CRF Completion Guidelines

Trial Title: PRedicting Outcomes For Crohn’s disease using a moLecular biomarkEr (PROFILE) trial

IRAS ID: 220851

Chief Investigator: Dr Miles Parkes

Trial Sponsor: Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

Email all completed CRFs to the Data Manager at the following:

Karlena Champion – Data Manager
Cambridge Clinical Trials Unit
Email: add-tr.profile@nhs.net

Weeks 4, 16, 32 & 48 CRF pages should be sent within five weeks of the end of a trial visit.

Screening, Baseline & SAE forms have more urgent timelines, detailed in Section 4.8.

Remember to retain a copy of each completed CRF for your site records.

Remember that CRFs (and any other study-related documentation) sent to the trial coordinator MUST NOT contain patient-identifiable data.
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<tbody>
<tr>
<td>Adalimumab Administration</td>
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<tr>
<td>Adverse Event Log</td>
</tr>
<tr>
<td>Adverse Event and Concomitant Medications Review</td>
</tr>
<tr>
<td>Azathioprine, Mercaptopurine and Methotrexate Administration</td>
</tr>
<tr>
<td>Blood Results</td>
</tr>
<tr>
<td>Blood Results Review</td>
</tr>
<tr>
<td>Colonoscopy</td>
</tr>
<tr>
<td>Concomitant Medications Log</td>
</tr>
<tr>
<td>Exclusion Criteria and Eligibility</td>
</tr>
<tr>
<td>Harvey Bradshaw Index (HBI) &amp; Perianal Disease</td>
</tr>
<tr>
<td>Height</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
</tr>
<tr>
<td>Infliximab Administration</td>
</tr>
<tr>
<td>Medical History - Baseline</td>
</tr>
<tr>
<td>Medical History - Screening</td>
</tr>
<tr>
<td>MRE</td>
</tr>
<tr>
<td>Pregnancy</td>
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<tr>
<td>Primary Outcome Week 4</td>
</tr>
<tr>
<td>Primary Outcome Weeks 16/32/48</td>
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<tr>
<td>Randomisation</td>
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<tr>
<td>Research bloods - Weeks 16/32/48</td>
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<tr>
<td>Serious Adverse Event</td>
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<tr>
<td>Screening Blood Results</td>
</tr>
<tr>
<td>Screening – Demographics</td>
</tr>
<tr>
<td>Screening Research Bloods</td>
</tr>
<tr>
<td>Stool Sample</td>
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<tr>
<td>Screening Visit – Sign Off</td>
</tr>
<tr>
<td>Thiopurine Monitoring</td>
</tr>
<tr>
<td>TPMT</td>
</tr>
<tr>
<td>Visit Confirmation</td>
</tr>
<tr>
<td>Visit</td>
</tr>
<tr>
<td>Weight &amp; Physical Exam</td>
</tr>
<tr>
<td>Week 16 Stool Sample</td>
</tr>
<tr>
<td>Week 32 Stool Sample</td>
</tr>
<tr>
<td>Week 48 Stool Sample</td>
</tr>
<tr>
<td>Withdrawal</td>
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### 2. List of PROFILE Participant Questionnaires

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>EQ-5D-5L</td>
</tr>
<tr>
<td>IDBQ</td>
</tr>
<tr>
<td>Resource Usage – Baseline</td>
</tr>
<tr>
<td>Resource Usage – Week 16, 32 &amp; 48</td>
</tr>
</tbody>
</table>
### 3. Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Term</th>
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<tbody>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>CCTU</td>
<td>Cambridge Clinical Trials Unit</td>
</tr>
<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>MedDRA</td>
<td>Medical Dictionary for Regulatory Activities</td>
</tr>
<tr>
<td>MRE</td>
<td>Magnetic Resonance Enterography</td>
</tr>
<tr>
<td>NA</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>ND</td>
<td>Not Done</td>
</tr>
<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
</tr>
<tr>
<td>NK</td>
<td>Not Known</td>
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### 4. Visit Schedule Overview

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Screening Wk -2</th>
<th>Baseline Wk 0</th>
<th>Wk 4</th>
<th>Wk 16</th>
<th>Wk 32</th>
<th>Wk 48</th>
<th>Ad-hoc Visit</th>
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</thead>
<tbody>
<tr>
<td>Consent</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Disease assessment - Harvey Bradshaw Index (HBI)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Concomitant medication</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td></td>
</tr>
<tr>
<td>Weight in Kg</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Physical examination</td>
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<td>✓</td>
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<td>✓</td>
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<td>Eligibility confirmed</td>
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<td>Randomisation</td>
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<tr>
<td>PAXgene RNA tube for biomarker assessment</td>
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<tr>
<td>PAXgene RNA tube for research sample</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Serum tube</td>
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<tr>
<td>EDTA tube</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloods (FBC, CRP, U&amp;E, Creatinine, LFT)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Bloods (Hepatitis B &amp; C, VZV, TPMT and Tuberculosis testing)</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloods (6-TGN and 6-MMP = thiopurine metabolites)</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>Stool sample for faecal Calprotectin</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>Buffered stool sample</td>
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<td>Patient rated Questionnaires</td>
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<td>Colonoscopy</td>
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</tr>
<tr>
<td>Adverse event reporting</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

α 6-TGN and 6-MMP Thiopurine metabolites only to be measured if participants are taking either Azathioprine or 6-Mercaptopurine.

† Results of blood tests and faecal Calprotectin performed as part of standard care can be used for eligibility provided performed within 4 weeks of screening visit – however a repeat stool sample should still be sent for central processing (as Central lab results will be used in subsequent analyses). Sample pot for faecal Calprotectin will be provided at screening visit and patients advised to provide sample promptly so that central Calprotectin result is available at the baseline visit.

* Screening colonoscopy results can be taken from the participants index colonoscopy performed as part of their standard care within 3 months of the screening visit. Ideally a video of the colonoscopy should be recorded for central reading to allow comparison with the colonoscopy at week 48.

¥ It is anticipated that all patients newly diagnosed with Crohn’s disease will undergo MRE. An MRE performed as part of standard of care can be used; and if not already performed should be undertaken within 3 months of the screening visit. The results of this index MRE will be collected at the week 16 visit. It will be used for central reading and allow comparison with MRE at week 48.
5. General Completion Guidelines

4.1 General Principles for CRF Completion

- All CRF pages must be clear and legible
  - Important as 1 and 7 can be misrepresented if the writing is not clear
    - 1 or I and 7 or Z
- The correct version of the CRF form must be completed.
- Once a patient is randomised, please label a CRF pack with the subject ID number
- Data reported on the CRF must be extracted from, and be consistent with, documented source data
- Where selection boxes indicate a selection of Y or N or numerical options (i.e. 1, 2, 3), only ONE entry should be recorded per box
- The CRFs must be completed, dated and initialled/signed by an Investigator or designee as appropriate
- COPIES of CRF pages should be returned or emailed promptly to the Data Manager at add- tr.PROFILE@nhs.net
- The investigator site should always retain a copy of each completed form
- Source data should always remain at the participating site
- Any changes made to the CRF pages once the copy has been returned to the Trial Coordinating centre must be sent to the Data Manager within one month - see section 4.9 Correcting Errors
- CRFs must only be completed by authorised personnel. They should have completed and signed the site’s trial Delegation Log
- The timely completion, legibility and accuracy of the CRFs remain the responsibility of the Principal Investigator
- The PI should retain regular oversight and timely sign off of the CRFs, particularly those relating to a patient’s eligibility
- An INVESTIGATOR is any person that has been delegated an activity.

4.2 Header Boxes

- The following data must be completed in the header of every completed CRF:
  - Patient Initials: First and last initials only
  - Patient Date of Birth: Enter using the DD/MMM/YYYY format (e.g. 13 AUG 2013)
  - Site Code: The four-digit site number allocated at site initiation (e.g. N001)
  - Subject ID number: Each subject will receive a unique 3-digit trial number upon randomisation (e.g. 001) – hence their trial number will be a 7 digit composite of Site Code and Subject ID number N001_001

4.3 Participant Data

- CRFs (and any other study-related documentation) sent to the Trial Coordinator MUST NOT contain any patient-identifiable information e.g. names, hospital number, NHS Number
- Please use partial identifiers ONLY e.g. the patient’s initials, date of birth and subject ID number when communicating with the coordination team

4.4 Completion of Dates

- All dates are to be completed in the sequence day/month/year (DD/MMM/YYYY) with the month written using LETTERS not numbers
- If the day or month is unknown/not known complete the boxes with NK
4.5 Entering numbers
- Enter a digit in each box provided, if three boxes are provided but only two are required please enter a preceding 0

  E.g. 0 2 3

4.6 Unavailable Data
- All applicable questions must be answered
- Where data are not available please do not leave the answer blank as this will create unnecessary data queries
- Please include one of the following abbreviations instead:
  - NK = Not known
  - NA = Not applicable
  - ND = Not done

4.7 Correcting Errors
- Errors should be crossed out with a single line (i.e. mistake), the correction inserted and the change initialled and dated by the investigator or designee
- Typing correction fluid should NOT be used
- If it is not clear why a change has been made, an explanation should be written next to the change

4.8 Sending CRFs to the Trial Coordinating site
- Please email COPIES of CRF forms to:
  - Karlena Champion
  - Email: add-tr.profile@nhs.net
- Ensure that the form is scanned, with the copy sent to the Data Manager and the original kept at your site.
- Please send the Screening visit CRF’s no later than two weeks after the visit date.
- Please send the Baseline visit CRF’s no later than four weeks after the visit date.
- Other CRF pages should be sent in a timely manner, ideally within five weeks after the end of a visit.
- Completed SAE forms should be sent to the trial coordinator by email (add-tr.profile@nhs.net) within 24 hours of becoming aware of the event.
6. CRF Completion Guidelines

Note: Not all questions on the CRFs are covered by these guidelines. Please contact the Trial Coordinator if you require clarification on any questions. All CRFs to follow in alphabetical order:

ADALIMUMAB ADMINISTRATION
Complete this form at the following point in the trial:
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

ADVERSE EVENT LOG
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- At each visit time point following consent adverse events should be reported.
- A copy of the adverse event log should be provided with the CRFs to the central coordinating site after each visit.
- One continuous log should be maintained for the duration of the participant’s enrolment in the trial.
- Resolution should remain blank until an end date has been entered. An event should only be completed as on-going at the end of the trial visit at Week 48.

ADVERSE EVENT AND CONCOMITANT MEDICATIONS REVIEW
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

AZATHIOPRINE, MERCAPTOPURINE AND METHOTREXATE ADMINISTRATION
Complete this form at the following point in the trial:
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

**BLOOD RESULTS**
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.
- Check units of values entered to ensure these match the units listed on the form. Enter ‘ND’ for those tests that were not done.

**BLOOD RESULTS REVIEW**
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

**COLONOSCOPY**
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.
- The time displayed on the endoscope output should be noted at the start of the recording and at each point that the endoscope transfers from one section of the bowel to the next i.e. when moving from the ileum to the caecum.

**CONCOMITANT MEDICATIONS LOG**
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.
- Enter only ONE value per field (e.g. do not enter a range such as ‘100-200’ for Dose).
- If the medication is on-going, leave blank until week 48.
- If the medication is NOT on-going, enter ‘0’ in the ‘On-going’ field AND PROVIDE THE STOP DATE.
- At Week 48 ensure medication on-going field is completed.

EXCLUSION CRITERIA AND ELIGIBILITY
Complete this form at the following point in the trial:
✓ Visit 1 - Baseline

- Tick the box confirming that the patient meets all exclusion criteria
- Please ensure this form is signed and dated by the principal investigator or an appropriately delegated member of staff prior to sending to the central coordinating site.

HARVEY BRADSHAW INDEX (HBI) & PERIANAL DISEASE
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

HEIGHT
Complete this form at the following point in the trial:
✓ Screening Visit

- Height is only mandatory at screening visit
- Ensure all relevant questions are completed.

INCLUSION CRITERIA
Complete this form at the following point in the trial:
✓ Visit 1 - Baseline

- Tick the boxes confirming that the patient meets all inclusion criteria

INFLIXIMAB ADMINISTRATION
Complete this form at the following point in the trial:
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

• Ensure all relevant questions are completed.

MEDICAL HISTORY - BASELINE
Complete this form at the following point in the trial:
✓ Visit 1 - Baseline

• Ensure all questions are completed.
• Measurements are **MANDATORY**. If any information is not known, please mark as NK, clearly stating the reason on the CRF.

MEDICAL HISTORY - SCREENING
Complete this form at the following point in the trial:
✓ Screening Visit

• Ensure all questions are completed.
• Measurements are **MANDATORY**. If any information is not known, please mark as NK, clearly stating the reason on the CRF.

MRE
Complete this form at the following point in the trial:
✓ Visit 3 - Week 16
✓ Visit 5 - Week 48

• Ensure all relevant questions are completed

PREGNANCY
Complete this form at the following point in the trial:
✓ Screening Visit

• Ensure all relevant questions are completed.

PRIMARY OUTCOMES – WEEK 4
Complete this form at the following point in the trial:
✓ Visit 2 – Week 4

• Ensure all relevant questions are completed.

PRIMARY OUTCOMES – Week 16/32/48
Complete this form at the following points in the trial:
✓ Visit 3 – Week 16
✓ Visit 4 – Week 32
✓ Visit 5 – Week 48
✓ Ad-hoc Visit

  • Ensure all relevant questions are completed.

RANDOMISATION
Complete this form at the following point in the trial:
✓ Visit 1 - Baseline

  • Ensure all questions are completed.

RESEARCH BLOODS - WEEKS 16/32/48
Complete this form at the following point in the trial:
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48

  • Ensure all relevant questions are completed.

SERIOUS ADVERSE EVENTS
Complete this form as appropriate during the trial:
  • Complete all sections of the form.
  • Deaths should be reported using the SAE form.
  • Report the SAE to the Trial Coordinating site as defined in the protocol.

The form should be sent to the trial coordinating site within 24 hours of becoming aware of the event. Provide a clear, chronological, clinical course of events from presentation to current time—including symptoms and signs at presentation/vital signs/examination findings. Please specify the severity or grade for all related symptoms (mild, moderate or severe).

Reporting Requirements:
For all initial reporting of any SAEs this form must be completed fully or with as much information as possible.

New SAE information after an initial submission should be indicated on an SAE follow up report and forwarded to the PROFILE Trial Coordinating Site as soon as possible. All SAEs must be followed up until resolution. There are two options for subsequent follow-up reporting of an SAE:

1. If only minimal follow-up data is being submitted (e.g. 2 or 3 fields): The site may submit the initial SAE form updated as a follow-up. In this case a reporter should add all new or missing information to the initial SAE form.

2. If significant or many changes are being submitted: A new SAE Reporting form should be completed with the following information provided as a minimum: trial and participant details (SAE form header), SAE term, SAE onset date and all new or missing information.

MedDRA coding will be assigned by the Cambridge Clinical Trials Unit.

SCREENING BLOOD RESULTS
Complete this form at the following point in the trial:
✓ Screening Visit

- Ensure all questions are completed.

**SCREENING – DEMOGRAPHICS**
Complete this form at the following point in the trial:
✓ Screening Visit

- Ensure all questions are completed.

**SCREENING RESEARCH BLOODS**
Complete this form at the following point in the trial:
✓ Screening Visit

- Ensure all questions are completed.

**STOOL SAMPLE**
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline Visit
✓ Visit 2 - Week 4 Visit
✓ Visit 3 - Week 16 Visit
✓ Visit 4 - Week 32 Visit
✓ Visit 5 - Week 48 Visit

- Ensure all questions are completed.

**SCREENING VISIT – SIGN OFF**
Complete this form at the following point in the trial:
✓ Screening Visit

- Ensure all questions are completed.

**THIOPURINE MONITORING**
Complete this form at the following point in the trial:
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

- Ensure all relevant questions are completed.

**TPMT**
Complete this form at the following point in the trial:
✓ Screening Visit
• Ensure all relevant questions are completed.

VISIT CONFIRMATION
Complete this form at the following point in the trial:
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

• Ensure all questions are completed.

WEIGHT & PHYSICAL EXAM
Complete this form at the following point in the trial:
✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 2 - Week 4
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48
✓ Ad-hoc Visit

• Ensure all relevant questions are completed.

WITHDRAWAL
Complete this form as appropriate during the trial if:
✓ The participant withdraws consent for any reason

• Participants may withdraw from either treatment, or follow up or both.
• Multiple forms can be used for a participant withdrawing consent for differing activities over time.
• Return this form to the Trial Coordinating site as soon as possible after the patient has withdrawn consent from an activity.
7. Participant Questionnaires Completion Guidelines

Complete the questionnaires cover before releasing the documents to the participant.

**QUESTIONNAIRE: EQ-SD-5L**

Ensure these forms are completed by the patient at the following points in the trial:

✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48

- Complete the headers of the questionnaires before releasing the documents to the patient.
- Only use first and last initials in header and cover.
- Review the completed form to ensure all questions have been answered

**QUESTIONNAIRE: IBDQ**

Ensure these forms are completed by the patient at the following points in the trial:

✓ Screening Visit
✓ Visit 1 - Baseline
✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48

- Complete the headers of the questionnaires before releasing the documents to the patient.
- Only use first and last initials in header and cover.
- Review the completed form to ensure all questions have been answered

**QUESTIONNAIRE: RESOURCE USAGE – BASELINE**

Ensure these forms are completed by the patient at the following points in the trial:

✓ Visit 1 - Baseline

- Complete the headers of the questionnaires before releasing the documents to the patient.
- Only use first and last initials in header and cover.
- Review the completed form to ensure all questions have been answered

**QUESTIONNAIRE: RESOURCE USAGE – WEEK 16, 32 & 48**

Ensure these forms are completed by the patient at the following points in the trial:

✓ Visit 3 - Week 16
✓ Visit 4 - Week 32
✓ Visit 5 - Week 48

- Complete the headers of the questionnaires before releasing the documents to the patient.
- Only use first and last initials in header and cover.
- Review the completed form to ensure all questions have been answered