

# 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  | <b>If 'Has the participant provided their email address to receive the BEST diary?' is equal to 'Yes' answer this question:</b><br>Has the email address been recorded on Castor?  | <input type="radio"/> Yes <input type="radio"/> No                          |
| 1.6.2  | <b>If 'Has the participant provided their email address to receive the BEST diary?' is equal to 'Yes' answer this question:</b><br>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  | <b>If 'Site' is equal to '01-Tayside' answer this question:</b><br><u>TAYSIDE ONLY</u> - Has the participant provided consent for sub-study?   | <input type="radio"/> Yes <input type="radio"/> No                          |

## 2. Visit 1 - Screening - Demographics

| Number | Question   | Answers   |
|--------|--|---|
| 2.1    | Age  | <input type="text"/>  |
| 2.2    | Gender at birth  | <input type="radio"/> Male <input type="radio"/> Female   |
| 2.3    | Ethnicity  | <input type="radio"/> White - English / Welsh / Scottish / Northern Irish / British<br><input type="radio"/> White - Irish<br><input type="radio"/> White - Gypsy or Irish Traveller<br><input type="radio"/> White - Roma<br><input type="radio"/> Any other White background<br><input type="radio"/> Mixed or multiple ethnic groups - White and Black Caribbean<br><input type="radio"/> Mixed or multiple ethnic groups - White and Black African<br><input type="radio"/> Mixed or multiple ethnic groups - White and Asian<br><input type="radio"/> Any other Mixed or multiple ethnic background<br><input type="radio"/> Asian or Asian British - Indian<br><input type="radio"/> Asian or Asian British - Pakistani<br><input type="radio"/> Asian or Asian British - Bangladeshi<br><input type="radio"/> Asian or Asian British - Chinese<br><input type="radio"/> Any other Asian background<br><input type="radio"/> Black, Black British - African<br><input type="radio"/> Black, Black British - Caribbean<br><input type="radio"/> Any other Black / Black British / Caribbean background<br><input type="radio"/> Arab<br><input type="radio"/> Any other ethnic group<br><input type="radio"/> Unknown<br><input type="radio"/> Prefer not to say |
| 2.3.1  | <p><b><i>If 'Ethnicity' is equal to 'Any other ethnic group' answer this question:</i></b></p> <p>If Ethnicity is Any other ethnic group, then provide details</p> | <input type="text"/>  |

### 3. Visit 1 - Screening - Medical History

| Number   | Question   | Answers  |
|--|--|--|
| <b>Smoking History</b>   |  |  |
| 3.1  | What is the participant's smoking status?  | <input type="radio"/> Current<br><input type="radio"/> Ex<br><input type="radio"/> Never |
| Pack years can be calculated by clicking here: ( <a href="https://www.smokingpackyears.com/">https://www.smokingpackyears.com/</a> ) |  |  |
| 3.1.2  | <b><i>If 'What is the participant's smoking status?' is not equal to 'Never' answer this question:</i></b><br>Approximate Pack Years | <input style="border: 1px dashed black;" type="text"/>                                   |
| <b>Has the participant had any of the following?</b>   |  |  |
| 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   | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.12  | Anxiety  | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.13  | Depression   | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.14  | Other relevant medical conditions (Please state below)   | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.14.1  | <b><i>If 'Other relevant medical conditions (Please state below)' is equal to 'Yes' answer this question:</i></b><br>If yes, provide details | <div style="border: 1px dotted black; height: 80px; width: 100%;"></div> |
| Has the participant had any of the following cancers? |  |  |
| 3.15  | Lung Cancer  | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.15.1  | <b><i>If 'Lung Cancer' is equal to 'Yes' answer this question:</i></b><br>If YES, Currently active?  | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.16  | Haematological Malignancy  | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.16.1  | <b><i>If 'Haematological Malignancy' is equal to 'Yes' answer this question:</i></b><br>If YES, Currently active?                            | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.17  | Other Solid Tumours (Please state below)   | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.17.1  | <b><i>If 'Other Solid Tumours (Please state below)' is equal to 'Yes' answer this question:</i></b><br>If YES, Currently active?             | <input type="radio"/> Yes <input type="radio"/> No                       |
| 3.17.2  | <b><i>If 'Other Solid Tumours (Please state below)' is equal to 'Yes' answer this question:</i></b><br>Details                               | <div style="border: 1px dotted black; height: 80px; width: 100%;"></div> |

## 4. Visit 1 - Screening - Concomitant Medications

| Number  | Question  | Answers |
|---|---|---------|
| <b>All medications for all visits will be shown below</b>                 |   |         |
| <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 |         |

## 5. Visit 1 - Screening - Vital Signs

| Question                   | Answers   |
|----------------------------|---|
| Blood pressure - Systolic  | <input data-bbox="884 309 1254 351" type="text"/> mmHg      |
| Blood pressure - Diastolic | <input data-bbox="884 510 1254 553" type="text"/> mmHg      |
| Pulse                      | <input data-bbox="884 716 1254 759" type="text"/> beats/min |
| Temperature                | <input data-bbox="884 889 1254 931" type="text"/> °C        |
| Oxygen saturation          | <input data-bbox="884 1057 1254 1099" type="text"/> %       |

## 6. Visit 1 - Screening - 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"/> %                             |


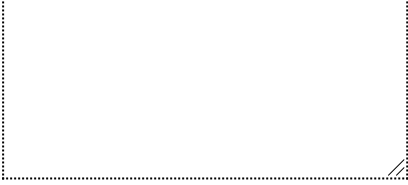



## 7. Visit 1 - Screening - ECG

| Number  | Question   | Answers  |
|---------|--|--|
| 7.1     | Was ECG performed?   | <input type="radio"/> Yes <input type="radio"/> No   |
| 7.1.1   | <b><i>If 'Was ECG performed?' is equal to 'Yes' answer this question:</i></b><br>ECG Result  | <input type="radio"/> Normal<br><input type="radio"/> Abnormal - not clinically significant<br><input type="radio"/> Abnormal - clinically significant |
| 7.1.2   | <b><i>If 'Was ECG performed?' is equal to 'Yes' answer this question:</i></b><br>Was the ECG reviewed by a doctor prior to randomisation | <input type="radio"/> Yes <input type="radio"/> No   |
| 7.1.2.1 | <b><i>If 'Was the ECG reviewed by a doctor prior to randomisation' is equal to 'Yes' answer this question:</i></b><br>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  |  |
| <b>Physical Examination - Please enter any abnormalities</b> |  |  |
| 8.6  | Has Physical Examination been performed?   | <input type="radio"/> Yes <input type="radio"/> No   |
| 8.6.1  | <b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question:</b><br>Respiratory    | <input type="radio"/> Normal<br><input type="radio"/> Abnormal - not clinically significant<br><input type="radio"/> Abnormal - clinically significant |
| 8.6.1.1  | <b>If 'Respiratory' is not equal to 'Normal' answer this question:</b><br>If abnormal, provide details         | <input type="text"/>   |
| 8.6.2  | <b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question:</b><br>Cardiovascular | <input type="radio"/> Normal<br><input type="radio"/> Abnormal - not clinically significant<br><input type="radio"/> Abnormal - clinically significant |

|         |   |   |
|---------|---|---|
| 8.6.2.1 | <p><b>If 'Cardiovascular' is not equal to 'Normal' answer this question:</b><br/>If abnormal, provide details</p>         |    |
| 8.6.3   | <p><b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question:</b><br/>Abdominal</p>         | <p><input type="radio"/> Normal<br/><input type="radio"/> Abnormal - not clinically significant<br/><input type="radio"/> Abnormal - clinically significant</p> |
| 8.6.3.1 | <p><b>If 'Abdominal' is not equal to 'Normal' answer this question:</b><br/>If abnormal, provide details</p>              |   |
| 8.6.4   | <p><b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question:</b><br/>Neurological</p>      | <p><input type="radio"/> Normal<br/><input type="radio"/> Abnormal - not clinically significant<br/><input type="radio"/> Abnormal - clinically significant</p> |
| 8.6.4.1 | <p><b>If 'Neurological' is not equal to 'Normal' answer this question:</b><br/>If abnormal, provide details</p>           |    |
| 8.6.5   | <p><b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question:</b><br/>Dermatological</p>    | <p><input type="radio"/> Normal<br/><input type="radio"/> Abnormal - not clinically significant<br/><input type="radio"/> Abnormal - clinically significant</p> |
| 8.6.5.1 | <p><b>If 'Dermatological' is not equal to 'Normal' answer this question:</b><br/>If abnormal, provide details</p>         |   |
| 8.6.6   | <p><b>If 'Has Physical Examination been performed?' is equal to 'Yes' answer this question</b></p>                        | <p><input type="radio"/> Abnormal - not clinically significant<br/>Abnormal - clinically significant<br/><input type="radio"/> Other</p>                        |
| 8.7     | Details Calculation   |   |
| 8.7.1   | <p><b>If 'Details Calculation' is equal to '1' answer this question:</b><br/>If 'Other' is 'Abnormal' provide details</p> |   |

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 | <b><i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i></b><br>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 |

## 12. Visit 1 - Screening - Pregnancy Test - Urine

| Number | Question   | Answers   |
|--------|--|---|
|        | Tick NA for male participants and female participants who are permanently sterile or post-menopausal |   |
| 12.1   | Has urine pregnancy test been performed on day of visit?   | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA |
| 12.2   | Is the participant male or female?   |   |
| 12.3.1 | <b><i>If 'female' answer this question:</i></b><br>Result of Pregnancy Test                          | <input type="radio"/> Positive <input type="radio"/> Negative               |

## 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 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i></b><br>Date of Visit 2                                | <input type="text"/> (dd-mm-yyyy)                  |
| 14.1.2 | <b><i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i></b><br>Is Visit 1 and Visit 2 on the same day?        |  |
| 14.1.3 | <b><i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i></b><br>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 | <b><i>If 'female' answer this question:</i></b><br>Result of Pregnancy Test                          | <input type="radio"/> Positive <input type="radio"/> Negative               |

## 16. Visit 2 - Baseline and randomisation - Concomitant Medications

| Number | Question  | Answers |
|--------|---|---------|
|        | <b>All medications for all visits will be shown below</b>                 |         |
|        | <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/> <b>All adverse events for all visits will be shown below</b> <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 | <b><i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>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"/> %       |

## 20. Visit 2 - Baseline and randomisation - 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"/> %                             |

## 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 <b>Arm 1: Standard care</b> ?  |   |
| 26.2   | Eligible for <b>Arm 2: Disulfiram</b> ?   |   |
| 26.3   | Eligible for <b>Arm 3: Dipyridamole</b> ?   |   |
| 26.4   | Eligible for <b>Arm 4: Doxycycline</b> ?  |   |
| 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   | <b><i>If 'Was the ECG reviewed by a doctor prior to randomisation' is equal to 'Yes' answer this question:</i></b><br>Is date of ECG review after randomisation date? |   |
| 26.10  | Randomised to Arm   | <input type="radio"/> <b>Arm 1: Standard care</b><br><input type="radio"/> <b>Arm 2: Disulfiram</b> - two 200mg oral tablets once daily<br><input type="radio"/> <b>Arm 3: Dipyridamole</b> - one 200mg oral prolonged/modified release capsule twice daily<br><input type="radio"/> <b>Arm 4: Doxycycline</b> - 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  | <b><i>If 'Was trial medication dispensed during visit?' is equal to 'No' answer this question:</i></b><br>Reason trial medication not dispensed during visit          | <input type="text"/>  |

## 27. Visit 2 - Baseline and randomisation - Blood & Sputum Samples

| Number | Question  | Answers  |
|--------|---|--|
| 27.1   | Have research blood samples been obtained as per laboratory manual? | <input type="radio"/> Yes <input type="radio"/> No |
| 27.2   | Have research sputum sample been obtained as per laboratory manual? | <input type="radio"/> Yes <input type="radio"/> No |



## 28. Visit 2 - Baseline and randomisation - Nasal samples

| Number | Question   | Answers  |
|--------|--|--|
| 28.1   | Has a nasal sample been obtained as per laboratory manual? | <input type="radio"/> Yes <input type="radio"/> No |

## 29. Visit 2 - Baseline and randomisation - Questionnaires

| Number | Question   | Answers  |
|--------|--|--|
| 29.1   | <b><i>If 'Screening and Randomisation on the same day?' is equal to 'No' answer this question:</i></b><br>Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed? | <input type="radio"/> Yes <input type="radio"/> No |
| 29.1.1 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>Add QoL-B questionnaire                     |  |
| 29.2   | Has the Bronchiectasis Impact Measure - Baseline Questionnaire (BIM) been completed?   | <input type="radio"/> Yes <input type="radio"/> No |
| 29.2.1 | <b><i>If 'Has the Bronchiectasis Impact Measure - Baseline Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></b><br>Add BIM-Baseline questionnaire      |  |

## 30. Visit 2 - Baseline and randomisation - BEST Diary

| Number | Question  | Answers  |
|--------|---|--|
| 30.1   | Has the BEST diary been completed during this visit?  | <input type="radio"/> Yes <input type="radio"/> No |
| 30.1.1 | <b><i>If 'Has the BEST diary been completed during this visit?' is equal to 'Yes' answer this question:</i></b><br>Add BEST diary |  |

## 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? |   |

## 32. Visit 3 - Pregnancy Test - Urine

| Number | Question   | Answers   |
|--------|--|---|
|        | Tick NA for male participants and female participants who are permanently sterile or post-menopausal |   |
| 32.1   | Has urine pregnancy test been performed on day of visit?   | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA |
| 32.2   | Is the participant male or female?   |   |
| 32.3.1 | <b><i>If 'female' answer this question:</i></b><br>Result of Pregnancy Test                          | <input type="radio"/> Positive <input type="radio"/> Negative               |

### 33. Visit 3 - Concomitant Medications

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

## 35. Visit 3 - Exacerbation recording

| Number | Question   | Answers  |
|--------|--|--|
| 35.1   | Has the participant experienced any signs and/or symptoms of Exacerbation since last visit?  | <input type="radio"/> Yes <input type="radio"/> No |
| 35.1.1 | <b><i>If 'Has the participant experienced any signs and/or symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>Add Exacerbation recording |  |



## 36. Visit 3 - 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"/> %         |

## 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 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i></b><br>Add BEST diary |  |

## 41. Visit 4 - Date of Visit 4

| Number | Question                             | Answers   |
|--------|--------------------------------------|---|
| 41.1   | Date of Visit 4                      | <input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy) |
| 41.2   | Is Visit 4 date within visit window? |   |

## 42. Visit 4 - Pregnancy Test - Urine

| Number | Question   | Answers   |
|--------|--|---|
|        | Tick NA for male participants and female participants who are permanently sterile or post-menopausal |   |
| 42.1   | Has urine pregnancy test been performed on day of visit?   | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA |
| 42.2   | Is the participant male or female?   |   |
| 42.3.1 | <b><i>If 'female' answer this question:</i></b><br>Result of Pregnancy Test                          | <input type="radio"/> Positive <input type="radio"/> Negative               |

## 43. Visit 4 - Concomitant Medications

| Number  | Question  | Answers |
|---|---|---------|
| <b>All medications for all visits will be shown below</b>                 |   |         |
| <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/> <b>All adverse events for all visits will be shown below</b> <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 | <b><i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>Add Exacerbation recording |  |

## 46. Visit 4 - 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"/> %         |

## 47. Visit 4 - 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"/> %                             |

## 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 | <b><i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i></b><br>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? |   |



## 52. Visit 5 - Pregnancy Test - Urine

| Number | Question   | Answers   |
|--------|--|---|
|        | Tick NA for male participants and female participants who are permanently sterile or post-menopausal |   |
| 52.1   | Has urine pregnancy test been performed on the day of visit?   | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA |
| 52.2   | Is the participant male or female?   |   |
| 52.3.1 | <b><i>If 'female' answer this question:</i></b><br>Result of Pregnancy Test                          | <input type="radio"/> Positive <input type="radio"/> Negative               |

## 53. Visit 5 - Concomitant Medications

| Number  | Question  | Answers |
|---|---|---------|
| <b>All medications for all visits will be shown below</b>                 |   |         |
| <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 |
|--------|----------|---------|
|--------|----------|---------|

---

All adverse events for all visits will be shown below

---

|      |               |  |
|------|---------------|--|
| 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 | <b><i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>Add Exacerbation recording |  |

## 56. Visit 5 - Vital Signs

| Question                   | Answers   |
|----------------------------|---|
| Blood pressure - Systolic  | <input data-bbox="884 311 1254 353" type="text"/> mmHg      |
| Blood pressure - Diastolic | <input data-bbox="884 512 1254 555" type="text"/> mmHg      |
| Pulse                      | <input data-bbox="884 719 1254 761" type="text"/> beats/min |
| Temperature                | <input data-bbox="884 893 1254 936" type="text"/> °C        |
| Oxygen saturation          | <input data-bbox="884 1061 1254 1104" type="text"/> %       |

## 57. Visit 5 - 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"/> %                             |

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

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

## 59. Visit 5 - 6-Minute Walk Test

| Number | Question  | Answers  |
|--------|---|--|
| 59.1   | Was 6-Minute Walk Test performed?                               | <input type="radio"/> Yes <input type="radio"/> No |
| 59.1.1 | <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"/>                               |



## 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 | <b><i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the BEST diary been completed?' is equal to 'Yes' answer this question:</i></b><br>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 |
|---|---|---------|
| <b>All medications for all visits will be shown below</b>                 |   |         |
| <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 |
|--------|----------|---------|
|--------|----------|---------|

---

All adverse events for all visits will be shown below

---

|      |               |  |
|------|---------------|--|
| 66.1 | Adverse Event |  |
|------|---------------|--|

## 67. Visit 6 - Exacerbation recording

| Number | Question  | Answers  |
|--------|---|--|
| 67.1   | Has the participant experienced any symptoms of Exacerbation since last visit?  | <input type="radio"/> Yes <input type="radio"/> No |
| 67.1.1 | <b><i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>Add Exacerbation recording |  |



## 68. Visit 6 - Vital Signs

| Question                   | Answers   |
|----------------------------|---|
| Blood pressure - Systolic  | <input data-bbox="884 309 1254 349" type="text"/> mmHg      |
| Blood pressure - Diastolic | <input data-bbox="884 510 1254 551" type="text"/> mmHg      |
| Pulse                      | <input data-bbox="884 712 1254 752" type="text"/> beats/min |
| Temperature                | <input data-bbox="884 891 1254 931" type="text"/> °C        |
| Oxygen saturation          | <input data-bbox="884 1059 1254 1099" type="text"/> %       |

## 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)**

## 71. Visit 6 - Blood & Sputum Samples

| Number | Question  | Answers  |
|--------|---|--|
| 71.1   | Have NHS blood samples been obtained?   | <input type="radio"/> Yes <input type="radio"/> No |
| 71.1.1 | <b><i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i></b><br>Add Blood Results |  |
| 71.2   | Have research blood samples been obtained as per laboratory manual?   | <input type="radio"/> Yes <input type="radio"/> No |
| 71.3   | Have research sputum sample been obtained as per laboratory manual?   | <input type="radio"/> Yes <input type="radio"/> No |

## 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 | <b><i>If 'Has the Quality of Life-Bronchiectasis Questionnaire (QoL-B) been completed?' is equal to 'Yes' answer this question:</i></b><br>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 | <b><i>If 'Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed?' is equal to 'Yes' answer this question:</i></b><br>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><b>If 'Did the participant complete the trial?' is equal to 'No' answer this question:</b><br/>           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<br><input type="radio"/> Adverse event<br><input type="radio"/> Participant's choice<br><input type="radio"/> Pregnancy<br><input type="radio"/> On advice of investigator<br><input type="radio"/> Lost to follow-up<br><input type="radio"/> Died<br><input type="radio"/> Screen fail<br><input type="radio"/> Other |
| 73.3.1 | <p><b>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:</b><br/>           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 |
|--|--|--|---|---|---|---|---|---|---|---|

|                                   |                     |   |                               |
|-----------------------------------|---------------------|---|-------------------------------|
| <b>Full Blood Count</b>           |                     | <input type="checkbox"/> yes              | <input type="checkbox"/> no   |
| <b>Haemoglobin</b>                |                     | <input type="checkbox"/> g/L              | <input type="checkbox"/> g/dL |
| <b>White Cell Count</b>           | X10 <sup>9</sup> /L | <input style="width: 100%;" type="text"/> |                               |
| <b>Neutrophil Count</b>           | X10 <sup>9</sup> /L | <input style="width: 100%;" type="text"/> |                               |
| <b>Eosinophil Count</b>           | X10 <sup>9</sup> /L | <input style="width: 100%;" type="text"/> |                               |
| <b>Platelets</b>                  | X10 <sup>9</sup> /L | <input style="width: 100%;" type="text"/> |                               |
| <b>Urea And Electrolyte Count</b> |                     | <input type="checkbox"/> yes              | <input type="checkbox"/> no   |
| <b>Sodium</b>                     | mmol/L              | <input style="width: 100%;" type="text"/> |                               |
| <b>Potassium</b>                  | mmol/L              | <input style="width: 100%;" type="text"/> |                               |
| <b>Creatinine</b>                 | umol/L              | <input style="width: 100%;" type="text"/> |                               |
| <b>Urea</b>                       | mmol/L              | <input style="width: 100%;" type="text"/> |                               |
| <b>eGFR</b>                       | ml/min              | <input style="width: 100%;" type="text"/> |                               |
| <b>Liver Function Tests</b>       |                     | <input type="checkbox"/> yes              | <input type="checkbox"/> no   |
| <b>Albumin</b>                    | g/L                 | <input style="width: 100%;" type="text"/> |                               |
| <b>Bilirubin</b>                  | umol/L              | <input style="width: 100%;" type="text"/> |                               |
| <b>Alkaline Phosphatase</b>       | U/L                 | <input style="width: 100%;" type="text"/> |                               |
| <b>Alanine Aminotransferase</b>   | 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<br>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<br>2. Moderate<br>3. Severe | 1. Unrelated<br>2. Possible<br>3. Probable<br>4. Definite | If yes has an SAE form been completed?<br>Y <input type="checkbox"/> N <input type="checkbox"/><br>Report within 10 days:<br><a href="http://hicservices.dundee.ac.uk/pharmacovigilance/">http://hicservices.dundee.ac.uk/pharmacovigilance/</a> | PI or delegated doctor<br>Date must be within 24h of AE reported to Investigator otherwise it is a breach | 1. None<br>2. Hospitalisation<br>3. Intervention stopped<br>4. ConMeds commenced (record on ConMeds Log)<br>5. Other (specify) | 1. Recovered<br>2. Recovered with sequelae<br>3. Recovering<br>4. Not recovered<br>5. Unknown<br>6. Fatal | Enter date recovered/<br>date of death<br>/date of last contact<br><br>(* 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<br>OR<br>ENTER START DATE | TICK IF ONGOING AT END OF TRIAL<br>OR<br>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 &amp; Antibiotic Concomitant Medication.</p> |   |   |
|   | <input type="checkbox"/><br>-- / -- / --                    | <input type="checkbox"/><br>-- / -- / --                |
|   | <input type="checkbox"/><br>-- / -- / --                    | <input type="checkbox"/><br>-- / -- / --                |
|   | <input type="checkbox"/><br>-- / -- / --                    | <input type="checkbox"/><br>-- / -- / --                |
|   | <input type="checkbox"/><br>-- / -- / --                    | <input type="checkbox"/><br>-- / -- / --                |
|   | <input type="checkbox"/><br>-- / -- / --                    | <input type="checkbox"/><br>-- / -- / --                |

| 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<br><input type="radio"/> mcg<br><input type="radio"/> puff<br><input type="radio"/> ml<br><input type="radio"/> Other _____ |               | <input type="checkbox"/><br>-- / -- / --              | <input type="checkbox"/><br>-- / -- / --          |
|  |      | <input type="radio"/> mg<br><input type="radio"/> mcg<br><input type="radio"/> puff<br><input type="radio"/> ml<br><input type="radio"/> Other _____ |               | <input type="checkbox"/><br>-- / -- / --              | <input type="checkbox"/><br>-- / -- / --          |
|  |      | <input type="radio"/> mg<br><input type="radio"/> mcg<br><input type="radio"/> puff<br><input type="radio"/> ml<br><input type="radio"/> Other _____ |               | <input type="checkbox"/><br>-- / -- / --              | <input type="checkbox"/><br>-- / -- / --          |
|  |      | <input type="radio"/> mg<br><input type="radio"/> mcg<br><input type="radio"/> puff<br><input type="radio"/> ml<br><input type="radio"/> Other _____ |               | <input type="checkbox"/><br>-- / -- / --              | <input type="checkbox"/><br>-- / -- / --          |
|  |      | <input type="radio"/> mg<br><input type="radio"/> mcg<br><input type="radio"/> puff<br><input type="radio"/> ml<br><input type="radio"/> Other _____ |               | <input type="checkbox"/><br>-- / -- / --              | <input type="checkbox"/><br>-- / -- / --          |



## 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) |
| <b>**Assessment of Exacerbation**</b>   |   |
| 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?  |   |
| <b><i>If 'Has the participant experienced 3 or more of the above symptoms?' is equal to 'Yes' answer this question:</i></b>   | <input type="radio"/> Yes <input type="radio"/> No                          |
| Has a clinician determined that the participant requires a <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                          |
| <b><i>If 'Has the participant attended for a safety visit? If YES, complete safety visit form' is equal to 'Yes' answer this question:</i></b>  |   |
| Repeating data for Safety Visit   |   |



## Discontinuation of Trial Medication

| Question   | Answers   |
|--|---|
| <b>**Permanent Discontinuation of Trial Medication**</b>   |   |
| 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"/> <span style="float: right;">(dd-mm-yyyy)</span>  |
| Reason for stopping of trial medication (main reason only)   |   |
| Reason   | <input type="radio"/> Advice from GP/other healthcare professional<br><input type="radio"/> Adverse event<br><input type="radio"/> Participant's choice<br><input type="radio"/> On advice of investigator<br><input type="radio"/> Other |
| Details  | <div style="border: 1px dashed black; height: 80px; width: 100%;"></div>  |
| 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  |
| <b><i>If 'Has the participant been reviewed by the PI or other delegated doctor?' is equal to 'Yes' answer this question:</i></b><br>Date of review  | <input type="text"/> <input type="text"/> <input type="text"/> <span style="float: right;">(dd-mm-yyyy)</span>  |



## 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 |
| <b><i>If 'Has the participant experienced any symptoms of Exacerbation since last visit?' is equal to 'Yes' answer this question:</i></b><br>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 |
| <b><i>If 'Have NHS blood samples been obtained?' is equal to 'Yes' answer this question:</i></b> |  |
| 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 |