Insight Brief

Activating Patient Participation in Clinical Trials

Key ways to humanize trial design, through patient and site engagement strategies

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Introduction

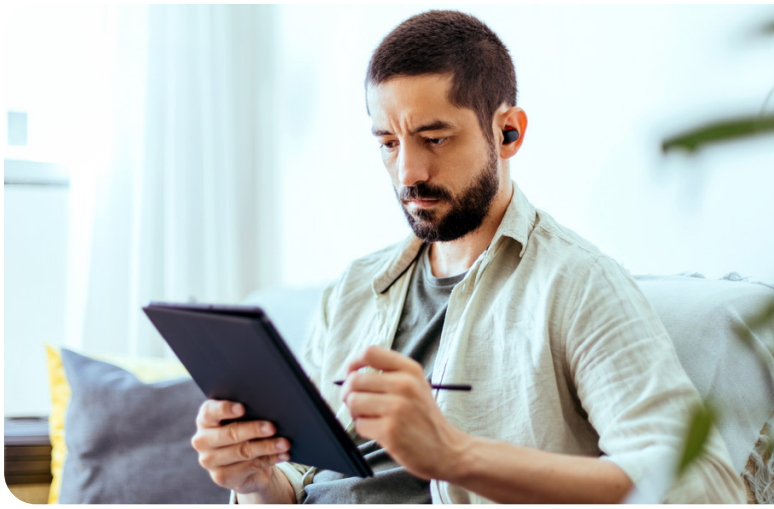
For decades, clinical trial sponsors relied on second-hand insights from internal experts, physician perspectives and academia to understand the patient's point of view. Recently, the research and development industry has transitioned from developing drugs for patients to developing drugs with patients, recognizing how patients and caregivers know their unique needs and challenges better than anyone else. They have also recognized that if patients are asked to commit their time — and their healthcare — for research, the industry needs to make it worth their while and treat them as active partners in the process.

Patients are more proactively managing their healthcare preferences. They are voicing their thoughts, especially in terms of what motivates or hinders them from participating in critical clinical research. In turn, trial sponsors, clinical research organizations and study teams have a tremendous opportunity to integrate valuable patient insights with trial design strategies to improve the patient experience and related health outcomes.

For sponsors and CROs, the question is, "Exactly how do we effectively secure patient insights and weave them into trial design to better tackle the challenges of recruitment and engagement?" The truth is that there is no one-size-fits-all approach. Rethinking the trial experience through the eyes of the patient and their needs must be addressed from multiple angles and solutions. Below, we discuss five noteworthy ways sponsors, CROs and study teams are improving trial participation and engagement by using patients as partners.

Active listening for empathetic trial design

To start off on the right track as early as possible in patient-first trial design, sponsors need to know when, how and where to approach potential patients to participate. The first step is to secure patient perspectives and design trials that work for them.



Surveying

Though sponsors cannot always anticipate the right path forward, actively listening to patients to understand which (and how) specific protocol elements can hinder or enhance engagement can help shape trial design.

In some cases, surveying patient groups found in proprietary databases, company-specific patient communities and registries, patient or disease advocacy groups, etc., can help sponsors learn why it can be difficult to find and engage a particular trial's ideal patient population if protocol elements don't fit their needs or experiences.

Surveying can help determine individuals' sensitivities to information they may not want to provide in a survey, such as number of sexual partners, race, or issues with study design (e.g., invasive procedures). It can also help gauge why individuals may not want to participate, such as lack of motivation, information or understanding of what's necessary to qualify for the protocol. Patients may not have access to required pre-qualifying information (e.g., specific lab value targets), understand it or simply not have documented medical visits to share. Understanding deterrents to participation helps set realistic expectations for how difficult recruitment may be with the current trial design and what may be needed to engage and support patients.

PATIENT SURVEY INSIGHTS CAN HELP ANSWER:

Based on participant location, how accessible are stable internet connections? Are patients likely to connect via mobile devices, laptops or other smart devices?

Are they willing to use electronic devices for a virtual study?

What are health literacy levels and the level of educational messaging needed?

Do participants receive information via culturally preferred messages and channels?

Is there a community leader and/or patient association representing patients locally who should be engaged first?

Are patients comfortable with a medical professional visiting their home or would they prefer onsite visits?

How far are they willing to travel for clinical trial treatment, and how long should a patient visit take?

Do they feel slighted or limited by their medical condition?

What other medical conditions do they have?

Are they dissatisfied with their current treatment, and if so, why?

Along with survey insights, feedback from principal investigators can be added to other deidentified patient data, such as demographics, lifestyle and clinical experience with the disease, to identify empathetic and tailored outreach approaches for specific patient populations and match their communication and trial conduct preferences.

Communication to patients should:

- Acknowledge the need for emotional support for patients who are worried, anxious or depressed regarding their disease concerns.
- Ensure they feel respected, heard and prioritized throughout the trial.
- Provide simple yet detailed language so individuals know what they are committing to and can prepare for requirements.
- Clearly state benefits, convenience and support available from participating in the trial (e.g., access to treatment, close monitoring, receipt of test results, improved quality of life and learning to manage their health concern better) while balancing the information regarding standard of care treatment.
- Help them navigate large sites like hospitals. This includes meeting them at the door, escorting them to the appropriate location and making them feel welcome and comfortable.

Intentional focus on protocol burden assessments via race and ethnicity

To reinforce the R&D industry's commitment to sufficient representation in clinical trials among those traditionally underserved, it is critical to drop assumptions regarding the lack of willingness to participate in a study or that focusing on diversity adds time and cost.

Sponsors can use advanced analytics to assess patient burden based on trial design aspects, incorporating patient-centric survey insights, virtual or face-to-face focus group discussions, and real-world data. With analytics, protocol elements can be scored to quantify patient burden according to race and ethnicity to identify and engage patient subpopulations. Sponsors can gauge whether protocols require the expected level of burden when compared to protocols for a similar phase, therapeutic area, disease, etc.

These nuances in trial participation motivators may indicate how well a trial's design will work for certain subpopulations. For example, if a trial

requires overnight stays or longer site visits, does that influence Black/African American patients' willingness to participate compared to other communities' (e.g., Asian, Hispanic or Caucasian)? Recent survey findings show there are subtle differences, and that visit lengths or overnight stays did not influence Black/African American respondents' willingness to enroll as much as it did other groups.

As sponsors calculate and compare protocol burdens, considering the perspectives of diverse populations during trial planning can help validate the study design or more quickly identify adjustments needed to increase enrollment potential among diverse populations.

AI-modeling to improve patient identification

To fine-tune recruitment efforts and related timelines, sponsors and CROs are leaning on artificial intelligence-driven modeling to mine millions of data points (e.g., claims data, pharmacy data, etc.) to better identify patients who may meet protocol requirements. With a list of deidentified individuals, sponsors can broaden the scope to a larger consumer database of demographics, lifestyle preferences, status, purchasing habits and other useful insights to understand areas of commonality, such as:

- Residing in a household with or without children or elderly parent.
- Ordering products via mail or shopping in stores.
- Participating in sports, tennis, fishing, yoga, etc.
- Entertainment preferences (e.g., TV shows, music, preferred media formats, etc.)
- Dietary preferences and eating habits (fast food, restaurants, homemade, etc.)

By modeling iterations of layering these insights, sponsors and CROs can rank patients from most likely to least likely to meet protocol requirements and connect the points of information sponsors need to make more informed decisions about recruitment and outreach efforts.

"Patient Insights can help guide outreach activities, from determining the optimal time of day for sending information to what communication channels will best reach specific patient subpopulations."

Creatives that resonate with patients

Being able to dive deeply into patient preferences and need for support gives sponsors the opportunity to develop customized marketing outreach plans that include insight-driven messaging in study branding, campaign themes and media channels. Patient insights can help guide outreach activities, from determining the optimal time of day for sending information to what communication channels will best reach specific patient subpopulations.

With a stronger understanding of the target patient population and their feelings regarding their healthcare journeys and support needs for trial participation, writers on the study team can help ensure recruitment messaging resonates and continues to engage patients well beyond trial completion. For a migraine study, for example, if patients describe their migraine as "dark" or "booming," the creative team can develop content with imagery that reflects these feelings while bringing attention to a clinical trial that may benefit them.

For an obesity study, patient-facing materials should consider targeted individuals' need for emotional support. Study teams should also develop materials and training that remind trial site staff of the emotional conflict and/or embarrassment participants may experience and to express empathy and respect instead of judgement.

Communications with patients throughout the trial and afterward should ensure they feel adequately supported and engaged.

Clinical Trial Educators: a critical role to enhance site engagement and accelerate trial recruitment

Securing patient insights allows sponsors and study teams to integrate the right support services, expertise and technologies into trial design to ensure sites are better supported from end-to-end to improve patients' participation and experience.

One key way to humanize research and support sites in parallel is involving trained Clinical Trial Educators in trial design. CTEs are therapeutically experienced recruitment specialists, who often have clinical backgrounds as registered nurses, therapists, and educators. They play a crucial role in creating trial awareness, educating sites, and removing barriers to clinical research participation. Additionally, they help reduce site burdens and quickly become the go-to person for study information, guidance, and problem-solving for everyone involved.

Building bridges with local patient populations, sites and referral pathways

CTEs are key experts for evaluating and using local relationships and resources to maximize awareness of clinical trials among providers and local patient populations. They can play a critical role in reaching patients through:

- Site and referral pathway engagement: Clinical Trial Educators fill in recruitment gaps and speed enrollment by:
  - » Educating the primary investigator and site staff about successful enrollment techniques and other site-affiliated health service professionals who may help identify patients.
  - » Accessing untapped recruitment pathways through referral networks, individual contacts or local inquiries.
  - » Informing health care facilities (e.g., emergency rooms, cardiology catheterization labs, other departments) that may refer potential patients.
  - » Reducing otherwise excluded patients from trials through identification prior to initiation of other therapies.
  - » Sharing best practices in focus groups of study coordinators or investigators, a significant value-added service.
- Direct community engagement: CTEs can help identify and staff community events, such as health fairs, festivals, concerts, etc., to share clinical trial materials and conduct preliminary screenings. Because CTEs are often regular participants in local events that connect with diverse racial, ethnic, sexual orientation and socioeconomic communities, trial awareness expands to even more patients.
- Resource development: As a trained clinician, a CTE understands challenges of patients and caregivers and can provide insight into what tools and best practices are needed to improve participation. Before a clinical trial begins, CTEs can help identify supplemental resources a community needs to remove barriers to participation, such as:
  - » Ensuring trial materials explaining complex health information are communicated in plain language without medical jargon.
  - » Listing useful transportation options on recruitment materials to reduce logistical challenges to participation.
  - » Determining when translating trial materials may benefit certain communities.

As the number of clinical trials increases and life sciences companies strive to conduct them more quickly and efficiently, the role of the CTE will continue to expand. In the future, CTEs will have access to more sophisticated tools and, with the growth of data on healthcare providers (HCPs), will be even better equipped to identify key contacts for patient referrals. CTEs serve as clinical trial ambassadors, increasing the likelihood that healthcare providers will have the trial top of mind when an eligible patient presents. This proactive approach helps recruit patients and supports the trial in reaching its enrollment goals.

Creating active partners in clinical research

As patients' desire to be valuable partners in the trial process grows, their insights will further guide patient-centered trial design. Diving deeper into what patients feel are burdens to participation, frustrations with their conditions and treatments, and where they need support helps take the guesswork out of the development process. It can also help to create a trusting environment where patients can feel a sense of collaboration beyond the immediate needs of one sponsor or trial.

Focusing on trial design with patient-centered insights and involving them in the process helps provide sponsors a more holistic view of what is needed to improve patient recruitment and engagement strategies that can steer trials in the right direction, improve clinical outcomes and accelerate R&D efforts that are for patients and driven by them.

About the authors

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As Senior Director of Medical Affairs at IQVIA, Sheela oversees the global resourcing and delivery of high-performing Clinical Trial Educator teams. Her role encompasses strategic development and deployment, tactical planning and execution, and key project and people management. Sheela supports the direction of all activities of the field-based medical team, ensuring alignment of clinical and scientific initiatives with strategic clinical study objectives. Additionally, she fosters collaboration among cross-functional teams to optimize study outcomes for clients.

Prior to joining IQVIA in 2008, Sheela held various leadership positions within the pharmaceutical industry, focusing on medical marketing, strategic integrated medical planning, clinical research, drug information, managed care, and government affairs. She also has extensive clinical and scientific research experience in Reproductive Endocrinology, Cardiovascular, Genetics, Immunology, and Ophthalmology. Sheela holds a Master of Science degree in Molecular Biology and Genetics from Washington University in St. Louis and is currently completing her Doctor of Philosophy degree in Health Sciences Research from Trident University in Cypress, CA. She has numerous publications from her clinical and research work and has presented her findings at scientific and national industry meetings, discussing scientific results as well as the evolving role of field-based medical teams in the face of current compliance and regulatory challenges.

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Karen Townsend is the Senior Director of Medical Affairs at IQVIA, overseeing global delivery of Clinical Trial Educator (CTE) projects. She ensures timely and excellent service, focusing on strategic development and implementation of project activities. Karen collaborates with leadership, sponsors, and project managers to enhance recruitment and streamline processes. Previously, she was a CTE for eight years, exceeding enrollment goals in various therapeutic areas including Critical Care, Renal Disease, Cardiovascular, Pulmonology, Diabetes, Neurology, and more. Karen also has experience as a Clinical Research Associate, meeting project metrics and expectations. Before clinical research, she worked for three medical non-profits, holding leadership roles and overseeing educational programs. She successfully recouped over $400,000 in lost charges due to her financial oversight proficiency.

Karen is a Registered Nurse licensed in Georgia, with experience in Intensive Care, Coronary Care, Renal, and Admit Recovery units. She was a preceptor for newly hired staff and one of the first RNs to receive certification in Critical Care. Her extensive experience and dedication have made her a respected leader in medical affairs and clinical research.

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