

12. Visit 2 - Randomisation - Date of Visit 2

Number	Question	Answers
12.1	Screening and Randomisation on the same day?	<input type="radio"/> Yes <input type="radio"/> No
12.1.1	Date of Visit 2	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
12.1.2	Is Visit 1 and Visit 2 on the same day?	Automatic Calculation on Castor
12.1.3	Is Visit 2 date within 35 days post-screening?	Automatic Calculation on Castor

13. Visit 2 - Randomisation - Inclusion Criteria

Number	Question	Answers
13.1	Age 18 or over	
13.2	Able to and provided informed consent	
13.3	Capable of complying with all trial procedures and of completing the trial, in the opinion of the investigator	
13.4	Bronchiectasis, confirmed by computed tomography (CT), showing bronchiectasis in 1 or more lobes	
13.5	In the opinion of the investigator, are able to be prescribed one of the inhaled antibiotics defined in the intervention arm	
13.6	P. aeruginosa infection	<input type="radio"/> Yes <input type="radio"/> No
13.7	Is this infection	<input type="radio"/> A new isolation of P. aeruginosa within the 6 months prior to randomisation <input type="radio"/> A new isolation of P. aeruginosa, within the 6 months prior to randomisation, following previous clearance of P. aeruginosa

If a P. aeruginosa infection within previous 6 months, record the date & result of previous sample on Castor

14. Visit 2 - Randomisation - Exclusion Criteria

Number	Question	Answers
14.1	Current treatment with inhaled antibiotics or treatment with inhaled antibiotics between screening and randomisation?	<input type="radio"/> Yes <input type="radio"/> No
14.2	Chronic <i>P. aeruginosa</i> infection defined as isolation of <i>P. aeruginosa</i> persistently in sputum, or the absence of negative sputum samples for <i>P. aeruginosa</i>	<input type="radio"/> Yes <input type="radio"/> No
14.5	Cystic fibrosis	<input type="radio"/> Yes <input type="radio"/> No
14.7	Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer. Current enrolment in non-interventional, observational studies will be allowed	<input type="radio"/> Yes <input type="radio"/> No
14.9	Currently pregnant or breast-feeding	<input type="radio"/> Yes <input type="radio"/> No
14.11	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	<input type="radio"/> Yes <input type="radio"/> No
14.13	Estimate eGFR<30 or abnormal liver function tests that in the opinion of the investigator make antibiotic treatment inappropriate	<input type="radio"/> Yes <input type="radio"/> No
14.15	A strong preference, either from the managing clinician or the patient, for one of the two trial arms such that in the opinion of the investigator adherence to the trial protocol would not be possible	<input type="radio"/> Yes <input type="radio"/> No

15. Visit 2 - Randomisation - Concomitant Medications

Number	Question
Review participant medications and record on Concomitant Log.	
<u>Review each medication and check it is still ongoing at each visit</u>	
15.1	Complete Concomitant Medications: Respiratory Medication
15.2	Complete Concomitant Medications: Other Concomitant Medication

16. Visit 2 - Randomisation - Vital Signs

Number	Question	Answers
16.1	Blood pressure - Systolic	<input type="text"/> mmHg
16.2	Blood pressure - Diastolic	<input type="text"/> mmHg
16.3	Pulse rate	<input type="text"/> beats/min
16.4	Temperature	<input type="text"/> °C
16.5	Oxygen saturation	<input type="text"/> %

17. Visit 2 - Randomisation - Sputum Samples

Number	Question	Answers
17.1	Have there been any routine sputum samples collected since the last visit?	<input type="radio"/> Yes <input type="radio"/> No
17.1.1	Add date of sample & P. aerugisa positive/negative result to Castor	
17.2	Was a clinical sputum sample collected at this visit, as per the lab manual?	<input type="radio"/> Yes <input type="radio"/> No
17.2.1	Add date of sample, P. aerugisa positive/negative result and antibiotics susceptibility results to Castor	
17.3	Was a research sputum sample collected at this visit, as per the lab manual?	<input type="radio"/> Yes <input type="radio"/> No
	If yes, post this sample on date of visit	
	If no, issue the sputum postage box, sputum postage form and instruction leaflet to the participant	

18. Visit 2 - Randomisation - Questionnaires

Number	Question
18.1	CAAT
18.2	EQ-5D-5L
18.3	QOL-B

19. Visit 2 - Randomisation - Randomisation

Number	Question	Answers
19.1	Has the PI/delegated doctor reviewed the eligibility criteria prior to randomisation?	<input type="radio"/> Yes <input type="radio"/> No
Perform Randomisation on the TRuST Randomisation System, prior to answering the questions below.		
19.2	Has the participant been randomised?	<input type="radio"/> Yes <input type="radio"/> No
19.2.1	Date of Randomisation	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
19.3	Is Date of Randomisation and Visit 2 on the same day?	Automatic Calculation on Castor
19.4	Treatment arm randomisation	<input type="radio"/> Background therapy only <input type="radio"/> Eradication treatment plus background therapy

20. Visit 2 - Randomisation - Trial Treatment

Number	Question	Answers
	Antibiotics prescribed for background therapies are to be recorded as a respiratory medication and not a trial treatment	
	Antibiotics prescribed for eradication treatment must be recorded as a trial treatment, all other background therapies are to be recorded as a respiratory medication	
20.1	Has the participant been prescribed any trial treatment?	<input type="radio"/> Yes <input type="radio"/> No
20.1.1	Was an oral antibiotic prescribed as trial treatment?	<input type="radio"/> Yes <input type="radio"/> No
20.1.1.1	Name of drug	<input type="radio"/> Ciprofloxacin
20.1.1.2	Dose	<input type="text"/>
20.1.1.3	Units	<input type="radio"/> mg <input type="radio"/> g <input type="radio"/> Other
20.1.1.3.1	'Other' unit	<input type="text"/>
20.1.1.4	Times per day	<input type="text"/>
20.1.1.5	Trial treatment start date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
20.1.1.6	Trial treatment end date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)



20.1.1.7 Is end date before start date? **Automatic Calculation on Castor**

20.1.1.8 Was this trial treatment taken for the full time period prescribed? Yes No

20.1.1.8.1 Were any trial treatment doses missed? Yes No

20.1.1.8.1.1 Number of days with any missed doses

20.1.1.8.1.2 Reason Adverse event
 Patients decision
 Doctors decision
 Changed to new medication
 Other

20.1.1.8.1.2.1 Details

If new medication: Please complete a new Concomitant Medications repeating data form

If adverse event: Please complete an adverse event repeating data form

20.1.1.8.2 Reason trial treatment not completed Adverse event
 Patients decision
 Doctors decision
 Changed to new medication
 Other

20.1.1.8.2.1 Details

If new medication: Please complete a new Concomitant Medications repeating data form

If adverse event: Please complete an adverse event repeating data form

20.1.2 Was an IV antibiotic prescribed as trial treatment? Yes No



20.1.2.1	Name of drug	<input type="radio"/> Piperacillin – Tazobactam <input type="radio"/> Ceftazidime <input type="radio"/> Meropenem <input type="radio"/> Aztreonam <input type="radio"/> Ceftolozone – Tazobactam <input type="radio"/> Gentamicin <input type="radio"/> Tobramycin <input type="radio"/> Amikacin <input type="radio"/> Fosfomycin <input type="radio"/> Levofloxacin
20.1.2.2	Dose	<input type="text"/>
20.1.2.3	Units	<input type="radio"/> mg <input type="radio"/> g <input type="radio"/> mg/ml <input type="radio"/> other
20.1.2.3.1	'Other' unit	<input type="text"/>
20.1.2.4	Times per day	<input type="text"/>
20.1.2.5	Trial treatment start date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
20.1.2.6	Trial treatment end date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
20.1.2.7	Is end date before start date?	Automatic Calculation on Castor
20.1.2.8	Was this trial treatment taken for the full time period prescribed?	<input type="radio"/> Yes <input type="radio"/> No
20.1.2.8.1	Were any trial treatment doses missed?	<input type="radio"/> Yes <input type="radio"/> No



20.1.2.8.1.1 Number of days with any missed doses

20.1.2.8.1.2 Reason

Adverse event
 Patients decision
 Doctors decision
 Changed to new medication
 Other

20.1.2.8.1.2.1 Details

If new medication: Please complete a new Concomitant Medications repeating data form

If adverse event: Please complete an adverse event repeating data form

20.1.2.8.2 Reason trial treatment not completed

Adverse event
 Patients decision
 Doctors decision
 Changed to new medication
 Other

20.1.2.8.2.1 Details

If new medication: Please complete a Concomitant Medications repeating data form

If adverse event: Please complete an adverse event repeating data form

20.1.3 Was an inhaled antibiotic prescribed as trial treatment? Yes No

20.1.3.1 Name of drug

Colistin
 Gentamicin
 Tobramycin

20.1.3.2 Dose

20.1.3.3 Units

mg
 MU
 Other

20.1.3.3.1 'Other' unit



20.1.3.4	Times per day	<input type="text"/>
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20.1.3.5	Trial treatment start date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
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20.1.3.6	Trial treatment end date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
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20.1.3.7	Is end date before start date?	Automatic Calculation on Castor
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20.1.3.8	Was this trial treatment taken for the full 12 weeks prescribed?	<input type="radio"/> Yes <input type="radio"/> No
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20.1.3.8.1	Were any trial treatment doses missed?	<input type="radio"/> Yes <input type="radio"/> No
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20.1.3.8.1.1	Number of days with any missed doses	<input type="text"/>
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20.1.3.8.1.2	Reason	<input type="checkbox"/> Adverse event <input type="checkbox"/> Patients decision <input type="checkbox"/> Doctors decision <input type="checkbox"/> Changed to new medication <input type="checkbox"/> Other
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20.1.3.8.1.2.1	Details	<input type="text"/>
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If new medication: Please complete a new Concomitant Medications repeating data form

If adverse event: Please complete an Adverse Event repeating data form

20.1.3.8.2	Reason trial treatment not completed	<input type="checkbox"/> Adverse event <input type="checkbox"/> Patients decision <input type="checkbox"/> Doctors decision <input type="checkbox"/> Changed to new medication <input type="checkbox"/> Other
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20.1.3.8.2.1 Details

If new medication: Please complete a new Concomitant Medications repeating data form

If adverse event: Please complete an Adverse Event repeating data form

21. Visit 2 - Randomisation - Symptom diary setup

Number	Question	Answers
21.1	Has the participant provided their email address to receive the daily symptom diary?	<input type="radio"/> Yes <input type="radio"/> No
21.1.1	Has the email address been recorded in Castor?	<input type="radio"/> Yes <input type="radio"/> No
Email address must be added to Castor at Visit 2 to ensure participant receives electronic diary access		
21.1.2	Would the participant prefer to install and use the Castor Connect mobile App to receive the daily symptom diary?	<input type="radio"/> Yes <input type="radio"/> No
If yes: Please set up the Castor Connect ESCAPE daily symptom diary & ESCAPE monthly question surveys as per ESCAPE Castor ePRO Site Guide		
If no: Please set up the web-based ESCAPE daily symptom diary & ESCAPE monthly question surveys as per ESCAPE Castor ePRO Site Guide		

22. Visit 2 - Randomisation - Exacerbations

Number	Question
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22.1	Record any exacerbations since previous visit
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23. Visit 2 - Randomisation - Adverse Events

Number	Question
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23.1	Record any adverse events since previous visit
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