Patients as People: Operational Empathy Remains a Key Driver of Recruitment Success

Big data, artificial intelligence and digital platforms have dramatically transformed the clinical research landscape. Yet despite these extraordinary advances in technology and communication tools, the prevailing challenge of clinical trials has remained constant for decades: recruiting and retaining qualified patients. According to US and UK studies, only a third of clinical trial sites meet their patient recruitment targets and around half are forced to extend their enrolment periods.[1]

At first glance, the COVID-19 pandemic has exacerbated these longstanding challenges, slowing or pausing recruitment and operations of large numbers of trials due to social isolation and travel restrictions. But a closer examination reveals a sizeable shift in attitude and practice toward innovative remote and virtual techniques that bring trials to patients, rather than patients to trial sites.

It's a positive trend that is long overdue and here to stay. The pandemic has accelerated the adoption of patient-centric trial models – virtual or decentralised clinical trial (DCT) models – that have historically had slower adoption into routine practice. DCTs mitigate many of the persistent barriers to trial participation: geographic distance, transportation, financial impact from missing work, scheduling conflicts and other logistical hurdles, and scientific evidence demonstrates their value. For example, drugs developed using patient-centric trial designs are 19% more likely to launch than drugs developed without this approach. Moreover, patient-centric trials take less time to recruit the first 100 participants: four months versus the average of seven months for all trials.[2]

But paradoxically, concepts that seem intuitive and straightforward have proven to be remarkably complex to execute, in part because they require sophisticated expertise, technology and tools, as well as the infrastructure to implement them.

Smart Use of High-tech, Low-contact Platforms

New technology often outpaces the industry's ability to adopt and incorporate it into clinical research. But the transformative social distancing measures imposed by the pandemic have accelerated opportunities to incorporate innovative devices and platforms that remotely connect us to patients and sites.

Wearable devices, for example, have become so small as to be easily hidden under clothing, and be unobtrusive while working, exercising and sleeping. Among the latest wearables, the FDA has approved small stick-on monitors, about the size of a large key, that continuously capture vital signs and specific health events over a 30-day period. These wearables are being integrated with apps that allow patients to virtually communicate with their clinical teams and health researchers about their experiences and even opt into clinical trials that match their health profiles. This remote technology is particularly useful for COVID-19 trials, in which patients are isolated yet there is still a need to frequently report their symptoms to clinicians.

Another new tool is a compact drug delivery device that dispenses preprogrammed doses of oral medication and reminds patients when it's time for a dose, to drink water with their medication, when the device needs to be refilled, and other tips designed to enhance compliance. The device's bluetooth function connects with wearables to capture biometric data in real time, while a small video screen enables patients to conduct telehealth visits, ask questions and stay engaged with sites from home. To help patients navigate new technology, a host of tutorials are now online to walk patients through their features in a step-by-step fashion, which aids compliance and comprehension.

There's no doubt that technology is facilitating more decentralised and patient-centric trials, but we have to remember that technology is just one tool in our arsenal. It's how we apply the technology in a patient-centric way to achieve the study objectives that make the difference.

Real-world Evidence in a Real-time Crisis

The pandemic has disrupted life as we know it, and it has exponentially hastened our need for accurate data in real time. We need answers in days or weeks to help drive sound medical decisions for COVID-19 patients and public health policies. Real-world evidence (RWE) platforms provide an essential means for capturing this data from multiple sources to quickly assess infection rates, risk factors, symptoms, outcomes and the efficacy of investigative therapies. Even in cases where real-world evidence can't be acted upon in the short term, the data we acquire will aid our understanding of COVID-19 and ultimately help inform the future studies we design.

From the patients' perspective, RWE will serve another valuable purpose: enabling us to share the results of studies in which they've participated more quickly. According to The Center for Information and Study on Clinical Research Participation (CISCRP), almost all patients want to know the results of their trial, but few if any patients are receiving them.[3]

This isn't a new or emerging issue. For decades, patients have requested information on trial outcomes, according to research about patient perspectives. To accommodate their requests, we need processes that allow us to routinely inform patients about the studies. RWE accelerates data collection, which in turn speeds data analysis, which will ultimately pave the way for enhanced ways to share trial outcomes with patients. Patients who understand the value of clinical research – and the real-world impact it has on the

discovery of new drugs – will be more engaged and committed to participating.

Connecting to Patients with Empathy

Patient-centricity, or putting patients first, is increasingly recognised as an essential element for clinical trial success, starting with the earliest stages of trial design. But as an industry, we're still missing opportunities to connect with patients as people. Recruitment is a prime example. We now have access to big data from medical claims, electronic medical records and other sources – data that help identify who and where the patients are, their demographics and disease state. But more insight is needed to gauge their willingness to participate in the study. Likewise, sophisticated digital media platforms can target patients with pinpoint precision, but additional expertise is required to translate interest into trial engagement and successful recruitment.

This is where sites play a critical role. It's essential that the doctors, nurses and physician assistants interacting with patients truly believe in the study and regard its merits with positivity and confidence. Research has clearly shown that healthcare providers refer only a small number of patients to clinical trials each year, in large part because they don't have the time to evaluate and confidently discuss clinical trial options with their patients. A Tufts study among practising healthcare physicians and nurses found that healthcare providers are "better positioned than expected as patient engagement facilitators if they have sufficient time, information, and confidence to advocate on behalf of their patients."[4]

Technology cannot replace operational empathy, the human element that conveys genuine compassion and which ultimately drives successful recruitment and retention. But the combination of technology and empathy has the potential to transform the patient experience.

Building Operational Empathy

Building empathy with patients starts within an organisation's culture. With patients at the heart of everything we do, we value compassion and patient-centricity, and we model the behaviours we want our network of more than 500 alliance sites and 18,700 investigators worldwide to display. In turn, they extend those same behaviours and attitudes to study participants.

We also provide sites with the resources they need to recruit and support patients during a trial. For example, during a paediatric pulmonary study involving newborn infants, new parents were faced with a diagnosis requiring their babies to remain in the hospital. Exhausted and scared, the last thing on parents' minds was enrolling their infants in a clinical trial.

We modified the site's recruitment materials to infuse genuine sensitivity to the parents' situation, and we counselled clinicians to sit with parents, not across the table from them. We wanted parents to know that we weren't just interested in their child because they had this virus; we wanted to make sure that they were coping, too. This kind of heart-felt empathy reduces fear and encourages parents to consider clinical trials in the context of helping not only their child, but other children whose parents are experiencing the same gripping fear and uncertainty.

Additionally, recognising site pain points and asking sites for input on decisions that impact their workload, schedules and technological capabilities creates an engaged research partner, not just a paid clinical site. The smallest of details can influence a site's perspective of a clinical trial. For instance, if multiple vendors are collaborating with a site, then providing the site with a single sign-on across multiple software platforms can exponentially reduce their burden and allow for rapid data entry in the midst of a busy private practice that's also juggling a clinical trial.

We take pride in providing hands-on training and support; for example, setting up a Facebook page for the clinic's patient community to bolster trial recruitment. For the cost of an hour-long engagement or a 20-minute walkthrough phone call, we can alleviate the burden for sites and establish a positive rapport that's the foundation of a long-lasting relationship.

Navigating informed consents is another well-known hurdle that we simplify through our Consent+ platform. From the patient's point of view, trial data and endpoints may not be their priority – they are more likely to care whether the study will ease their pain, help them sleep, minimise discomfort and improve their quality of life. No matter how much data is provided to patients, they want to understand, on a human level, what the trial means to them. We provide sites with interactive videos that explain, in patient-friendly terms, what the study involves. This reduces fear and confusion while encouraging potential participants to open a dialogue with site staff and ultimately make an informed decision about whether to participate.

In short, patient empathy in a trial setting means we always consider the trial through the lens of the patient and the site staff, and our recruitment approaches reflect their needs and preferences.

Passive Listening and Active Engagement

On a more structured level, the industry is now routinely convening site and patient advisory groups to address specific aspects of a particular study and fully understand the patient experience. It's critical to use both passive and active listening to encourage open and constructive dialogue, and to drill down into the specific protocol requirements. For example, in an asthma study, what are the patient concerns about switching from one inhaler to another? Is a mother of three more likely to join an asthma study if a home nurse visits and takes her child's peak flow measurements before school instead of having to drive her child to the clinic? It's imperative that we obtain actionable feedback to inform real-world study designs that parents, busy professionals, grandparents, teens and kids can work into their routines without too much burden.

In other words, studies must answer critical scientific and medical questions, but patients can help tell us whether the studies will be successful in answering them.

The Pandemic as a Teachable Moment

It's hard to think of a pandemic in terms of silver linings, but COVID-19 has given us teachable moments that we can't afford to ignore. The pandemic has brought to the surface the critical need to address emotions that drive patient behaviour: fear of the unknown, reassurance from trusted experts, altruistic versus personal motives (e.g., protecting oneself or protecting society at large). These are enduring human traits that technology and data will never overcome.

In many respects, the future of patient-centric trials has already begun. But while there are huge advancements in technology, big data and AI machine learning, we must remember that our

industry is made up of real people whose interactions with patients can demonstrably enhance recruitment and retention: Talking with patients in authentic and compassionate ways; engaging them as partners in the fight against their disease; and empowering them as advocates whose participation in clinical research gives them control over their conditions can shift their perspectives from fear and powerlessness to strength and a desire to contribute to the greater good.

The Comforts of Home: A Paediatric Study Keeps Kids in Their Own Beds

In supporting a two-year study evaluating a night-time sleep aid in young patients with a rare disorder, our company recognised how intrusive it would be on patients and families to sleep away from home or require numerous site visits. Our solution was a hybrid decentralised trial that provided child-friendly actigraphy watches that unobtrusively collected sleep quality data, combined with at-home nurse visits, direct-to-patient drug shipments, eDiaries, and only three in-clinic visits over the course of two years.

The approach not only worked, but we also attracted patients from as far as 150 miles from the investigative site. Patients and their families gave us positive feedback and told us they would not have been able to participate in a traditional study. They especially appreciated the flexible visit dates and times for home nursing visits to minimise schedule disruptions.

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Tom Ruane brings more than 28 years of experience in clinical research operations to Parexel. For the past 18 years, he has worked across the industry to drive innovative strategies for patient engagement and recruitment for clinical trials. Tom began his career as a registered nurse caring for patients in a critical care setting and has a keen understanding of the patient experience, drawing upon patient insights to drive successful trial outcomes. His strategic roles at biopharmaceutical companies, CROs and the UK National Health Service have provided a holistic view of the clinical trial recruitment landscape, which he applies to advance patient recruitment and retention strategies.

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