CASE STUDY

Embedded Qualitative Patient Interviews Support Regulatory Approval of Novel Oncology Treatment

Evidera's Patient-Centered Research team has industry-leading expertise in conducting exit and embedded interviews to illuminate the patient voice throughout drug development

10+

Years' experience in designing and implementing embedded patient interviews

20

Companies supported across 25 therapeutic areas in 35 different studies

Key Takeaways

Embedded qualitative interviews were conducted as part of Phase I and Phase II clinical trials to better understand the product safety profile using real-time information as the patient experience of treatment-related symptoms changed

Insights from these interviews helped lessen regulatory concerns about the ocular side effects as patients described their changes in severity and resolution as treatment ended, as well as their value for the efficacy of the treatment despite these side effects

Objective

There is a high unmet need for effective treatments in relapsing/refractory multiple myeloma (RRMM), and very few existing treatments show positive patient outcomes. A large biopharmaceutical client's novel therapeutic agent showed positive efficacy; however, many patients reported the expected significant side effect of impaired vision. More information on the patient experience with this new treatment in real time was needed to better understand the product safety profile.

Approach

Our patient-centered research experts helped to design the process and conduct the interviews that were embedded into Phase I and II clinical trials. Phase I patients participated in end-of-treatment interviews as well as six-month follow-up interviews. Phase II patients were interviewed at treatment Cycle 4 as well as end of treatment.

The semi-structured qualitative interviews focused on patient reports of their experiences in the study with treatment-related symptoms and impacts, and their overall satisfaction with their treatment experience. Questions were highly focused around ocular symptoms, fatigue, and pain, and how these factors changed as patients began, continued, and concluded their experimental treatment regimen.

Researchers used a mixed methods analytic approach to compare qualitative interview data, numeric rating scale (NRS) scores for severity and symptom bother, and select variables from the clinical trial datasets. The interview results provided a patient-centric picture of the occurrence of ocular symptoms, changes in their severity over time, and descriptions of their resolution once treatment was completed.

Results

Results from the patient interviews showed:

- Most patients experienced new ocular symptoms once their treatment began, including poor vision, sensitivity to light, dry itchy irritated eyes, and/or painful burning eyes. However, they were generally described as manageable and improved after the patient stopped treatment
- At end-of-trial interviews, patients noted continued decrease in the severity of ocular symptoms, rated by NRS severity scores between when symptoms were worst and two weeks prior to end-of-trial interviews
- Patients registered high levels of treatment satisfaction and noted less overall impact on their daily life compared to other treatments

Impact

- Phase I and Phase II interview results provided valuable insights into the symptom and impact experiences of patients in real time as they changed during and following treatment
- Results from the patient interviews helped to lessen regulatory concerns about the ocular side effects by describing their changes in severity and progress toward resolution once treatment was completed, and describing their overall value for the treatment despite these side effects

Qualitative patient interview data helped to overcome concerns, leading to an **EU approval nod from the European Medicines Agency as well as a US Food and Drug Administration panel endorsement**

High-quality patient experience data has become increasingly important for various stakeholders. Evidera's diverse team of qualitative researchers, epidemiologists, biostatisticians, psychologists, decision analysts, and public health experts will work with you to map out your exit and embedded interview study objectives and determine the best study type based on timing, sample size, and design.

Learn more at evidera.com/exit-and-embedded-qualitative-interviews/