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Scientific and operational guidelines for conduct of embedded interviews with participants in clinical trials

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Introduction

The United States' Food and Drug Administration's patient-focused drug development guidance series[1] shows an increase in attention paid to using qualitative methods to collect patient experience data. The value of integrating interviews in clinical trial was described in a recent literature review[2].

As more in-trial interviews are conducted and not yet common practice, harmonized guidelines for the healthcare industry are needed. With 10 years of experience managing such interviews, we propose here an overview of scientific and operational steps to consider when in-trial interviews are planned.

Key scientific considerations

Interview objectives

Depending on the interview objectives, different types of interviews can be conducted. **Table 1** provides an overview.

Table 1: Interview objectives and techniques

Objectives	Interview techniques
– Develop a questionnaire – Explore participation in the clinical trial – Explore the experience with treatment – Explore the impact of disease on health-related quality	– Methodology similar to concept elicitation/exploratory interviews can be used
– Assess the relevance of an already existing questionnaire	– Cognitive interviewing techniques, coupled with usability testing if a device is involved
– Explore concepts and test a questionnaire	– Hybrid concept elicitation and cognitive interviews
– Understand what constitutes a meaningful change in response to questionnaire items	– Methodology similar to concept elicitation can be used, along with some cognitive interview techniques

Population of interest and sampling

Depending on the interview objectives, interviews may be conducted with patients, and/or caregivers and/or healthcare professionals, such as the principal investigator or the site coordinator.

The question of which participants in the clinical trial will be invited to participate in the interviews is important to consider. All or a specific sub-group of participants in the clinical trial may be invited to participate depending on the objectives of the interviews. Regardless of the sampling strategy chosen, the rationale and the procedures must be explained in the protocol.

Other scientific considerations

- The timing of the conduct of interviews and the timing of the sharing of transcripts must respect trial integrity, notably in the context of:
  - Double-blind placebo trials
  - Trials with multiple interview time points (e.g., longitudinal interviews)
  - Trials where clinical outcome assessments (COAs) are a primary or a secondary endpoint
- Training and monitoring of interview conduct
- Rigorous qualitative analysis and reporting processes

Key operational considerations

Preparatory steps: Conduct feasibility assessments with sites where interviews might be conducted and review legal/regulatory framework for each country/site where interviews may take place to determine timelines for ethics approval and other approvals (e.g., data privacy bodies).

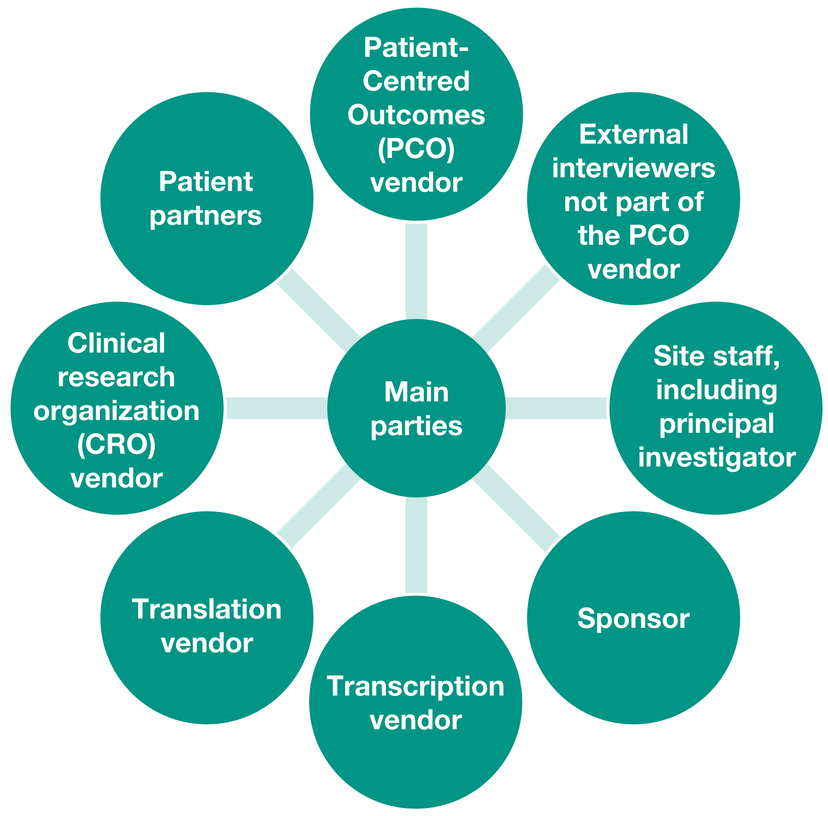
Key operational considerations *(cont.)*

Site study start-up: Study document translation, ethics submissions, investigator meetings and site initiation visits, establishment of procedures for safety reporting and establishment of procedures for data protection of audio recordings of interviews, transcription and translation.

Study and site monitoring: Participant consent at sites, interview conduct, safety reporting, transcription of interviews, translation, archiving/deletion of audio recordings and archiving of transcripts.

Communications and responsibilities: Development of a RACI (Responsible, Accountable, Consulted, Informed) matrix describing the roles of main parties in **Figure 1** below.

Figure 1: Main parties involved when conducting embedded interviews with clinical trial participants



Challenges and solutions

Every innovative method brings with it new challenges. **Table 2** presents frequently occurring issues and associated solutions.

Table 2: Possible challenges and solutions

Challenge	Potential solutions
Data privacy	– Collaborate with the information technology departments of parties in Figure 1 to address data privacy concerns in advance of questions. – Prepare a document with processes related to data protection/participant confidentiality that can be shared with ethics committees' and data privacy bodies.
Safety reporting	– Describe processes in the study protocol. – Provide training to interviewers and sites on safety reporting and document this training.
Sites following interview procedures	– Coordinate with CRO and sites in advance of trial execution to assess sites' needs and capacities. – Identify point person at sites and at CRO for questions and follow-up. – Provide sites with sufficient training and written documentation on site procedures. – Monitor sites on a regular basis and plan for contingencies in advance.

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References: 1. FDA. (2022) Patient-focused drug development: methods to identify what is important to patients. Maryland, US: Food and Drug Administration. **2.** Michel A-S, et al (2023) Integrating qualitative interviews in drug development and the use of qualitative evidence in product labelling and health technology assessments: a review. Front. Med. 10:1197529.

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