

## **Working Practice Guideline for Questionnaires**

### **Questionnaires**



#### **General Guidance**

- The latest approved version of the questionnaires/diaries should be used at all times. These can be found in the Documents - Generic Study folder on the VitalBE website ([www.vitalbe.org.uk](http://www.vitalbe.org.uk)).
- Ensure the participant identification number, the correct visit number and date of visit are entered on each page.
- The questionnaires are intended for self-completion.
- If the respondent is unable to complete the questionnaire by themselves, it may help for the researcher to read aloud the questionnaire. It is acceptable for a third party to record the respondent's replies but care should be taken to avoid prompting.
- If the respondent finds statements too limiting - the researcher should repeat the questionnaire instruction 'to indicate which statements best describe your own health state today' and that there are no right or wrong answers. NB it is the respondent's own evaluation that is required and no prompts should be given.
- If a participant has completed the questionnaire themselves or with the help of a relative/friend the researcher should check the questionnaire for completeness and go through any missing questions or ambiguous answers with the participant.
- If a respondent has ticked 2 statements on a dimension, unless it is possible to clarify, these answers should be treated as missing data.
- The completed questionnaire entered into Castor and the paper copy filled in the participants medical notes.



## Quality of Life Questionnaire – bronchiectasis (QoL-B)

### Equipment

QoL-B Questionnaire

### Procedure

- We want the QoL-B to be completed every month after the participant has had either 28 days of trial medication or 28 days with no trial medication. We will then compare quality of life when the participant has been taking trial medication and when they haven't been.
- The QoL-B should be completed every 4 weeks on the last day of each treatment on/off cycle. i.e. ask the participant to complete the QoL-B at visit 2 then every 4 weeks: on the last day they take their trial medication and then the day before they start their next 28 days of trial medication.
- The participant should complete the questionnaire at visit 2
- Provide the participants with copies of the QoL-B to be completed in between trial visits. (i.e at randomisation provide copies to be completed at week 8, 16, and 20 and at visit 5 provide copies of QoL-B to be completed at week 28, 32, 36, 40 and 44.) Participants should bring the completed questionnaires with them to the next visit.
- Ensure the questionnaire has the correct participant number, add a post-it note to tell the participant which day to complete the questionnaire. The participant should add the actual date they complete the questionnaire to the front page.
- Phone the participant a day or 2 before they are due to complete the questionnaire to remind them. Take this opportunity to remind them to start their medication when appropriate.
- When returned ensure the participant number and date completed has been recorded
- The QoL-B will be entered into a central database by trial staff at Tayside Clinical Trials Unit (TCTU).
- Store the QoL-B securely until transferred to TCTU.
- **Ensure any participant identifiable information added to the questionnaire by the participant has been redacted prior to transfer to TCTU.**

## Bronchiectasis Health Questionnaire (BHQ)

### Equipment

BHQ questionnaire.

### Procedure:

- The BHQ should be completed on the day of the visit.
- When the questionnaire has been returned please check for completeness and if any questions are missed or answered incorrectly e.g. 2 answers ticked instead of one, go through the questionnaire with the participant.
- Transcribe questionnaire to Castor



## St Georges Respiratory Questionnaire (SGRQ)

### Equipment

SGRQ Questionnaire

### Procedure:

- The SGRQ should be completed on the day of the visit.
- When the questionnaire has been returned please check for completeness and if any questions are missed or answered incorrectly e.g. 2 answers ticked instead of one, go through the questionnaire with the participant.
- Enter questionnaire data to Castor DMS

## VISITS 3 & 4 TELEPHONE VISITS

### Equipment

BHQ questionnaire

SGRQ questionnaire

QoL-B questionnaire

### Procedure:

- Complete visit questions before questionnaires (any AEs, con med changes and so on)
- Questionnaires should be completed over the telephone.
- Some sections of the questionnaires require set responses (e.g. all of the time, most of the time, a good bit of the time and so on) It may be helpful to ask the participant to make a note of the possible responses before asking the relevant questions.
- RN to complete participant responses on the appropriate questionnaire
- Enter questionnaire data for BHQ and SGRQ to Castor DMS
- QoL-B questionnaire to be filed with participant notes until transfer to TCTU.