ESCAPE Worksheet

1. Visit 1 - Screening - Informed Consent

Number	Question	Answers
1.1	Date of Screening V1	☐ ☐ ☐ *(dd-mm-yyyy)*
1.2	Date of Informed Consent	☐ ☐ ☐ *(dd-mm-yyyy)*
1.3	Is the date of consent after date of screening?	**Automatic Calculation on Castor**
1.4	Has the participant agreed to be contacted by trial staff for further ethically approved future research	◯ Yes ◯ No

2. Visit 1 - Screening - Inclusion Criteria

Number	Question	Answers
2.1	Age 18 or over	○ Yes ○ No
2.2	Able to and provided informed consent	○ Yes ○ No
2.3	Capable of complying with all trial procedures and of completing the trial, in the opinion of the investigator	○ Yes ○ No
2.4	Bronchiectasis, confirmed by computed tomography (CT), showing bronchiectasis in 1 or more lobes and the appropriate clinical syndrome	○ Yes ○ No
2.5	Able to be prescribed one of the inhaled antibiotics defined in the intervention arm, in the opinion of the investigator	○ Yes ○ No
2.6	P. aeruginosa infection	○ Yes ○ No*
2.6.1	Is this infection:	○ A new isolation of P. aeruginosa within the 6 months prior to randomisation ○ A new isolation of P. aeruginosa, within the 6 months prior to randomisation, following previous clearance of P. aeruginosa
2.6.2	Date of positive sample	[ ] [ ] [ ] (dd-mm-yyyy)

* If a patient does not have a positive sputum sample within 6 months prior to randomisation but otherwise meets inclusion criteria, the investigator may send a sputum sample at the screening visit.

3. Visit 1 - Screening - Exclusion Criteria

Number	Question	Answers
3.1	Current treatment with inhaled antibiotics or treatment with inhaled antibiotics within the previous 6 months?	○ Yes ○ No
3.2	Chronic P. aeruginosa infection defined as isolation of P. aeruginosa persistently in sputum, or the absence of negative sputum samples for P. aeruginosa	○ Yes ○ No
3.3	Cystic fibrosis	○ Yes ○ No
3.4	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	○ Yes ○ No
3.5	Currently pregnant or breast-feeding	○ Yes ○ No
3.6	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
3.7	Estimate eGFR<30 or abnormal liver function tests that in the opinion of the investigator make antibiotic treatment inappropriate	○ Yes ○ No
3.8	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	○ Yes ○ No

4. Visit 1 - Screening - Demographics

Number	Question	Answers
4.1	Age	[.....................................]
4.2	Gender at birth	○ Male ○ Female
4.3	Ethnicity	○ White - English / Welsh / Scottish / Northern Irish / British ○ White - Irish ○ White - Gypsy or Irish Traveller ○ White - Roma ○ Any other White background ○ Mixed or multiple ethnic groups - White and Black Caribbean ○ Mixed or multiple ethnic groups - White and Black African ○ Mixed or multiple ethnic groups - White and Asian ○ Any other Mixed or multiple ethnic background ○ Asian or Asian British - Indian ○ Asian or Asian British - Pakistani ○ Asian or Asian British - Bangladeshi ○ Asian or Asian British - Chinese ○ Any other Asian background ○ Black, Black British - African ○ Black, Black British - Caribbean ○ Any other Black / Black British / Caribbean background ○ Arab ○ Any other ethnic group ○ Unknown ○ Prefer not to say
4.3.1	If Ethnicity is Any other ethnic group, then provide details	[.....................................]
4.4	Ensure participant completes Demographics Questionnaire	

5. Visit 1 - Screening - Medical History

Number	Question	Answers
	Please indicate any history of chronic medical conditions by selecting yes	
5.1	Asthma	◯ Yes ◯ No
5.2	Nasal polyps	◯ Yes ◯ No
5.3	COPD	◯ Yes ◯ No
5.4	Rhinosinusitis	◯ Yes ◯ No
5.5	Angina	◯ Yes ◯ No
5.6	Atrial Fibrillation	◯ Yes ◯ No
5.7	Myocardial Infarction	◯ Yes ◯ No
5.8	Cardiac Failure	◯ Yes ◯ No
5.9	Liver Cirrhosis	◯ Yes ◯ No
5.10	Osteoporosis	◯ Yes ◯ No
5.11	Anxiety	◯ Yes ◯ No
5.12	Depression	◯ Yes ◯ No
5.13	Other relevant medical conditions (Please state below)	◯ Yes ◯ No
5.13.1	If yes, provide details	
	Has the participant had any of the following cancers?	
5.14	Lung Cancer	◯ Yes ◯ No
5.14.1	If YES, Currently active?	◯ Yes ◯ No

5.15	Haematological Malignancy	◯ Yes ◯ No
5.15.1	If YES, Currently active?	◯ Yes ◯ No
5.16	Other Solid Tumours (Please state below)	◯ Yes ◯ No
5.16.1	If YES, Currently active?	◯ Yes ◯ No
5.16.2	Details	

6. Visit 1 - Screening - Concomitant Medications

Number	Question
	Review participant medications and record on Concomitant Log.
6.1	Complete Concomitant Medications: Respiratory Medication
6.2	Complete Concomitant Medications: Other Concomitant Medication

7. Visit 1 - Screening - Pregnancy Test

Number	Question	Answers
	Choose 'not of childbearing age' for female participants who are permanently sterile or post-menopausal	
7.1	Has a urine pregnancy test been performed at visit 1 or at home prior to the visit?	◯ Yes ◯ No ◯ Not of childbearing age
7.1.1	Result of Pregnancy Test	◯ Positive ◯ Negative

8. Visit 1 - Screening - ECG

Number	Question	Answers
8.1	Was ECG performed?	○ Yes ○ No
8.1.1	ECG Result	○ Normal ○ Abnormal - not clinically significant ○ Abnormal - clinically significant
8.1.2	Was the ECG reviewed by a doctor prior to randomisation	○ Yes ○ No
8.1.2.1	Date of review	[ ] [ ] [ ] *(dd-mm-yyyy)*

9. Visit 1 - Screening - Vital Signs

Number	Question	Answers
9.1	Blood pressure - Systolic	[............................] mmHg
9.2	Blood pressure - Diastolic	[............................] mmHg
9.3	Pulse rate	[............................] beats/min
9.4	Temperature	[............................] °C
9.5	Oxygen saturation	[............................] %

10. Visit 1 - Screening - Physical Examination

Number	Question	Answers
	Enter Height to 2 decimal places.	
10.1	Height	[................................] m (to the nearest cm - e.g. 1.64m)
	Enter Weight to 1 decimal place.	
10.3	Weight	[................................] kg (to the nearest 0.1kg - e.g. 68.2kg)
	Physical Examination - Please enter any abnormalities	
10.6	Has Physical Examination been performed?	◯ Yes ◯ No
10.6.1	Respiratory	◯ Normal ◯ Abnormal - not clinically significant ◯ Abnormal - clinically significant
10.6.1.1	If abnormal, provide details	[ ]
10.6.2	Cardiovascular	◯ Normal ◯ Abnormal - not clinically significant ◯ Abnormal - clinically significant
10.6.2.1	If abnormal, provide details	[ ]
10.6.3	Abdominal	◯ Normal ◯ Abnormal - not clinically significant ◯ Abnormal - clinically significant
10.6.3.1	If abnormal, provide details	[ ]

10.6.4	Neurological	○ Normal
		○ Abnormal - not clinically significant
		○ Abnormal - clinically significant

| 10.6.4.1 | If abnormal, provide details | |

10.6.5	Dermatological	○ Normal
		○ Abnormal - not clinically significant
		○ Abnormal - clinically significant

| 10.6.5.1 | If abnormal, provide details | |

11. Visit 1 - Screening - Bronchiectasis Severity Index

Number	Question	Answers
	http://www.bronchiectasisseverity.com/15-2/	
11.1	Age	○ <50 ○ 50-59 ○ 60-69 ○ 70-79 ○ 80+
11.2	BMI	○ <18.5 ○ 18.5-25 ○ 26-30 ○ >30
11.3	% FEV1 Predicted	○ >80% ○ 50-80% ○ 30-49% ○ <30%
11.4	Has the participant been hospitalised with a severe exacerbation in the past 2 years?	○ NO ○ YES
11.5	Number of exacerbations in previous year	○ 0 ○ 1-2 ○ 3+
11.6	MRC Breathlessness Score	○ 1 - Not troubled by breathlessness except on strenuous exercise ○ 2 - Short of breath when hurrying or walking up a slight hill ○ 3 - Walks slower then contemporaries on level ground because of breathlessness or has to stop for breath when walking at own pace ○ 4 - Stops due to breathlessness after walking 100m ○ 5 - Housebound due to breathlessness or breathless on dressing or undressing
11.7	Pseudomonas colonisation	○ NO ○ YES

| 11.8 | Colonisation with other organisms | ○ NO |
| | | ○ YES |

11.9	Radiological severity	○ Less than 3 lobes involved
		○ 3 or more lobes involved
		○ Cystic bronchiectasis

| 11.10 | Bronchiectasis Severity Index score | [   ] |