Listening to the Patient for Better Outcomes

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The aim of drug development is to improve patient outcomes. Historically, clinical research has been driven by researchers, with little or no input from patients, contributing to many of the challenges and inefficiencies we see in today's clinical trials. Some of these challenges include low enrolment and retention rates, in addition to poor engagement.

Implementing patient-centricity within a trial, starts with listening to the patient voice. Conversations with patients need to begin at the early stages of clinical trial design to inform whether the drugs being developed will be beneficial to a specific patient population and improve quality of life. Here, we outline the challenges and potential solutions of integrating patient insights for improved outcomes.

Listening to the Patient in the Early Stages for Better Outcomes

Patient insights can provide important intelligence to inform study design, leading to more meaningful outcomes for all stakeholders. It isn't enough to engage patients pre-trial or during recruitment. Sponsors need to initiate conversation with the patient at the discovery stage to determine whether the investigational product has the potential to truly improve lives.

In addition, patients can influence the selection of patient-reported outcomes or endpoints. For instance, in rare disease therapy areas where treatment options are non-existent or restricted and costly, there is often a push to research the natural history of the disease, which requires input from patient populations and can capture the disease characteristics that matter to the patient. The data collected can serve as primary or secondary endpoints in clinical trials and other epidemiological studies, developing and evaluating new therapies, and even inform shared-decision making, pharmaceutical labelling claims, clinical guideline development and health policy.

Establishing and Maintaining Patient Connection

True patient engagement doesn't just happen in the beginning stages of drug development. Rather, this conversation needs to continue throughout the development and after the launch. Therefore, keeping the patient engaged throughout the drug development process requires an understanding of the experience of a patient with the disease, developing a profile that reflects commonalities and mapping out the contact points for ongoing communication in the patient journey. For example, patient insights can help sponsors determine the trial burden on patients and caregivers, such as financial outgoings and travel. Basic support such as helping patients get to the site and recognizing that the patient burden often extends to family and caregivers can all support better retention. Further, checking in with patients regularly, especially during "quiet times" and between visits, can prevent an information vacuum, which could, in turn, lead to cynicism or a negative reaction to the trial experience.

When appropriate, sponsors can also consider the application of digital health technologies to connect with the patient to build trust and increase engagement. For instance, patients may prefer to record diaries using a smartphone, rather than paper. In fact, a survey conducted by the ICON in 2019 found that 70 percent of respondents preferred to use technology rather than paper for recording patient diaries.

Lastly, when conducting global clinical trials, sponsors need to have an infrastructure in place that understands not only the local culture, but also the legal and compliant methods for engaging patients. This requires having a presence in the geography where sponsors are conducting a study.

Overcoming Structural Barriers with Decentralized and Hybrid Trials

Leveraging innovative trial design and data collection methodologies can enhance patient centricity. In fact, the recent FDA guidance around clinical trials during COVID-19 referred to looking at alternative methods to on-site patient assessments to keep clinical research on track. The benefits of in-home visits, as part of a decentralized trial, to the patient are wide, including convenience to participate without major disruptions to daily life, regardless of mobility challenges, and more flexibility in scheduling visits. Further, remote patient monitoring can collect data to inform outcomes such as how a drug may impact a patient's daily life, in addition to being able to report adverse reactions and intervene in real-time.

A Vision for the Future

The goal of clinical research is to establish the safety, efficacy and, most importantly, the impact on the patient – when it comes time for regulatory approval. As the industry moves towards more decentralized clinical trials, industry stakeholders should continue to focus not just on treating the disease but also on taking a more holistic approach that would provide optional interventions to alleviate symptoms and ultimately, enhance the patient's quality of life. PV

Editor's Note: To learn more about patient centricity in clinical research from diverse industry stakeholder perspectives, read ICON's Patient Centricity Report at iconplc.com/centricity-report.

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Patient Centricity Report

Exploring the patient perspective from different angles

ICON invited distinguished speakers to participate in a panel discussion on patient centricity, based on their global experience and varying stakeholder positions in the industry; an investigator, patient advocate and a senior executive from pharma.

Read our summary report for insights on:

- Getting to grips with patient centricity
- Establishing and maintaining patient connection and engagement
- Improving access to trials and patient awareness of clinical research as a care option
- Decentralised and hybrid trials to overcome structural barriers
- Vision of the future

Find the report at ICONplc.com/patient-centricity