

AIR-NET worksheet



1. Visit 1 - Screening - Informed Consent

Number	Question	Answers
1.2	Date of Screening V1	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.3	Date of Informed Consent	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.4	Is the date of consent after date of screening?	
1.5	Has the participant agreed that any leftover samples will be stored for future research?	<input type="radio"/> Yes <input type="radio"/> No
1.6	Has the participant provided their email address to receive the BEST diary?	<input type="radio"/> Yes <input type="radio"/> No
1.6.1	If 'Has the participant provided their email address to receive the BEST diary?' is equal to 'Yes' answer this question: Has the email address been recorded on Castor?	<input type="radio"/> Yes <input type="radio"/> No
1.6.2	If 'Has the participant provided their email address to receive the BEST diary?' is equal to 'Yes' answer this question: Would the participant prefer to install and use the CastorConnect mobile App to receive the BEST diary?	<input type="radio"/> Yes <input type="radio"/> No
1.1.1	If 'Site' is equal to '01-Tayside' answer this question: <u>TAYSIDE ONLY</u> - Has the participant provided consent for sub-study?	<input type="radio"/> Yes <input type="radio"/> No

3. Visit 1 - Screening - Medical History

Number	Question	Answers
Smoking History		
3.1	What is the participant's smoking status?	<input type="radio"/> Current <input type="radio"/> Ex <input type="radio"/> Never
Pack years can be calculated by clicking here: (https://www.smokingpackyears.com/)		
3.1.2	<p><i>If 'What is the participant's smoking status?' is not equal to 'Never' answer this question:</i></p> Approximate Pack Years	<input style="border: 1px dashed black;" type="text"/>
Has the participant had any of the following?		
Please indicate any history of chronic medical conditions by selecting yes		
3.2	Asthma	<input type="radio"/> Yes <input type="radio"/> No
3.3	Nasal polyps	<input type="radio"/> Yes <input type="radio"/> No
3.4	COPD	<input type="radio"/> Yes <input type="radio"/> No
3.5	Rhinosinusitis	<input type="radio"/> Yes <input type="radio"/> No
3.6	Angina	<input type="radio"/> Yes <input type="radio"/> No
3.7	Atrial Fibrillation	<input type="radio"/> Yes <input type="radio"/> No
3.8	Myocardial Infarction	<input type="radio"/> Yes <input type="radio"/> No
3.9	Cardiac Failure	<input type="radio"/> Yes <input type="radio"/> No
3.10	Liver Cirrhosis	<input type="radio"/> Yes <input type="radio"/> No

3.11 Osteoporosis Yes No

3.12 Anxiety Yes No

3.13 Depression Yes No

3.14 Other relevant medical conditions (Please state below) Yes No

3.14.1 ***If 'Other relevant medical conditions (Please state below)' is equal to 'Yes' answer this question:***
If yes, provide details

Has the participant had any of the following cancers?

3.15 Lung Cancer Yes No

3.15.1 ***If 'Lung Cancer' is equal to 'Yes' answer this question:***
If YES, Currently active? Yes No

3.16 Haematological Malignancy Yes No

3.16.1 ***If 'Haematological Malignancy' is equal to 'Yes' answer this question:***
If YES, Currently active? Yes No

3.17 Other Solid Tumours (Please state below) Yes No

3.17.1 ***If 'Other Solid Tumours (Please state below)' is equal to 'Yes' answer this question:***
If YES, Currently active? Yes No

3.17.2 ***If 'Other Solid Tumours (Please state below)' is equal to 'Yes' answer this question:***
Details

4. Visit 1 - Screening - Concomitant Medications

Number	Question	Answers
All medications for all visits will be shown below		
<u>Review each medication and check it is still ongoing at each visit</u>		
4.1	Repeating Data for each separate Respiratory Medication	
4.2	Repeating Data for each separate other Concomitant Medication	

7. Visit 1 - Screening - ECG

Number	Question	Answers
7.1	Was ECG performed?	<input type="radio"/> Yes <input type="radio"/> No
7.1.1	<i>If 'Was ECG performed?' is equal to 'Yes' answer this question:</i> ECG Result	<input type="radio"/> Normal <input type="radio"/> Abnormal - not clinically significant <input type="radio"/> Abnormal - clinically significant
7.1.2	<i>If 'Was ECG performed?' is equal to 'Yes' answer this question:</i> Was the ECG reviewed by a doctor prior to randomisation	<input type="radio"/> Yes <input type="radio"/> No
7.1.2.1	<i>If 'Was the ECG reviewed by a doctor prior to randomisation' is equal to 'Yes' answer this question:</i> Date of review	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)

8. Visit 1 - Screening - Physical Examination

Number	Question	Answers
	Enter Height to 2 decimal places.	
8.1	Height	<input type="text"/> m (to the nearest cm - e.g. 1.64m)
8.2	Is Height given to 2 decimal places?	
	Enter Weight to 1 decimal place.	
8.3	Weight	<input type="text"/> kg (to the nearest 0.1kg - e.g. 68.2kg)
8.4	Is Weight given to 1 decimal place?	
8.5	BMI	
Physical Examination - Please enter any abnormalities		
8.6	Has Physical Examination been performed?	<input type="radio"/> Yes <input type="radio"/> No
8.6.1	If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question: Respiratory	<input type="radio"/> Normal <input type="radio"/> Abnormal - not clinically significant <input type="radio"/> Abnormal - clinically significant
8.6.1.1	If 'Respiratory' is not equal to 'Normal' answer this question: If abnormal, provide details	<input type="text"/>
8.6.2	If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question: Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal - not clinically significant <input type="radio"/> Abnormal - clinically significant

9. & 10.

Visit 1 - Screening - Complete Inclusion and Exclusion criteria in AIR-NET ELIGIBILITY FORM

11. Visit 1 - Screening - Blood & Sputum Samples

Number	Question	Answers
11.1	Have NHS blood samples been obtained?	<input type="radio"/> Yes <input type="radio"/> No
11.1.1	<i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i> Add Blood Results	
11.2	Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
11.3	Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

13. Visit 1 - Screening - Questionnaires

Number	Question	Answers
13.1	Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?	<input type="radio"/> Yes <input type="radio"/> No
13.1.1	<i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i> Add QoL-B questionnaire	

14. Visit 2 - Baseline and randomisation - Date of Visit 2

Number	Question	Answers
14.1	Screening and Randomisation on the same day?	<input type="radio"/> Yes <input type="radio"/> No
14.1.1	<i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i> Date of Visit 2	<input type="text"/> (dd-mm-yyyy)
14.1.2	<i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i> Is Visit 1 and Visit 2 on the same day?	
14.1.3	<i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i> Is Visit 2 date within 35 days post-screening?	

15. Visit 2 - Baseline and randomisation - Pregnancy Test - Urine

Number	Question	Answers
	Tick NA for male participants and female participants who are permanently sterile or post-menopausal	
15.1	Has urine pregnancy test been performed on day of visit?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
15.2	Is the participant male or female?	
15.3.1	<i>If 'female' answer this question:</i> Result of Pregnancy Test	<input type="radio"/> Positive <input type="radio"/> Negative

16. Visit 2 - Baseline and randomisation - Concomitant Medications

Number	Question	Answers
	All medications for all visits will be shown below	
	<u>Review each medication and check it is still ongoing at each visit</u>	
16.1	Repeating Data for each separate Respiratory Medication	
16.2	Repeating Data for each separate other Concomitant Medication	

17. Visit 2 - Baseline and randomisation - Adverse Events

Number	Question	Answers
<hr/> All adverse events for all visits will be shown below <hr/>		
17.1	Adverse Event	

18. Visit 2 - Baseline and randomisation - Exacerbation recording

Number	Question	Answers
18.1	Has the participant experienced any symptoms of Exacerbation since last visit?	<input type="radio"/> Yes <input type="radio"/> No
18.1.1	<i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i> Add Exacerbation recording	

19. Visit 2 - Baseline and randomisation - Vital Signs

Question	Answers
Blood pressure - Systolic	<input data-bbox="884 338 1254 376" type="text"/> mmHg
Blood pressure - Diastolic	<input data-bbox="884 544 1254 582" type="text"/> mmHg
Pulse	<input data-bbox="884 748 1254 786" type="text"/> beats/min
Temperature	<input data-bbox="884 920 1254 958" type="text"/> °C
Oxygen saturation	<input data-bbox="884 1093 1254 1131" type="text"/> %

21. Visit 2 - Baseline and randomisation - Pulse Wave Velocity, Iontophoresis and FLPI

***Tayside Only (optional sub-study participants)**

22. Visit 2 - Baseline and randomisation - 6-Minute Walk Test

Number	Question	Answers
22.1	Was 6-Minute Walk Test performed?	<input type="radio"/> Yes <input type="radio"/> No
22.1.1	<i>If 'Was 6-Minute Walk Test performed?' is equal to 'Yes'</i>	
	Question	Answers
	Distance walked in 6 minutes?	<input type="text"/> m
	Number of stops?	<input type="text"/>

23. & 24. & 25.

Visit 2 - Baseline and randomisation - Complete
Inclusion, Exclusion and Intervention Specific
Exclusion Criteria in AIR-NET ELIGIBILITY FORM

26. Visit 2 - Baseline and randomisation - Randomisation

Number	Question	Answers
26.1	Eligible for Arm 1: Standard care ?	
26.2	Eligible for Arm 2: Disulfiram ?	
26.3	Eligible for Arm 3: Dipyridamole ?	
26.4	Eligible for Arm 4: Doxycycline ?	
26.5	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.		
26.6	Has the participant been randomised?	<input type="radio"/> Yes <input type="radio"/> No
26.7	Date of Randomisation	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
26.8	Is date of Visit 2 after randomisation date?	<input type="radio"/> Yes <input type="radio"/> No
26.9	<i>If 'Was the ECG reviewed by a doctor prior to randomisation' is equal to 'Yes' answer this question:</i> Is date of ECG review after randomisation date?	
26.10	Randomised to Arm	<input type="radio"/> Arm 1: Standard care <input type="radio"/> Arm 2: Disulfiram - two 200mg oral tablets once daily <input type="radio"/> Arm 3: Dipyridamole - one 200mg oral prolonged/modified release capsule twice daily <input type="radio"/> Arm 4: Doxycycline - one 100mg oral tablet once daily
26.11	Was trial medication dispensed during visit?	<input type="radio"/> Yes <input type="radio"/> No
26.11.1	<i>If 'Was trial medication dispensed during visit?' is equal to 'No' answer this question:</i> Reason trial medication not dispensed during visit	<input type="text"/>

27. Visit 2 - Baseline and randomisation - BEST Diary

Number	Question	Answers
	Please set up the electronic BEST diary surveys with reference to the AIR-NET Castor ePRO Guidelines for Participants document. Paper BEST diaries can be entered below:	
27.1	Has the BEST diary been completed during this visit?	<input type="radio"/> Yes <input type="radio"/> No
27.1.1	<i>If 'Has the BEST diary been completed during this visit?' is equal to 'Yes' answer this question:</i> Add BEST diary	

28. Visit 2 - Baseline and randomisation - Blood & Sputum Samples

Number	Question	Answers
28.1	Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
28.2	Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

29. Visit 2 - Baseline and randomisation - Nasal samples

Number	Question	Answers
29.1	Has a nasal sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

30. Visit 2 - Baseline and randomisation - Questionnaires

Number	Question	Answers
30.1	<p><i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i></p> <p>Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?</p>	<input type="radio"/> Yes <input type="radio"/> No
30.1.1	<p><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></p> <p>Add QoL-B questionnaire</p>	
30.2	<p>Has the Bronchiectasis Impact Measure - Baseline Questionnaire (BIM) been completed?</p>	<input type="radio"/> Yes <input type="radio"/> No
30.2.1	<p><i>If 'Has the Bronchiectasis Impact Measure - Baseline Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></p> <p>Add BIM-Baseline questionnaire</p>	

31. Visit 3 - Date of Visit 3

Number	Question	Answers
31.1	Date of Visit 3	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
31.2	Is Visit 3 date within visit window?	

33. Visit 3 - Concomitant Medications

Number	Question	Answers
All medications for all visits will be shown below		
<u>Review each medication and check it is still ongoing at each visit</u>		
33.1	Repeating Data for each separate Respiratory Medication	
33.2	Repeating Data for each separate other Concomitant Medication	

34. Visit 3 - Adverse Events

Number	Question	Answers
<hr/> All adverse events for all visits will be shown below <hr/>		
34.1	Adverse Event	

37. Visit 3 - Spirometry

Question	Answers
Bronchodilation given (as per WPG)	<input type="radio"/> Yes <input type="radio"/> No
FEV1 Base	<input type="text"/> L
FVC Base	<input type="text"/> L
FEV1 - Percentage % of predicted values	<input type="text"/> %
FVC - Percentage % of predicted values	<input type="text"/> %
FEF - 25-75% Percentage of predicted values	<input type="text"/> %

38. Visit 3 - Blood & Sputum Samples

Number	Question	Answers
38.1	Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
38.2	Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

39. Visit 3 - Questionnaires

Number	Question	Answers
39.1	Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?	<input type="radio"/> Yes <input type="radio"/> No
39.1.1	<i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i> Add QoL-B questionnaire	
39.2	Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?	<input type="radio"/> Yes <input type="radio"/> No
39.2.1	<i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i> Add BIM-Follow up questionnaire	

40. Visit 3 - BEST Diary

Number	Question	Answers
40.1	Has the BEST diary been completed?	<input type="radio"/> Yes <input type="radio"/> No
40.1.1	<i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i> Add BEST diary	

41. Visit 4 - Date of Visit 4

Number	Question	Answers
41.1	Date of Visit 4	<input data-bbox="954 271 1050 309" type="text"/> <input data-bbox="1062 271 1158 309" type="text"/> <input data-bbox="1171 271 1294 309" type="text"/> (dd-mm-yyyy)
41.2	Is Visit 4 date within visit window?	

43. Visit 4 - Concomitant Medications

Number	Question	Answers
All medications for all visits will be shown below		
<u>Review each medication and check it is still ongoing at each visit</u>		
43.1	Repeating Data for each separate Respiratory Medication	
43.2	Repeating Data for each separate other Concomitant Medication	

44. Visit 4 - Adverse Events

Number	Question	Answers
<hr/> All adverse events for all visits will be shown below <hr/>		
44.1	Adverse Event	

45. Visit 4 - Exacerbation recording

Number	Question	Answers
45.1	Has the participant experienced any symptoms of Exacerbation since last visit?	<input type="radio"/> Yes <input type="radio"/> No
45.1.1	<i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i> Add Exacerbation recording	

48. Visit 4 - Blood & Sputum Samples

Number	Question	Answers
48.1	Have NHS blood samples been obtained?	<input type="radio"/> Yes <input type="radio"/> No
48.1.1	<i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i> Add Blood Results	
48.2	Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
48.3	Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

49. Visit 4 - Questionnaires

Number	Question	Answers
49.1	Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?	<input type="radio"/> Yes <input type="radio"/> No
49.1.1	<i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i> Add QoL-B questionnaire	
49.2	Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?	<input type="radio"/> Yes <input type="radio"/> No
49.2.1	<i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i> Add BIM-Follow up questionnaire	

50. Visit 4 - BEST Diary

Number	Question	Answers
50.1	Has the BEST diary been completed?	<input type="radio"/> Yes <input type="radio"/> No
50.1.1	<i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i> Add BEST diary	

51. Visit 5 - Date of Visit 5

Number	Question	Answers
51.1	Date of Visit 5	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
51.2	Is Visit 5 date within visit window?	

53. Visit 5 - Concomitant Medications

Number	Question	Answers
All medications for all visits will be shown below		
<u>Review each medication and check it is still ongoing at each visit</u>		
53.1	Repeating Data for each separate Respiratory Medication	
53.2	Repeating Data for each separate other Concomitant Medication	

54. Visit 5 - Adverse Events

Number	Question	Answers
<hr/> All adverse events for all visits will be shown below <hr/>		
54.1	Adverse Event	

55. Visit 5 - Exacerbation recording

Number	Question	Answers
55.1	Has the participant experienced any symptoms of Exacerbation since last visit?	<input type="radio"/> Yes <input type="radio"/> No
55.1.1	<i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i> Add Exacerbation recording	

58. Visit 5 - Pulse Wave Velocity, Iontophoresis and FLPI

***Tayside Only (optional sub-study participants)**

60. Visit 5 - Blood & Sputum Samples

Number	Question	Answers
60.1	Have NHS blood samples been obtained?	<input type="radio"/> Yes <input type="radio"/> No
60.1.1	<i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i> Add Blood Results	
60.2	Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
60.3	Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

61. Visit 5 - Nasal samples

Number	Question	Answers
61.1	Has a nasal sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No

62. Visit 5 - Questionnaires

Number	Question	Answers
62.1	Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?	<input type="radio"/> Yes <input type="radio"/> No
62.1.1	<i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i> Add QoL-B questionnaire	
62.2	Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?	<input type="radio"/> Yes <input type="radio"/> No
62.2.1	<i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i> Add BIM-Follow up questionnaire	

63. Visit 5 - BEST Diary

Number	Question	Answers
63.1	Has the BEST diary been completed?	<input type="radio"/> Yes <input type="radio"/> No
63.1.1	<i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i> Add BEST diary	

64. Visit 6 - Date of Visit 6

Number	Question	Answers
64.1	Date of Visit 6	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
64.2	Is Visit 6 date within visit window?	

65. Visit 6 - Concomitant Medications

Number	Question	Answers
All medications for all visits will be shown below		
<u>Review each medication and check it is still ongoing at each visit</u>		
65.1	Repeating Data for each separate Respiratory Medication	
65.2	Repeating Data for each separate other Concomitant Medication	

66. Visit 6 - Adverse Events

Number	Question	Answers
<hr/> All adverse events for all visits will be shown below <hr/>		
66.1	Adverse Event	

69. Visit 6 - Spirometry

Question	Answers
Bronchodilation given (as per WPG)	<input type="radio"/> Yes <input type="radio"/> No
FEV1 Base	<input type="text"/> L
FVC Base	<input type="text"/> L
FEV1 - Percentage % of predicted values	<input type="text"/> %
FVC - Percentage % of predicted values	<input type="text"/> %
FEF - 25-75% Percentage of predicted values	<input type="text"/> %

70. Visit 6 - Pulse Wave Velocity, Iontophoresis and FLPI

***Tayside Only (optional sub-study participants)**

72. Visit 6 - Questionnaires

Number	Question	Answers
72.1	Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?	<input type="radio"/> Yes <input type="radio"/> No
72.1.1	<i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i> Add QoL-B questionnaire	
72.2	Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?	<input type="radio"/> Yes <input type="radio"/> No
72.2.1	<i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i> Add BIM-Follow up questionnaire	

73. Completion of Trial/Early Withdrawal - Completion of Trial/Early Withdrawal

Number	Question	Answers
73.1	Did the participant complete the trial?	<input type="radio"/> Yes <input type="radio"/> No
73.2	Date of Completion/Withdrawal	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
73.1.1	<p>If 'Did the participant complete the trial?' is equal to 'No' answer this question: If participant did not complete the trial, what was the main reason (tick one only)</p>	<input type="radio"/> Advice from GP/other healthcare professional <input type="radio"/> Adverse event <input type="radio"/> Participant's choice <input type="radio"/> Pregnancy <input type="radio"/> On advice of investigator <input type="radio"/> Lost to follow-up <input type="radio"/> Died <input type="radio"/> Screen fail <input type="radio"/> Other
73.3.1	<p>If '73.1.1' is equal to 'advice from GP/other healthcare professional' / 'adverse event' / 'participant's choice' / 'on advice of investigator' / 'screen fail' / 'other' answer this question: Details</p>	<input type="text"/>

To be electronically verified by the PI once participant has completed the trial and all data entered

When the participant has Completed/Withdrawn, please check and follow up any unresolved AEs/SAEs. Also review Concomitant and Respiratory medications and enter End dates or mark as Ongoing (if applicable).

Participant ID				

Initials		



Blood Results – Visit

Date of blood test:

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Reviewed by (initials*) & date:

			D	D	M	M	Y	Y	Y	Y
--	--	--	---	---	---	---	---	---	---	---

Full Blood Count		<input type="checkbox"/> yes	<input type="checkbox"/> no
Haemoglobin		<input type="checkbox"/> g/L	<input type="checkbox"/> g/dL
White Cell Count	X10 ⁹ /L	<input style="width: 100%;" type="text"/>	
Neutrophil Count	X10 ⁹ /L	<input style="width: 100%;" type="text"/>	
Eosinophil Count	X10 ⁹ /L	<input style="width: 100%;" type="text"/>	
Platelets	X10 ⁹ /L	<input style="width: 100%;" type="text"/>	
Urea And Electrolyte Count		<input type="checkbox"/> yes	<input type="checkbox"/> no
Sodium	mmol/L	<input style="width: 100%;" type="text"/>	
Potassium	mmol/L	<input style="width: 100%;" type="text"/>	
Creatinine	umol/L	<input style="width: 100%;" type="text"/>	
Urea	mmol/L	<input style="width: 100%;" type="text"/>	
eGFR	ml/min	<input style="width: 100%;" type="text"/>	
Liver Function Tests		<input type="checkbox"/> yes	<input type="checkbox"/> no
Albumin	g/L	<input style="width: 100%;" type="text"/>	
Bilirubin	umol/L	<input style="width: 100%;" type="text"/>	
Alkaline Phosphatase	U/L	<input style="width: 100%;" type="text"/>	
Alanine Aminotransferase	U/L	<input style="width: 100%;" type="text"/>	

*Bloods must be reviewed by a doctor on the Delegation Log, with a copy of the results dated and initialled by the doctor filed in the participant's medical notes.

Any results outwith the normal range should be documented in the participant's medical notes as either not clinically significant or clinically significant with details of actions, if appropriate.

Any missing results should be recorded on the Breach Log.

Participant ID				

Initials		

DESCRIPTION OF ADVERSE EVENT	ONSET DATE	DATE REPORTED TO INVESTIGATOR	SEVERITY	RELATIONSHIP TO TRIAL DRUG	IS THIS A SAE?	SIGNATURE AND DATE	ACTION TAKEN please list all that apply	OUTCOME	DATE RESOLVED
Where possible give diagnosis. If diagnosis is not known give sign or symptom. Update if diagnosis is determined.	DD/MM/YYYY	DD/MM/YYYY	1. Mild 2. Moderate 3. Severe	1. Unrelated 2. Possible 3. Probable 4. Definite	If yes has an SAE form been completed? Y <input type="checkbox"/> N <input type="checkbox"/> Report within 10 days: http://hicservices.dundee.ac.uk/pharmacovigilance/	PI or delegated doctor Date must be within 24h of AE reported to Investigator otherwise it is a breach	1. None 2. Hospitalisation 3. Intervention stopped 4. ConMeds commenced (record on ConMeds Log) 5. Other (specify)	1. Recovered 2. Recovered with sequelae 3. Recovering 4. Not recovered 5. Unknown 6. Fatal	Enter date recovered/ date of death /date of last contact (* see below)
1	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__
2	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__
3	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__
4	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__
5	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__
6	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>	__/__/__			__/__/__

AEs & SAEs must be followed up until resolved or until 30 days after participant's last visit. **SUSARs** must be followed up until resolved.

*If the outcome of the AE is '1.Recovered', '2.Recovered with sequelae' or '6.Fatal' then enter 'Date resolved' or 'Date of death'.

*If the Outcome is '3.Recovering', '4.Not Recovered' or '5.Unknown' then enter the 'Date of last contact'.

Participant ID				

Initials		



Concomitant Medications Log

NAME OF DRUG (GENERIC)	TICK IF ONGOING AT START OF TRIAL OR ENTER START DATE	TICK IF ONGOING AT END OF TRIAL OR ENTER END DATE
<p>Instructions: Do not add antibiotics prescribed for pulmonary exacerbations, inhaled medications, leukotriene receptor antagonists, theophylline and any other respiratory medications. They should be entered on Respiratory & Antibiotic Concomitant Medication.</p>		
	<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
	<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
	<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
	<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
	<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --

Participant ID				

Initials		



Respiratory Medications Log

Respiratory & Antibiotic Concomitant Medication

NAME OF DRUG	DOSE	UNITS	TIMES PER DAY	TICK IF ONGOING AT START OF TRIAL OR ENTER START DATE	TICK IF ONGOING AT END OF TRIAL OR ENTER END DATE
<p>Instructions: It is necessary to include the name, dose, units and frequency of administration of antibiotic and respiratory medication. It is not necessary to include additional information for non-respiratory antibiotic medication. These can simply be named in the Other Concomitant Medication. Please use brand names for inhaled therapies and generic names for non-inhaled therapies.</p> <p style="text-align: center;">**Include all antibiotics, inhaled medications, leukotriene receptor antagonists, theophylline and any other respiratory medications.**</p>					
		<input type="radio"/> mg <input type="radio"/> mcg <input type="radio"/> puff <input type="radio"/> ml <input type="radio"/> Other _____		<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
		<input type="radio"/> mg <input type="radio"/> mcg <input type="radio"/> puff <input type="radio"/> ml <input type="radio"/> Other _____		<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
		<input type="radio"/> mg <input type="radio"/> mcg <input type="radio"/> puff <input type="radio"/> ml <input type="radio"/> Other _____		<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
		<input type="radio"/> mg <input type="radio"/> mcg <input type="radio"/> puff <input type="radio"/> ml <input type="radio"/> Other _____		<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --
		<input type="radio"/> mg <input type="radio"/> mcg <input type="radio"/> puff <input type="radio"/> ml <input type="radio"/> Other _____		<input type="checkbox"/> -- / -- / --	<input type="checkbox"/> -- / -- / --



Exacerbation recording

Question	Answers
Onset Date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
End Date	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
Assessment of Exacerbation	
Has the participant experienced a deterioration in any of the following key symptoms for at least 48 hours?	
Cough	<input type="radio"/> Yes <input type="radio"/> No
Sputum volume and/or consistency	<input type="radio"/> Yes <input type="radio"/> No
Sputum purulence	<input type="radio"/> Yes <input type="radio"/> No
Breathlessness and/or exercise tolerance	<input type="radio"/> Yes <input type="radio"/> No
Fatigue and/or malaise	<input type="radio"/> Yes <input type="radio"/> No
Haemoptysis	<input type="radio"/> Yes <input type="radio"/> No
How many Symptoms experienced?	
Has the participant experienced 3 or more of the above symptoms?	
If 'Has the participant experienced 3 or more of the above symptoms?' is equal to 'Yes' answer this question:	
Has a clinician determined that the participant requires a change in their bronchiectasis treatment?	
<input type="radio"/> Yes <input type="radio"/> No	
<i>Protocol defined exacerbation: 'Complete safety visit - If participant has been prescribed antibiotics, add to Concomitant Medications - This is NOT an AE'</i>	
Has the participant attended for a safety visit? If YES, complete safety visit form	<input type="radio"/> Yes <input type="radio"/> No
If 'Has the participant attended for a safety visit? If YES, complete safety visit form' is equal to 'Yes' answer this question:	
Repeating data for Safety Visit	



Discontinuation of Trial Medication

Question	Answers
Permanent Discontinuation of Trial Medication	
Instructions: Where a participant is withdrawing completely from the trial do not complete this form but complete the Completion of Trial Form. When participants stop trial medication they should be encouraged to continue with the trial visits and the trial wherever possible.	
On which date was the last dose taken?	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
Reason for stopping of trial medication (main reason only)	
Reason	<input type="radio"/> Advice from GP/other healthcare professional <input type="radio"/> Adverse event <input type="radio"/> Participant's choice <input type="radio"/> On advice of investigator <input type="radio"/> Other
Details	<input type="text"/>
Participant must be assessed by the PI and changes to medication noted on ConMeds Log. Changes to participant's medication and any other actions taken must be recorded in the participant's medical notes and their GP informed.	
Has the participant been reviewed by the PI or other delegated doctor?	<input type="radio"/> Yes <input type="radio"/> No
<i>If 'Has the participant been reviewed by the PI or other delegated doctor?' is equal to 'Yes' answer this question:</i> Date of review	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)



Safety Visit

Question	Answers
Date of Safety Visit Assessment	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)

Concomitant Medications

Question	Answers
All medications for all visits will be shown below	
Review each medication and check it is still ongoing at each visit	
Repeating Data for each separate Respiratory Medication	
Repeating Data for each separate other Concomitant Medication	

Adverse Events

Question	Answers
All adverse events for all visits will be shown below	
Adverse Event	

Exacerbation recording

Question	Answers
Has the participant experienced any symptoms of Exacerbation since last visit?	<input type="radio"/> Yes <input type="radio"/> No
<i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i> Add Exacerbation recording	



Safety Visit

Vital Signs

Question	Answers
Blood pressure - Systolic	<input type="text"/> mmHg
Blood pressure - Diastolic	<input type="text"/> mmHg
Pulse	<input type="text"/> beats/min
Temperature	<input type="text"/> °C
Oxygen saturation	<input type="text"/> %

Spirometry

Question	Answers
Bronchodilation given (as per WPG)	<input type="radio"/> Yes <input type="radio"/> No
FEV1 Base	<input type="text"/> L
FVC Base	<input type="text"/> L
FEV1 - Percentage % of predicted values	<input type="text"/> %
FVC - Percentage % of predicted values	<input type="text"/> %
FEF - 25-75% Percentage of predicted values	<input type="text"/> %

Blood & Sputum Samples

Question	Answers
Have NHS blood samples been obtained?	<input type="radio"/> Yes <input type="radio"/> No
<i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i>	
Add Blood Results	
Have research blood samples been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No
Have research sputum sample been obtained as per laboratory manual?	<input type="radio"/> Yes <input type="radio"/> No