**Objective:** Develop an instrument to explore the patient clinical trial experience that can be used to improve the clinical trial experience for future participants.

**Methods:**
- A draft questionnaire focusing on participant experience through various stages of the trial (pre-trial, during trial, and post-trial) was developed with input from patient advocates or from those who have provided support to trial participants.
- Additional concepts related to patient experience in clinical studies were identified from the literature.
- Qualitative research was performed using 33 interviewer-led focus groups of 93 attendees per group to confirm these concepts and identify further relevant concepts from the patient perspective.
- A focus group included patients with cancer, 1 group comprised participants in early stage research.
- Focus group members had participated in a clinical trial within the past 12 months prior to the focus group.
- The questionnaire was updated based on results from the concept elicitation process. This updated questionnaire went through cognitive debriefing with 12 participants.
- Participants in cognitive debriefing included 8 oncology patients and 4 participants in early phase research.
- The questionnaire was also reviewed by one patient advocate and two non-patient advocates who provided input on the content and wording of the questionnaire.
- Cognitive debriefing findings were used to improve the understandability and relevance of all items in the questionnaire, resulting in a final questionnaire draft.
- All participant interaction including the focus groups and cognitive debriefing were approved by the ethics committee (UK REC reference 14/LO/0767).

**Results:**
- A total of 35 concepts were identified including 13 pre-trial, 17 during trial, 5 post-trial concepts. Of these concepts, 28 were felt to have achieved saturation, defined as spontaneous mention in 2 out of 3 focus groups (Table 1).
- These identified concepts led to the development of a conceptual model for the clinical trial experience (Figure 1).

**Table 1. Concepts identified in focus groups by clinical trial participants**

<table>
<thead>
<tr>
<th>Concept</th>
<th>Pre-Trial</th>
<th>Saturated</th>
<th>Concept</th>
<th>Saturated</th>
<th>Concept</th>
<th>Saturated</th>
<th>Concept</th>
<th>Saturated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asking questions</td>
<td>✓ Financial support</td>
<td>✓ Staff behaviour/interruption</td>
<td>✓ Training to travel site</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-study considerations</td>
<td>Impact on family</td>
<td>Travel to trial site</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial-motivation</td>
<td>Impact on work</td>
<td>Facilities</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing about trial</td>
<td>Information/medical results</td>
<td>Interventions</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implications of decision to join trial/fat</td>
<td>Interaction with other participants</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informed consent process</td>
<td>Monitoring</td>
<td>Post-Trial</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motivation</td>
<td>Motivation to continue/premature termination</td>
<td>Cessation of treatment</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>Personal service</td>
<td>Loss of support/monitoring</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study information</td>
<td>Randomisation</td>
<td>Official debrief/results</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study staff communication</td>
<td>Scheduling of tests/treatment</td>
<td>Opportunity to join other trials</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timing</td>
<td>Side effects</td>
<td>Awareness of study end</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panel registration process</td>
<td>X</td>
<td>Study commitments/impact on life</td>
<td>✓</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial-rearrangement</td>
<td>Study organisation/management</td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Conceptual model based on concept elicitation**

**Figure 1.**

- Based on cognitive debriefing, the following changes were made to the questionnaire.
  - 5 items were recommended for deletion.
  - 5 items were recommended to be made optional.
- The final questionnaire consists of 24 core items with 5 additional optional items all of which are well understood and relevant to patients. Figure 2 presents the conceptual framework for the post-trial questionnaire to be taken forward for use in clinical trials.
- In the final questionnaire, the items that were considered most important by respondents were interactions with trial staff, convenience of trial visits and being informed that their involvement the trial was ending.

**End of trial experience**

- The results provide evidence to support the content validity of the end of trial questionnaire. Assessing the clinical trial experience from the patient perspective using a robust questionnaire may offer the potential to improve trial design, trial recruitment and patient retention in trials.

**Acknowledgements.** We would like to thank the participants who inputted into the development of this questionnaire and Sarah Walsh from GSK. EB, NB and AT are employees of Adelphi Values which received funding to perform this work. SK, OD, GT and SCM are GSK employees and hold stock in GSK.

**Conclusions:**
- Using a formal questionnaire to understand patient experience is an important step forward in systematically collecting data about patient participation in clinical studies.
- By quantitatively collecting data from patients about their trial experience, it is possible to measure the level of patient-centrivity of the trial conduct. It is also possible to compare the patient experience across trials with the intention of making improvements.
- Regardless of the type of research, the feedback from respondents indicates that the researchers need to pay attention to optimise the number of visits, and that the research site staff need to pay attention to the way they interact and communicate with the participants.
- In addition to obtaining data about study execution, a questionnaire administered at the end of the study brings finality to the study process. It also provides an important opportunity to thank participants for their contribution to research.

- This project was funded by GlaxoSmithKline (GSK).

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**Figure 2.** Post-clinical trial questionnaire conceptual framework

- Aspects of the draft questionnaire were reviewed by patients, trial staff and potential patient research leads.
- Focus groups were conducted to collect information on trial site facilities, staff interactions, sites, and trial arrangements.
- The results provided evidence to support the content validity of the end of trial questionnaire. Assessing the clinical trial experience from the patient perspective using a robust questionnaire may offer the potential to improve trial design, trial recruitment and patient retention in trials.

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**Figure 3.** Conceptual model of questionnaire development