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Health Solutions

Clinical Trial Exit Interviews

Presented at the Clinical Outcome Assessments: Establishing and Interpreting Meaningful Within-Patient Change Meeting

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The power of **knowledge.**
The value of **understanding.**

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What is an “Exit Interview?”

- The collection of (mostly) qualitative data from clinical trial participants
  - Most commonly, interviews are conducted soon after participants complete the treatment period
  - However, patients’ (and/or caregivers’) experiences and perspectives regarding treatment benefit may not be fully captured with traditional COAs.
- Interviews with clinical trial participants provide the opportunity to more fully explore the impacts of investigational products
  - Describe the meaningfulness of treatment-related changes (positive and negative)
  - Identify unanticipated treatment benefits
- Information regarding pre-study experiences, as well as treatment-related expectations and unmet needs can also be collected.

Why Do Exit Interviews?

To identify

- Characteristics of (sometimes new or rare) patient populations
- What symptoms/impacts are most important to patients
  - Allows participants to articulate concepts that may be important to them but that are not obtained (or fully obtained) in the trial, thus
    - Enriching researchers' and sponsors' understanding of the patient experience
    - Aiding in interpretation of other clinical data
- Full impact of treatment (meaningful changes)
- Unmet needs of treatment
- Expectations for and experiences with disease and of treatment
- Thematic information used to inform future COA strategies and clinical trial designs
- Potential treatment differentiators

Exit Interviews

- Supplement, support, and facilitate the interpretation of data from traditional PRO, PerfO, ObsRO and/or clinical measures
  - Provide greater depth and rationale for data from traditional measures
  - Describe treatment effects
  - Explore the relevance and clinical meaningfulness of specific treatment changes beyond clinical indices and side effects
  - Explain anomalous results

Sample Interview Concepts

Patients' (and Caregivers') Experiences With and Attitudes About Treatment

- Symptoms/impact prior to study start
- Expectations of changes/outcomes
  - Can compare pre-study expectations with clinical outcomes
- Anticipated or unanticipated benefits, impact of those benefits
  - Impact of treatment on daily life/functioning
  - Impact of treatment on most important/bothersome symptoms
  - Onset of benefits/changes
- Treatment experiences
  - Convenience of visits, monitoring
  - Managing treatment schedule (e.g., regimen schedule, infusions, monitoring)
  - Most challenging aspect of study treatment
  - Managing adverse events
- How well treatment addresses most important/bothersome symptoms
- Impact of treatment on daily life/functioning, quality of life
- Satisfaction levels with treatment
  - Reasons for satisfaction

Potential Applications

When to conduct interviews

- Both within and outside the context of a clinical trial
  - Implementing as part of a clinical trial is generally more efficient and maximizes participation as compared with a separate or subsequent study
- At various time points (not just at the end of a study)
  - Baseline, at key time point(s) during the study, at the end of a randomized treatment phase, at the end of open-label extension, etc.
- With all participants or select samples of study participants
  - Participants can be selected by site, country, experience of a particular side effect, patient-reported data

Approaches to Conducting Patient Interviews

Approach 1: Experienced, trained qualitative researchers conduct interviews

- Interviews conducted via telephone or in-person at designated time(s)
- Can be prospectively planned into the CT protocol or done as a substudy
- Interviews follow a semi-structured guide
- Values of this approach
  - Richest source of data, robust methodologically
  - Level of granularity from experienced interviewers
  - Limits the variability in data quality (vs large number of individuals with varying degrees of qualitative experience)…
  - Qualitative analysis usually done by interviewers themselves

Approach 2: Study coordinators (SCs) conduct interviews

- Qualitative interviewers would develop interview guide/related materials, and provide training to SCs
  - Certify, demonstrate proficiency
- Use a more standardized and heavily scripted interview guide
- SCs provide field notes, audio recording etc. to qualitative researchers who analyze qualitative results
- Values of this approach
  - Although data may be less in-depth than Approach 1
  - Particularly effective in global trials in which interview process needs to be scaled to allow for maximal participation
  - Allows for interview to be conducted by a someone familiar to patient

Issues to Consider in Operationalizing

- What questions are you trying to answer with the interviews?
  - Exploratory, looking for a signal vs providing data/support for primary endpoint?
  - Do you need patients from all countries to answer your questions or sample of participants?
- Population
- Sample size
- Who is going to conduct interviews?
- Method
- Timelines
- Budget
- Senior-management buy in

Potential Methodological Considerations / Limitations

- How, if at all, exit interview activities influence CT data
- Self-selection bias of exit interview volunteers (site and patient level)
- Sample
  - All patients, subsample(s), size
- How data will be analyzed
  - How interview data relate to CT data
- Potential for additional adverse event reporting

Factors Contributing to a More Successful Interview Study

- General rule of thumb: the more sites and patients, the easier and less expensive it is to recruit
- Include prospectively in clinical trial (vs. relying on sites and patients to volunteer their participation)
  - Increases site and patient willingness and compliance
  - Increases patient sample size
  - Interview substudy can be included as a component of a clinical trial for select countries (does not have to be for the entire study)
  - Additional protocol amendments and IRB reviews would not be needed
  - Does not significantly add to site burden
  - Training for interview substudy adds ~ 30 minutes to site initiation visits

Factors Contributing to a More Successful Interview Study

- Adequate time to design interview substudy and materials
- Target an adequate sample size (e.g., 30-50 interviewed patients)
  - More likely to identify themes/signals (vs. 10-15 patients)
- Larger site and patient pool increases likelihood of success
  - Easier and more efficient to recruit
  - More “buy-in” from sites and patients
- Include in phase 1B or phase 2 study
  - Increases chances of early identification of signals (e.g., treatment benefits, impacts)
  - Learn what is important to patients that may not be included in protocols
  - Early signals can help inform future study design, PRO measurement strategy, selection of other study endpoints, systematic measurement of new endpoints

Exit Interview Study Examples

Example 1: Exit Interviews with COPD and Asthma Patients in Prospective, Real World Clinical Studies

- RTI-HS designed and is implementing an exploratory study to capture patient-centered information in the context of two real-world studies being conducted in chronic obstructive pulmonary disease (COPD) and asthma.
- The study is investigating the impact and management of COPD and asthma from the patients' perspective and highlighting the potential relationship between treatment and both behavioral and psychological factors on patients' experiences.
  - Goal is to identify key risk factors for exacerbations and treatment adherence.
- A mixed methods approach is being used:
  - Quantitative data is being collected through the administration of structured, closed-ended questions administered to all patients via telephone interviews.
  - Qualitative data is also being collected through semi-structured, open-ended questions on key topic areas administered to a subset of patients via face to face interviews.

Example 2: Interviews with Patients with Diabetic Gastroparesis Before and After Treatment

- RTI-HS recently collaborated with a pharmaceutical client developing a new treatment for diabetic gastroparesis (DG)
- Participation in qualitative interviews at both the beginning (pre-treatment) and end (post-treatment) of a phase 2 study was offered to all clinical trial participants
- Primary objective of the pre-treatment interviews was to inform the development of a new PRO measure or modification of an existing PRO measure by:
  - Identifying a comprehensive set of DG symptoms
  - Learning how patients describe the burden and natural variation in these symptoms
  - Understanding the relative bothersomeness of the symptoms
  - Describing expectations related to successful treatment
- Primary objective of the post-treatment interviews was to gather in-depth information about participants' experience with the study drug, including the magnitude and relative importance of both positive and negative changes
- A manuscript describing the methods and results of this study have just been submitted for publication

Example 3: Exit Interviews with Clinical Trial Participants with Carcinoid Syndrome (CS)

- Task: Regulatory requirement that client assess and document the relevance and clinical meaningfulness of specific CS-related symptoms and their impacts
- Designed and implemented a qualitative study to explore perceptions and experiences of patients following their participation in a clinical trial.
  - Conducted telephone exit interviews with 35 patients across 16 sites in 5 countries enrolled in a phase 3 clinical trial investigating a new treatment for carcinoid syndrome to assess:
    - Participants' experiences (symptoms and impacts) with their disease
    - Perceived benefits of the study treatment
    - The clinical meaningfulness of specific symptom improvements and their associated impact to the patients
  - Mixed methods (qualitative and quantitative data)
  - Data analyzed
    - Qualitative
    - Quantitative
    - Compared with selected clinical trial data

Example 3: Exit Interviews with Clinical Trial Participants with Carcinoid Syndrome (CS): Results

- Supported the primary endpoint of decrease in diarrhea
- The 3 most important symptoms to treat and the most bothersome symptoms were diarrhea, BM frequency, and urgency.
  - BM frequency was reported as being more important to treat than stool form/consistency.
- Meaningfulness of changes with treatment
- 95% of participants who reported reductions in BM frequency noted that this was meaningful to them, allowing them to better enjoy life, leave the house, and participate in social and other activities.
  - *"I definitely feel like I'm not a prisoner in my house, staying 10 feet to the nearest bathroom. I can go out to activities…"*
  - *"But the biggest change is not having to run to the toilet constantly…You can't live going 20 times a day. I was able to go out more often…"*
- Most participants reported that a BM frequency reduction of at least 30% would be considered meaningful.