other
	54.2.1 If Other – give reason)	
	54.1.2 If Yes – Was trial medication given	on date of visit?
	54.1.2.1 If 54.1.2 No – Date Medication giv	ren dd/mm/yyyy
	54.1.2.2 If 54.1.2 No –Reason trial medica	tion Previous reaction/toxicity
	not given on date of visit	Other clinical decision
		O Participant's decision
	5404 1504	Other
	54.3.1 If Other – please give reason	
	54.1.3 If 54.1 is Yes - Was IV antihistamin to trial medication infusion?	e given prior Yes O No
	54.1.3.1 If No –Reason not given	On regular oral antihistamine
	g	Other
	54.1.3.1.1 If Other –please give reason	
	54.1.4 If 54.1.2 is Yes - Was trial medicati (250ml over 240 minutes)	on given as per protocol? O Yes O No
	54.1.4.1 If No - Was infusion slowed or ten	pporarily stopped?





	54.1.4.1.1 If Yes - Reason infusion was slowed or temporarily stopped	(Please	n/toxicity to trial infusion ensure this has been on AE Log)
		Other cl	inical decision
		O Participa	ant's decision
		Other (an AE m	nay need to be recorded)
54.4.1	If Other – please give reason		
	2 If 54.1.4 No - Was full volume (250mL) sion received?		○ Yes ○ No
	54.1.4.2.1 If No - Total volume of infusior (NB Total volume of infusion should not be or be above 249 ml)		
	54.1.4.2.2 If No - Reason total volume of infusion not received	(Please e	n/toxicity to trial infusion ensure this has been on AE Log)
		Other cl	inical decision
		O Participa	ant's decision
		Other	
		(an AE m	nay need to be recorded)
	54.5.1 If Other – Please give reason		
Ques	tionnaires		
	ne Quality of Life-Bronchiectasis tionnaire (QOL-B) been completed?		○ Yes ○ No
	ne Bronchiectasis Impact Measure tionnaire (BIM) been completed?		○Yes ○No

55.

55.1

55.2



O Yes O No



56.	Sputum samples	
56.1	Have sputum samples for research been as per laboratory manual?	obtained O Yes O No
56.2	Result of sputum colour assessment	○ Clear
		 Clear to yellow
		O Yellowish-green
		O Brownish-dark
		O Green with traces of blood
		O No sputum produced
		Other
	56.2.1 If Other – please provide details	
57.	Spirometry	

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)

Bronchodilation given (as per WPG)

· %