Data and Technology: The Key to Patient-Centric Clinical Research

▶ A convergence of trends is transforming the trial experience and increasing efficiencies.

Susan Bacheller
Program Director, Health
Research Ecosystem
IQVIA

Ann Dokus
Technology Innovation — Global
Patient and Site Solutions (GPSS)
IQVIA

Patient-centricity has become a driving force in clinical research. Patients expect trials to be built around their needs as a factor of participation, while regulators expect to see more diverse patient populations in trials and a greater depth of voices captured in the data collected.

The convergence of patient data and advances in analytics technology is making that patient-centric vision a reality.

Analytics technologies have evolved to the point where we can now identify trends about specific patient populations within massive volumes of data, making it possible to predict individual needs at a granular level. And the emergence of direct-to-patient (DTP) recruiting, decentralized clinical trials (DCTs), and efforts to engage more diverse communities is finally making trials more accessible for all populations. The key now is figuring out how sponsors can leverage technology, data, and patient feedback to transform the entire trial experience.

Personalized Trials

Patient-centricity is about more than reducing travel times or using technology to ease access to documents and investigators. While these decisions lessen the burden, a truly patient-centric trial is about creating a personalized experience for every patient, from first contact through the end of the trial and future follow-up. It requires a fundamental shift in thinking about patients' role in clinical

research and how sponsors can use existing data and technology to engage them as active stakeholders whose needs and opinions are relevant to every touchpoint in the research journey.

The pandemic only accelerated this trend. DTP recruitment technologies, combined with global coverage of vaccine trials and easily accessible signups for research opportunities helped sponsors draw thousands of patients to these clinical trials in a matter of weeks. These capabilities enhanced by the adoption of voice enabled digital assistants, significantly accelerated trial timelines while delivering ease of access to the global community.

Technology partners also stepped up, adapting their platforms to streamline engagement, recruitment, and ease of access for patients in these trials. These include IQVIA, whose teams worked round-the-clock to repurpose cloud-native technologies for massive vaccine trials. They quickly provided integrated patient platforms supporting diverse global patient recruitment, consent, patient diaries, and biometric data, all in a single virtual environment. It gave sponsors the scale and flexibility they needed to launch these studies rapidly and to use collaborative technologies to ease engagement and maintain connections with those patients for long term follow up.

Structured Insights From Unstructured Data

The right combination of talent, technology, and data can provide granular insights

from patient history. Sponsors utilize de-identified longitudinal patient data as part of the trial design and delivery strategy. Investigators can review a patient's entire disease journey, rather than just a snapshot in time. They can learn when and why patients are diagnosed, what treatments they receive, what outcomes they desire and experience — and how these trends vary across different populations.

This data isn't hypothetical or an amalgamation of all patients in a specific disease category. Current technology can provide detailed insights into individual patient experiences, which study teams can use to find actual patients, not just profiles.

The current analytics platforms can also analyze unstructured data, including clinicians' notes, scans, faxes, and emails. Advanced data platforms can decipher all these valuable data sets, into meaningful text that can be analyzed to identify the location and needs of patients. Together, these insights inform endpoint selection, site locations, recruiting strategies, decentralized trial technology options, and other trial design features.

Pandemic Drives Innovation

Once study teams find patients of interest, they can leverage a host of technology solutions, like IQVIA's Patient Portal, to connect patients with their clinical research journey. Providing a suite of tools, including selected data share-back, interactive educational tools, gamification, telehealth platforms, e-diary integration, and connected wearable devices, technology makes it easy for patients to communicate with site staff and share relevant healthcare data from afar. These tools give sponsors the interactive capabilities needed to keep patients engaged even when they can't meet face to face.

During the pandemic, sponsors used these technologies to rapidly access patients and build the trial experience around their needs. At the same time, the push to develop COVID vaccines and treatments put clinical research into the spotlight, educating consumers through mainstream media about these opportunities and the benefits they can bring to individuals and the broader community.

It raised their awareness and comfort with the idea of trial participation. Sponsors and sites took advantage of this interest by recruiting to broad audiences using direct-to-patient recruiting capabilities that provided consumers with an easy path to participation by clicking on a link. It gave patients the power to decide whether a trial was right for them, determine eligibility, and find a site in their area quickly.

Sponsors were also able to understand the response to outreach in real-time, achieving population diversity goals throughout the recruiting funnel. These efforts resulted in some of the fastest and most diverse trial recruiting in recent history. One of the IQVIA supported vaccine trials, for example, exceeded diversity goals laid out by Operation Warp Speed (OWS) and the Biomedical Advanced Research and Development Authority (BARDA). In Phase 3 of one of its COVID-19 studies, 19% of participants were Black, 45% were Hispanic, and 34% were 65+ older.

Lessons Learned

Running trials during the pandemic pushed many sponsors out of their comfort zone, challenging them to quickly embrace new trial technologies. That experience helped them see the benefits of using technology and data to engage patients and improve the trial experience. If sponsors want to make that access and engagement a permanent part of their research process, they must embed these technologies in clinical studies planning from the beginning. That includes working with partners who understand when and where data, analytics, and industry expertise can make their trials more engaging and accessible to the patients they are trying to recruit.

Forward-thinking sponsors are already using data and analytics to personalize study experiences, including finding patients of interest, tailoring outreach strategies, and tuning inclusion/exclusion criteria for targeted patient populations. It is helping them identify hard-to-find patients and streamline their outreach and trial experiences to eliminate barriers and make research a more appealing care option.

Many of these sponsors leverage the health research ecosystem and global data sets to inform these journeys. Using IQVIA's data and analytics technologies, Sponsors can discover buried insights in structured and unstructured data to drive smarter decisions, unleash new opportunities to guide future trial designs, and connect with patients of interest.

Unprecedented access to data and insights is also helping sponsors recruit for much smaller studies that target specific populations of patients for highly targeted therapies. For some rare diseases, finding patients can be the most challenging element, and the data can determine whether the research can go forward.

The Future is Patient-Driven

The pandemic proved that technology and data could drive a more patient-centric experience — and the results benefit sponsors and patients. These technologies will continue to evolve, giving sponsors the tools, they need to adapt their trials to the needs of their patients.

But they will only add value if pharma companies are open to new approaches to patient-finding and building trials around the needs and obstacles patients face in their everyday lives. The sponsors who embrace this value proposition and are willing to treat patients as active stakeholders in the research process will be best positioned to benefit from these trends now and in the future. (PV)

The Undiagnosed Patient: A Case Study

In some cases, the convergence of data and technology makes it possible to identify patients with extremely rare diseases before they are even diagnosed.

IQVIA recently worked with a large pharmaceutical company that leveraged our CTcue technology platform to help research sites find patients with an ultra-rare cardiovascular disease. CTcue mines structured and unstructured patient data using natural language processing (NLP) to identify trends in data that indicate a patient has a condition. The patient data remains behind the hospital firewall with role-based access controls to ensure patient privacy.

The pharma company used the platform to search for possible patients at a selected hospital in the Netherlands. They found 1,765 patients who met inclusion criteria and had certain risk factors most predictive of the disease. Then they refined the and iterated upon the search to narrow the results so, allowing a cardiologist to review a reasonable subset of 22 patient records. The final analysis identified three patients who were then assessed by a treating

physician, resulting in one diagnosis.

The pharma company had research sites searching for similar patients in three other countries for an entire year with no success. CTcue's advanced AI-driven technology, along with practical review of query results by experts, gave them the insights they needed to identify a patient in just four months, and that patient's treating physician can now provide the most appropriate care with a better survival forecast.

Once patients are engaged in the trial, technology makes it easier to bring their treatment history details to the experience. Access to personal EHRs, scans and other treatment data means patients don't have to constantly fill out forms and recall in detail every medication, medical appointment, and healthcare interaction they've had since being diagnosed. Their data follows them to the trial and through the trial, making the experience easier and more data driven. That data tells the patient's story and can be accessed at any point in the journey to inform their treatment and care experience.

IQVIA is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. IQVIA Connected Intelligence™ delivers powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 74,000 employees, IQVIA conducts operations in more than 100 countries.
For more information, visit iqvia.com.