Informed Consent Engagement

PROBLEM STATEMENT

The informed consent process is often one of the first and most critical introduction points a patient may have to the clinical trial process. Despite the importance of this crucial process, informed consent is not without issues. The consent process can be tedious and quite cumbersome - overwhelming patients with pages of documents outlining potential risks, benefits, and consequences of their proposed clinical trials while troubling them with long, complex, and difficult to understand forms. The Center for Information and Study on Clinical Research Participation (CISCRP) has reported that up to 35% of patients who decide not to participate in a clinical trial decline because they could not understand the informed consent document. Informed consent documents are often widely re-used, perpetuating flaws, omissions, and customizations made in prior documents or templates. To best support clinical trial participants, sponsors need to invest more time and effort in developing simplified informed consent forms (ICF) that are clear, concise, and easier to understand. Value lies in creating ICF documents with patients' unique perspectives and experiences at the forefront rather than presenting potential participants with lengthy and difficult to understand legal contracts.

In order to optimize this process, Sponsors may engage patients or focus groups to provide feedback on proposed participant communications, including consent documents. While patient engagement continues to improve, there are still challenges in incorporating patient perspectives that could directly affect trial experiences and materials. Even organizations that have strong engagement programs face hurdles getting patient input actioned by often-overburdened trial startup teams. This may result in missed opportunities to promote significant procedural, educational, and experiential change alongside document adjustments.

Medidata is committed to driving patient-centered change in the design, development, and delivery of clinical trial solutions and services to ensure that the patient voice is heard and clinical trials become more engaging and rewarding for patients. To this end, Medidata engaged with an existing Top 25 pharmaceutical client interested in comparing patient comprehension and the ease of use of a simplified ICF with their current standard ICF template. Working with the advocate experts on the Medidata Patient Insights Board (PIB), the Sponsor was given the opportunity to explore more engaging ways to leverage a standardized and improved ICF in order to enhance their participants' consenting process.

Medidata's Patient Centricity by Design is is the formal methodology the Patient Insights team uses to make patient insights actionable elements in product development. By infusing the patient perspective into the solution development life cycle, Medidata ultimately creates technical solutions that improve the overall patient experience in clinical research operations.

This framework is now being extended to sponsors and CROs to help address needs in making clinical trials more patient-focused. Medidata's Patient Design Studios are workshops tailored to meet internal and client needs,that draw on the experience of the advocates on our Patient Insights Board to develop insights on core themes, issues, and topics.

"If I can't get through the ICF, how will I get through the trial?"

SOLUTION

The Medidata Patient Insights team was engaged to evaluate two variations of the proposed ICF examples, using their award-winning Patient Centricity by Design methodology to deliver actionable insights. Over four weeks, ten advocates from the PIB engaged directly with the sponsor to conduct interviews, collect information, and develop a multi-stage analysis to measure ICF comprehension. The advocates provided recommendations to transform the ICF and enhance the consent process from a burdensome document-based event into a patient-centric, informative experience.

ASSESSMENT AND CONSENT SIMULATION

The Medidata Patient Insights team scheduled one-on-one conversations between individual PIB members and the Sponsor to evaluate comprehension and burden in a simulated consent process. The PIB advocates were randomized to review either a long-form or short-form ICF, with the ICF review followed by a discussion between the advocate and the Sponsor serving in the role of the clinical trial coordinator.

An online survey was also sent to a separate group of patient advocates to gather written input and capture feedback using the same questions used by the PIB, but this time without the Sponsor interaction.

METRICS AND ANALYSIS

The Sponsor provided Medidata's Patient Insights team with the results of the interviews to identify key themes and areas for improvement. The output was analyzed for quantitative metrics on length, time to completion, and likelihood of participation. These metrics were also analyzed for the survey-only group, and results were compared to the interview group to identify differences in responses based on form length and modalities of administration.

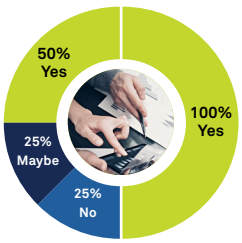
Qualitative feedback was also collated and summarized into high-level themes such as patient pain points, areas of opportunity, and suggestions for document and process improvement. This feedback was presented for workshop discussion and included in the final report to the client.

PATIENT DESIGN STUDIO: VALUE IN MULTI-STAKEHOLDER COLLABORATION

The second phase of engagement involved a deep dive into high-value areas with the sponsor's team of executive, clinical operations, and legal representatives. The Patient Insights team and the PIB provided tactical and strategic recommendations to address the Sponsor's goal of better presenting information to potential trial participants. The Sponsor representatives worked directly with PIB advocates to learn from their lived experiences and expertise in study design.

Trial Participation Impacted by ICF Administration

Survey-Based Long ICF Process



Conversation-Based Long ICF Process

"When it comes to the informed consent, words do matter — one wrong word could potentially scare a patient away from a trial."

PATIENT CENTRICITY BY DESIGN

INFORMED CONSENT ENGAGEMENT CASE STUDY

The Patient Insights team delivered custom recommendations to the client's informed consent process along with suggestions on revisions to their templated ICF based on the interview results and workshop output.

RESULTS

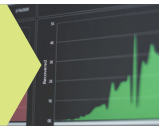
Major findings include that a thoughtful layout is key to helping participants understand the ICF and structuring the consent process as a conversation leads to more knowledgeable participants.

Patient Centricity by Design Process Results

Enhancing the clarity of language
instead of length or brevity as the main driver for a more optimal participant experience.

Improving the presentation of the ICF
by prioritizing impactful patient information and increasing the use of graphics and visual aids.

Increasing the use of graphics and visual aids



Providing 1:1 support
through conversation-based informed consent process.

The PIB evaluated the clinical trial literacy level within the ICF and recommended changes to document wording and phrases, including reduction of unnecessary text and identifying opportunities to update entire sections in order to be easier to understand for a non-healthcare audience.

In addition to editorial recommendations, the Patient Insights team made program-level recommendations to the Sponsor's informed consent process. Additional suggestions included making resources and support available to potential participants to help them better understand their disease and the overall clinical trial process.

Delivering insights on how to improve the process of consent along with the action of completing the ICF allowed the Sponsor to see how a more effective process coupled with an improved document could exponentially improve patient satisfaction and comprehension during the pre-trial phase, leading to quicker trial accruals and greater trial adherence by more informed participants.

The PIB provided clear direction at a critical decision point in the Sponsor's preparation of the consent process and documents for an upcoming trial. The Sponsor took the recommendations of Medidata's Patient Insights team and is redesigning their informed consent forms to prioritize important information layout within the template, refine the messaging and graphics for complex concepts, and establish the right balance of thoroughness and concise wording. Together, with process recommendations and a renewed perspective, the Sponsor recognized the need to better support the patient experience throughout the entire consenting process.