Clarivate

Multinational In-Trial Patient Interviews

Case Study | Patient Interview Program

Multinational In-Trial Patient Interviews to Strengthen PRO Content Validity in Crohn's Disease

Background

A biopharmaceutical company conducting a global Crohn's disease clinical trial needed to strengthen the evidence supporting its key symptom patient-reported outcome (PRO) measures. Regulatory feedback, including recommendations from the FDA, highlighted the need for additional qualitative evidence to confirm content validity and interpretability of both PRO measures and associated anchor items.

The Challenge

The client was required to demonstrate that its trial PRO measures were:

- Understood by patients as intended
- Relevant to the lived experience of Crohn's disease
- Supported by clearly differentiated response options
- Capable of capturing meaningful symptom change

This evidence needed to be generated efficiently, without disrupting the ongoing clinical trial or introducing logistical complexity across multiple countries.

The Solution

Clarivate designed and implemented a multinational exit interview program embedded directly within the clinical trial.

Key elements included:

In trial qualitative research:
Exit interviews implemented as a trial protocol addendum, avoiding the need for a separate study.

Global patient interviews:
Cognitive debriefing interviews conducted with 62 patients across the US, UK, Australia, Canada, Germany, Poland, and the Czech Republic.

Local language execution:
Collaboration with a service partner to conduct interviews in patients' native languages, supported by gold standard transcription and translation.

Efficient study design:
Select objectives split across patient cohorts to ensure sufficient qualitative depth while optimizing sample size.

The Results

Clarivate generated robust qualitative evidence supporting the content validity of the trial PRO measures and anchor items.

Outcomes included:

- Confirmation that PRO measures were generally understood as intended
- Evidence that patients could clearly define and distinguish response options
- Validation that patients considered key Crohn's disease symptoms when completing anchor measures
- Documented understanding of meaningful score changes and response thresholds
- Positive insights into overall patient trial experience derived from blinded data

This work enabled the client to address FDA feedback, strengthen regulatory confidence in the PRO strategy, and support the integrity of key clinical trial endpoints.

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