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Maximizing the Impact of In-Trial Interviews Through AI-Assisted Analysis

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INTRODUCTION

- In-trial interviews are increasingly being used to explore various aspects of the disease and treatment experience, including treatment benefit perspectives, which may not be fully captured with traditional clinical outcome assessments
- In-trial interviews can be conducted at various points during the trial (i.e. entry, interim, exit), and they can be embedded within the clinical trial protocol or conducted as an independent stand-alone study
- In-trial interviews may be used to explore various research objectives (**Figure 1**)
  - The United States Food and Drug Administration (FDA) has stated that in-trial interviews can be used for various purposes, including supporting responder thresholds, complementing the quantitative data used to define meaningful change scores, and informing endpoint selection for registration trials[1]
  - Health technology assessment (HTA) bodies have also utilized embedded in-trial interview data to support reimbursement decisions[2]
- The value of in-trial interviews for exploring clinically meaningful change and supporting overall drug approval has been documented in the literature.[3,4] In-trial interviews have been used to generate data to determine whether change in a primary endpoint was meaningful to patients, with the results ultimately being included in a summary review for FDA approval[5]
- With the increased utilization of in-trial interviews, there is a need for innovative solutions to efficiently analyze data to support multiple key objectives and patient-centered outcomes

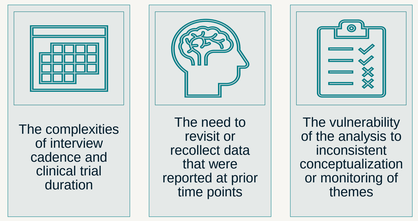
OBJECTIVE

This conceptual work explores best practices and approaches for using AI-assisted qualitative analysis to support the conduct and analysis of in-trial interviews.

CHALLENGE AND OPPORTUNITY

- In-trial interviews offer unique challenges to data collection and analysis (**Figure 2**)

Figure 2. Unique aspects of in-trial interview data collection and analysis

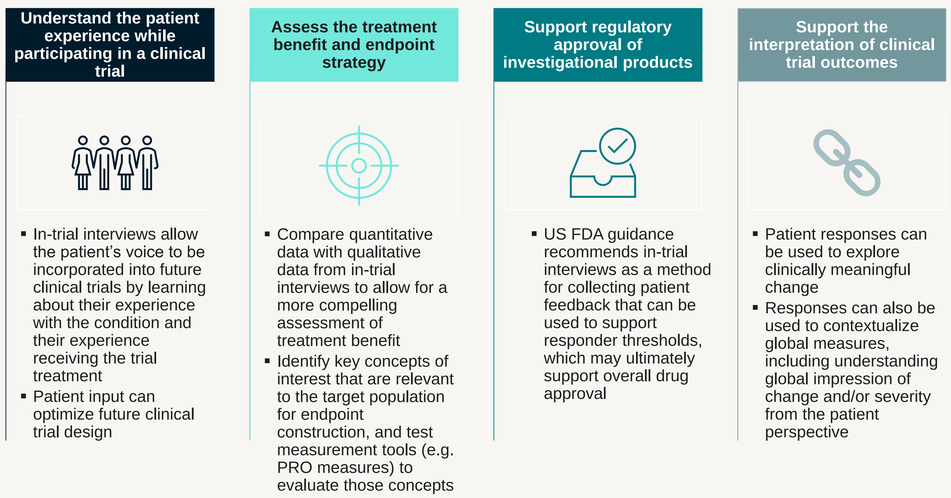


- Some in-trial interviews reference previously collected data (e.g. concepts reported at entry), which requires "re-grounding" the interviewer to the data before conducting the interview and may cause analysis challenges
- As interview cadence is contingent upon the clinical trial enrollment and trial schedule, interviews are often conducted over a long duration of time and at infrequent intervals
  - This is especially the case with oncology clinical trials, where interviews may be conducted months or years apart
    - Patients in these clinical trials also frequently experience cognition issues that may impair their ability to recall specific symptoms or impacts
  - Interview cadence is further complicated by extended clinical trial enrollment periods, which may result in overlapping interviews across time points (e.g. some baseline interviews may take place simultaneously with other participants' interim or exit interviews)
- The themes that emerge within in-trial interview data may be less apparent than in "traditional" qualitative interview studies, where interviews and analyses generally occur within a confined timeframe
- Relying on anecdotal interviewer feedback to identify themes within the data is challenging when interviews occur in isolation
- For globally conducted clinical trials, there may be a lack of real-time coordination between interviewers in different countries, leading to less feedback shared
- Temporal lags in coding may result in inconsistent coding concepts or themes within and across coders
- Use of artificial intelligence (AI)-assisted qualitative analysis may mitigate some of these challenges unique to in-trial interviews

IMPLICATIONS AND AI USE CASES

- AI-assisted qualitative analysis can be used to support the conduct and analysis of in-trial interviews across several areas (**Figure 3**)

Figure 1. Possible research objectives for in-trial interviews



Key: FDA, Food and Drug Administration; PRO, patient-reported outcome; US, United States

Figure 3. Areas of research that may be supported by AI-assisted qualitative analysis

KEY TAKEAWAYS

- AI-assisted qualitative analysis tools have the potential to improve the quality of analysis procedures by making "real-time" analysis more accessible and potentially reducing bias in the interpretation of data before the full analysis
- The preliminary reporting of clinical trial results using AI-assisted tools may lead to more informed decision-making based on preliminary data
- The patient in-trial interview experience can be improved through interviewer preparedness and the possibility of including key themes ahead of the interviews

CONCLUSIONS

- AI-assisted qualitative analysis tools have the potential to improve the efficiency and quality of data analyses, uncover new themes in data, and improve the patient in-trial interview experience
- Researchers are encouraged to apply and refine these strategies to maximize their impact and to fully realize the benefits of these approaches with respect to efficiency and quality
- While AI offers many benefits, human involvement is still needed to ensure that the priming and prompting of the data are appropriate and that AI-generated outputs are accurate
- Due to the sensitivity of the information discussed during in-trial interviews, it is critical to ensure that AI-assisted qualitative analysis tools meet compliance requirements before use

An electronic version of the poster can be viewed by scanning the QR code.

REFERENCES

1. US Food and Drug Administration. 2022. https://www.fda.gov/media/131230/download. Accessed: March 25, 2025. **2.** Michel et al. *Front Med*. 2023; 10:1197529. **3.** Gelhorn et al. *Clin Ther*. 2016; 38:759-768. **4.** Ervin et al. *Adv Ther*. 2017; 34:2680-2692. **5.** US Food and Drug Administration. 2016. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208794Orig1s000OtherR.pdf. Accessed: March 25, 2025.

Poster presented at ISPOR US 2025; May 13-16, 2025; Montreal, QC, Canada