Insight Brief

From First Impressions to Final Reflections: Maximizing Value and Insights from Longitudinal In-Trial Interview Studies

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Table of contents

Brief summary

Longitudinal in-trial interviews offer a powerful lens into the evolving experiences of clinical trial participants, capturing nuanced insights that static, one-time qualitative assessments and even longitudinal quantitative assessments may lack. This insights guide explores innovative and practical applications of longitudinal qualitative research within clinical trials, focusing on interviews conducted at multiple timepoints — typically at the beginning, midpoint, and end of the trial.

Participant interviews illuminate the evolution and interplay between lived experiences of the individual, trial processes, and intervention effects. By capturing changes in perception, motivation, and experience, they provide critical reflections that enrich the evidence base, support patient-centered research, and amplify the patient voice.[1,2]

Importance of qualitative insights in clinical trials

In-trial qualitative interviews offer a valuable perspective on patients' experiences with their illness, their journey through the clinical trial, and the effects of both on their health-related quality of life. These accounts offer unique opportunities to hear from patients about their experiences with a drug experiences with a drug within a trial before it becomes available on the market for use in real-world practice. They also provide an in-depth, contextualized understanding of how patients view symptom burdens, treatment effects, and support for validating and understanding Clinical Outcomes Assessments (COAs) within specific patient populations.[1]

They also reveal factors influencing adherence, engagement, and retention, such as trust in the research team, clarity of communication, and perceived relevance of the intervention. By identifying these elements in real time, sponsors and investigators can modify protocols to better meet patient needs. Furthermore, qualitative data can clarify the reasons behind quantitative results in clinical trials, such as unexpected trends in Patient-Reported Outcomes (PROs) or dropout patterns.[1,3]

The value of longitudinal in-trial interviews

Longitudinal interviews — conducted at baseline, midpoint, and exit — offer a dynamic view of treatment impact and disease progression. They facilitate ongoing dialogue with participants, enabling researchers to understand how treatment effects and patient perceptions evolve over time.[2,4]

Specific value points include:

- **Mapping disease trajectory, treatment journey, and changes over time:** Multi-timepoint interviews can be used to create detailed maps of symptom evolution, expectations, and coping strategies offering detailed insights into how symptoms evolve, how patients adapt and cope over time, and how their expectations shift — information that can enrich insights into early indicators of treatment response or disease progression, experiences with side effects, impacts on quality of life, and/or can enhance benefit-risk assessments by contextualizing clinical outcomes with lived patient experiences.[1,2,4]
- **Enhancing endpoint interpretation:** Patient narratives support interpretation of Clinical Outcome Assessments (COAs), aiding in defining meaningful change thresholds per FDA guidance,[5] as well as a more holistic view of treatment efficacy
- **Supporting regulatory and HTA submissions:** Both FDA and EMA emphasize the importance of Patient Experience Data (PED), including in-trial interviews, in supporting regulatory decisions around label claims and marketing authorization.[5-8] Specifically, longitudinal in-trial interviews provide contextual insights into patient priorities, treatment expectations, and lived experiences that can inform benefit-risk assessments and can be especially supportive of regulatory decision-making when integrated early and systematically into trial design.[5,7,9] In Health Technology Assessments (HTAs), they provide rich contextual data on treatment impact over time, which can strengthen evidence packages for HTA by demonstrating meaningful change from the patient perspective[1,6]
- **Optimizing protocol changes:** Feedback at various stages identifies burdensome procedures or unclear instructions, allowing mid-trial adjustments to improve trial efficiencies and engagement such as identifying and mitigating logistical barriers that may lead to improving patient information to reduce participant confusion, adjusting training materials and site guidance to improved protocol adherence, or revising assessment schedules to reduce participant burden[1,3]
- **Providing insights for post-marketing and real-world use:** Insights derived from longitudinal in-trial interviews such as patient expectations and symptom evolution can inform strategy for real-world and lifecycle management such as real-world positioning, post-marketing communication, indication expansion, or supportive care planning[1,6]

When designing in-trial interview studies, remember that they require early coordination with protocol teams to align interview objectives, scheduling windows, and data collection procedures with trial milestones, minimizing disruption to clinical operations and ensuring regulatory compliance.[1] Longitudinal designs add complexity through repeated patient engagement, increased burden, and risks of attrition or response bias over time.[1,2]

Case example and lessons learned

The situation

A biopharmaceutical company running a Phase II trial for a promising therapy faced a familiar challenge: an intensive treatment schedule early on that could strain patients emotionally and logistically. Frequent clinic visits and lifestyle disruptions were expected, but the company remained optimistic about the maintenance phase, which promised sustained benefits with fewer side effects.

To better understand the patient journey, the team embedded longitudinal interviews at three key points — baseline, midpoint, and trial exit. These interviews explored evolving perceptions of treatment burden, expectations, and early signs of benefit, complementing the quantitative PRO data.

What was known?

There were some challenges that were known; these insights were derived from a mix of known challenges from the literature, anecdotal feedback, key opinion leaders, and other sources.

- **Logistical burdens**: Frequent clinic visits disrupt patients' lives, impacting work and family commitments, especially for those in rural areas. Transportation issues and scheduling conflicts can exacerbate health problems and create frustration
- **Emotional and psychological stress:** Patients encounter emotional challenges from treatment demands and side effect fears, leading to isolation and uncertainty about their health journey, which can hinder adherence to treatment plans
- **Lifestyle disruptions:** Treatment alters daily routines, affecting diet, exercise, and sleep. Fatigue and restrictions may limit social interactions and job performance, impacting mental health, and quality of life
- **Treatment perception and expectations:** Patients begin treatment with mixed feelings, which can evolve based on results and side effects. Discrepancies between patient desires for quick relief and providers' focus on long-term outcomes can strain relationships, emphasizing the need for clear communication

Why were longitudinal in-trial interviews conducted?

In order to contextualize and enhance their understanding of patient experiences and provide evidence to support their understanding in this population, a strategy that included interviews to be conducted at baseline, mid-trial, and at trial exit was discussed. There was a general understanding of what was hoped to be learned from each timepoint, but clearer guidance on what could be achieved with these interviews was desired. A comprehensive plan was provided which established the goals and expected outputs of the interviews at each timepoint. A brief overview of the plan is provided below.

Use of interviews at each timepoint

BASELINE INTERVIEWS[1,2]

- Establish a thorough pre-treatment benchmark that captures patient expectations, concerns, and lifestyle factors in detail. This initial evaluation is essential as it enables healthcare providers to comprehend the distinct situations of each patient, including their health history, daily habits, and specific anxieties regarding their treatment
- Assess comprehension of trial participation and identify informational gaps by exploring what patients understand about the study's purpose, procedures, and expectations. Baseline interviews can uncover misunderstandings or missing information, enabling sponsors to refine consent materials, improve site communication, and tailor educational resources to enhance informed engagement
- Identify expected barriers to adherence and engagement by examining potential challenges that patients anticipate encountering during their treatment journey. This may encompass logistical issues such as transportation problems or emotional obstacles like anxiety related to the treatment process
- Information for effectively tailoring support resources to address barriers, such as transportation assistance for those who might have difficulty attending appointments, and counseling services to address psychological or emotional needs. This approach ensures that patients receive the necessary support to improve their treatment experience

MID-POINT INTERVIEWS[1,3]

- Real-time experiences during the intensive phase of treatment gathers insights into how patients are responding to the intervention at this critical stage; this provides understanding into patient experiences during the trial with signs, symptoms, and impacts (including any changes they may experience). This approach also enables moderators to leverage data from the baseline interview to facilitate connections of the patient's story between timepoints and inform the discussion
- Capture of emerging difficulties and coping strategies by encouraging patients to share their experiences, facilitating a better understanding of how they are managing any challenges that arise. This information can be instrumental in developing additional support mechanisms
- Feedback to modify trial logistics based on patient input, which may involve suggestions for appointment flexibility to accommodate personal schedules or the introduction of remote monitoring solutions to enhance patient convenience and adherence
- Identify early indicators of therapeutic benefit or dissatisfaction by closely observing patient feedback, allowing healthcare teams to make timely adjustments to treatment plans if needed

EXIT INTERVIEWS[1,4]

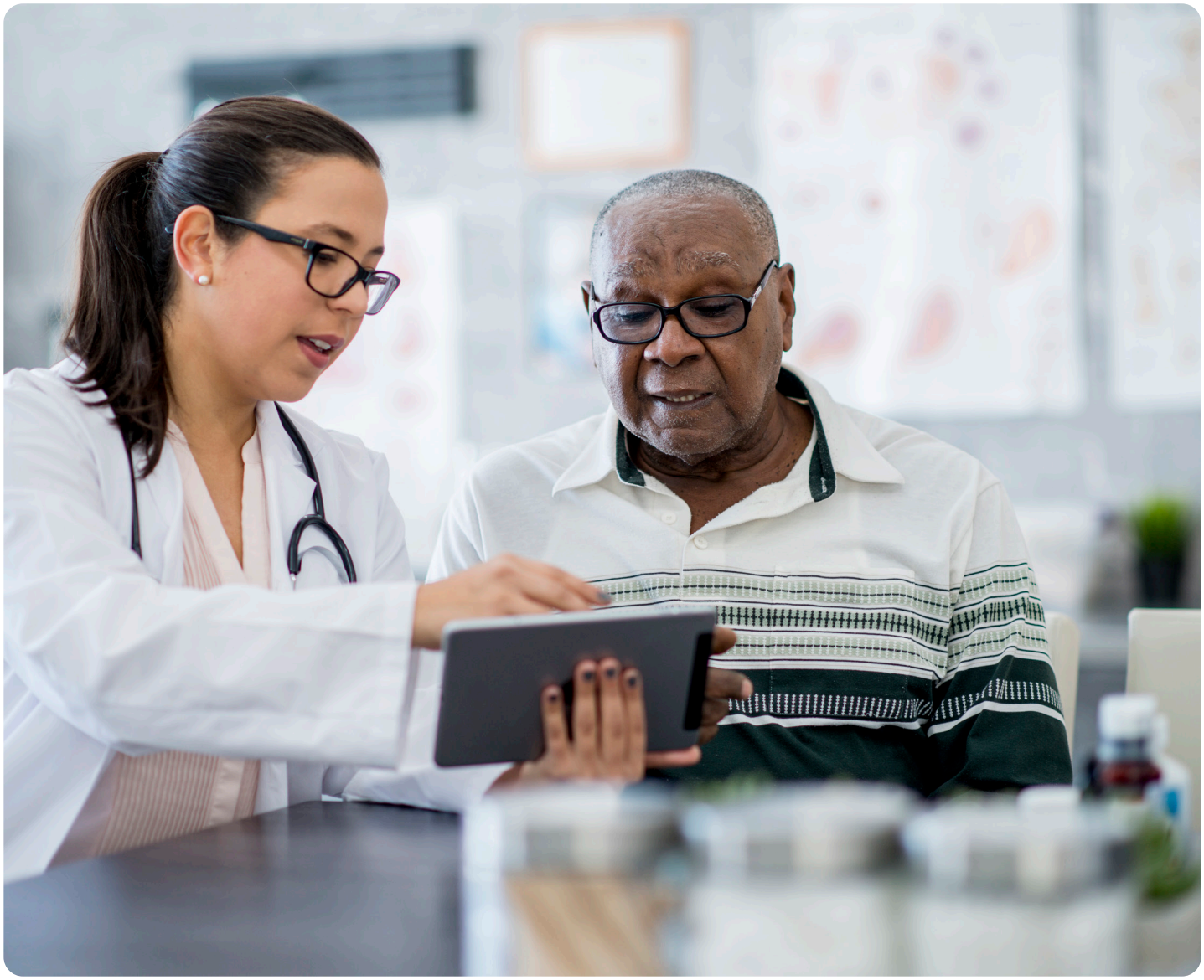
- Overall satisfaction with the treatment and the perceived value that patients assign to their experience; how the treatment met (or did not meet) their expectations and whether it affected their health and quality of life
- Long-term tolerability and the emotional effects of the treatment after its conclusion
- Factors affecting ongoing adherence and the willingness to recommend or continue therapy by examining the motivations and deterrents patients face as they consider their future treatment options
- Inform Phase III design by validating key themes that arise from the interviews, ensuring that the study is anchored in patient experiences. Additionally, refining interview focus areas based on this feedback will enhance relevance

Conclusion

Longitudinal in-trial interviews offer a robust, patient-centered approach to understanding treatment impact over time. They can be used to support endpoint validation, regulatory submissions, HTA evaluations, and more. As agencies increasingly prioritize patient experience data, longitudinal interviews will be central to future evidence generation.[5,6] Beyond their methodological rigor, these interviews bring the human narrative to the forefront — capturing the lived realities behind the data. In a landscape where patient voice is no longer optional, longitudinal interviews do not just inform — they transform.

Looking ahead

Stay tuned for a deep dive into the art and science of in-trial interviews — where credibility meets efficiency. We will start by exploring the nuances of the methodological rigor required in these studies to ensure scientific credibility, then spotlight the operational strategies to support efficiency and successful study execution.



References

1. Williamson N, Howse C, Hodson N, Stein J, Arbuckle R. Qualitative in-trial interviews: methods, challenges, and best practice. Patient. 2025;18(3):199–209

2. Neale B. What is Qualitative Longitudinal Research? London: Bloomsbury Academic; 2022

3. Devonald M, Jones N. Possibilities and pitfalls for dealing with large longitudinal qualitative datasets. Int J Qual Methods. 2023;22:1–13

4. Audulv Å, Hall EOC, Kneck Å, et al. Qualitative longitudinal research in health research: a method study. BMC Med Res Methodol. 2022;22:255

5. FDA. Patient-Focused Drug Development Guidance Series. [Internet]. Available from: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

6. Martin JD, Frear D, Roberts SA, Dohnal VA, Kieffer C, Morin SL, Lock I, Balogun A, Chhina N. Patient Experience Data (PED) in 2019–2023 US FDA NME Drug Approvals: Analysis and Recommendations. Therapeutic Innovation & Regulatory Science. 2025 May 9:1-2

7. Almeida D, Umuhire D, Gonzalez-Quevedo R, António A, Burgos JG, Verpillat P, Bere N, Sepodes B, Torre C. Leveraging patient experience data to guide medicines development, regulation, access decisions and clinical care in the EU. Frontiers in medicine. 2024 May 23;11:1408636

8. U.S. Food and Drug Administration; Eastern Research Group, Inc. Assessment of the use of patient experience data in regulatory decision-making. Silver Spring (MD): FDA; 2021. Available from: https://www.fda.gov/media/150405/download

9. EMA. European Medicines Agency. Reflection paper on patient experience data (draft for public consultation) [Internet]. London: EMA; 2025 Sep 29 [cited 2025 Nov 7]. Available from: https://www.ema.europa.eu/en/patient-experience-data-ped-reflection-paper

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