Approaches to Participant Sampling in In-Trial Interviews

PCR23

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Key messages

- This work documents the sampling approaches for in-trial interview studies described in the literature and offers a reflection on factors for researchers to consider when selecting a sampling approach
- This review of the available literature exposes gaps in how interview sampling within a clinical trial is reported and justified
- **Targeting all trial participants** for in-trial interviews ensures representativeness of the sample selected to address interview research objectives; however, this approach is not always logistically feasible nor scientifically necessary to achieve research objectives
- **A convenience sampling approach** to target a subset of trial participants for interviews across select clinical sites was common in the studies reviewed, and can be appropriate provided researchers thoughtfully and clearly justify sampling strategies to achieve interview objectives

Introduction

- Qualitative in-trial interviews, a valuable method of understanding patient perspectives within a clinical trial, explore important research questions including:[1,2]

- Patient's hopes and expectations for treatment
- Patient's experience with treatment during the clinical trial (tolerability, side effects, dosing regimen, clinical trial participation, etc.)
- Reported changes in symptoms or functioning experienced by patients throughout a trial (including the meaningfulness of such changes)
- Benefit/risk perspectives from the patient (and caregiver)

- Previous research has helped to shape best practices[2-4] for in-trial interviews, including operational considerations and sample sizes, but little guidance on sampling approaches exists
- The goal of this research is to explore and document approaches to participant sampling for in-trial interviews and to help define the factors that influence sampling approaches

Methods

- The methodology for the literature review and extraction of sampling-related data from in-trial interview studies is described below in **Figure 1**

Figure 1. Literature review methods

10 publications were identified from the reference list of a previous study

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Supplementary searches for additional, relevant publications were conducted in PsycINFO, MEDLINE, Embase, Google Scholar, and an internal database

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Abstracts were screened for relevancy based on pre-defined inclusion/exclusion criteria

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17 publications[5-21] describing 19 clinical trials were selected for full review and information on the studies' interview sampling strategy was extracted

Results

- Of the N=19 clinical trials, in-trial interviews were conducted in Phase 2 or Phase 3 (n=18) or longitudinal (n=1) trials across 11 therapeutic areas
- 15 studies (78.9%) used a convenience sampling strategy, in which a subset of clinical trial participants were recruited in select countries/sites **(Figure 2)**
- Sample size justifications provided by study authors were varied; many studies did not provide sample size justification (n=7) **(Figure 3)**

Figure 2. Reported sampling strategies

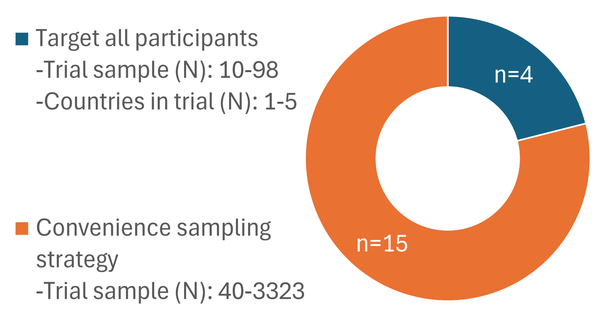
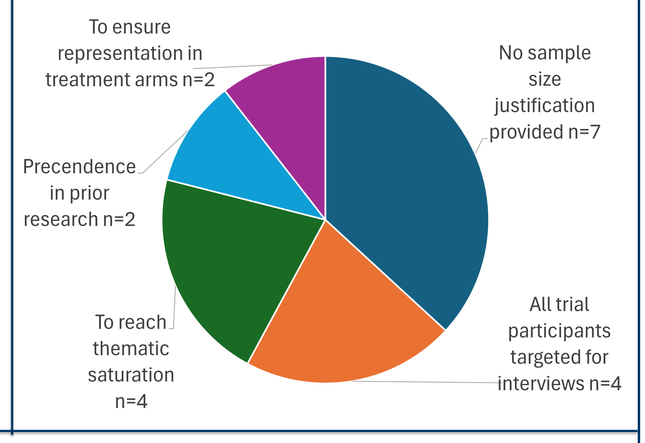


Figure 3. Sample size justifications



- On average, trials with sample sizes <50 (n=4) interviewed 74% of participants; trials between 50-100 (n=6) interviewed 41%; trials between 100-400 (n=5) interviewed 18%; and trials >400 (n=4) interviewed 2% **(Figure 4)**
- Trials that included >5 countries targeted a subset of countries for interviews. Of trials with multiple countries, the maximum number of countries where interviews were conducted was 7, and most commonly 3-4 **(Figure 5)**

Figure 4. Percentage of trial sample interviewed

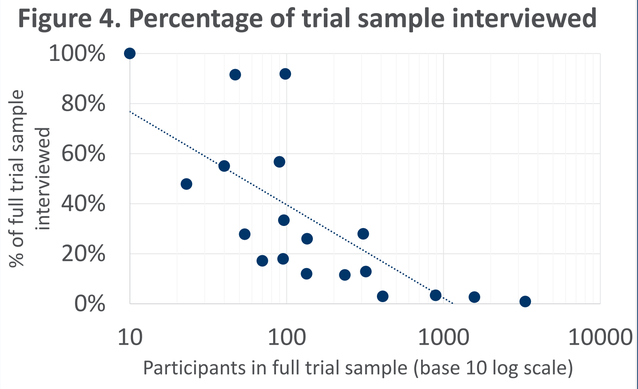
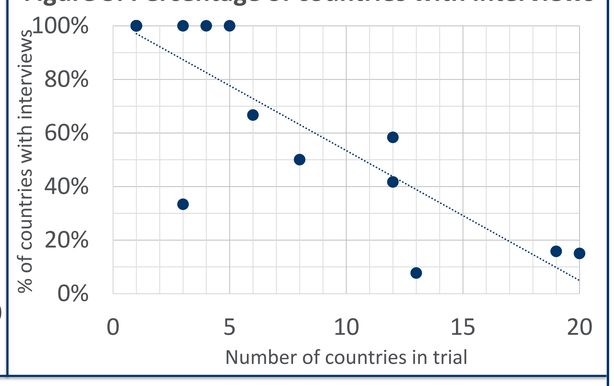


Figure 5. Percentage of countries with interviews



- Developed based on experience executing in-trial interview studies, **Table 1** describes sampling strategy considerations based on logistical factors such as study budget, timelines, ethics approvals, and data quality

Table 1. Logistical factors influencing sampling strategy

Factors	Sampling strategy considerations
Study budget	Costs for interview conduct will be higher with larger interview sample sizes and number of countries/languages involved. Interview costs include translation, interviewer training/conduct, and clinical site coordination.
Study timelines	It may not be feasible to interview all trial participants if the interviews were part of a protocol amendment after some patients have exited the trial and/or passed the interview timepoint. Additionally, depending on the rate of enrollment, timelines may be much longer for interviews being conducted with all trial participants versus on a first come first serve basis.
Ethics submissions & approval	Ethics approvals will be required in all clinical trial countries across all clinical trial sites recruiting patients. Targeting a single or select countries can reduce the burden of multiple ethics submissions for the interviews. However individual country requirements for ethics approval (e.g., sharing of personal data, compensation for interviews) will still need to be considered.
Quality and consistency of data	Conducting interviews across multiple countries/languages requires document translation and multiple interviewers. Comprehensive reviews of back translated documents are needed to ensure consistency across interview documentation. Interviewer training is required to ensure quality and consistency of interview data.

Conclusions

- The most frequently identified sampling strategy for in-trial interviews in the literature was a convenience strategy; some studies targeted all trial participants for interviews
- Factors that inform sampling approach include trial sample size, number of trial countries, and sample size justifications (developed in consideration of interview objectives)
- As trials increase in sample size/number of countries, logistical factors inform decision-making and convenience sampling is common
- When determining a sampling approach for in-trial interviews, researchers should establish and justify recruitment targets while considering interview study objectives, representation of the trial population, and logistical/operational considerations

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