Changing Ways

Recruitment rates can be improved through increased patient-centricity, whether that be through transport, study design, or remote monitoring initiatives, to minimise administrative and practical difficulties

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For many patients across a wide range of therapeutic areas, participation in a clinical trial can provide access to important life-saving medications. However, the efficient conduct of studies has long been complicated by complex protocols, inefficient recruiting methods and logistics that can make participation burdensome, if not impossible. Consequently, numerous trial sponsors, CROs, and clinical services companies are striving to facilitate patient access to studies while also making the trials themselves more patient-centric. In addition to improving recruitment processes and easing the burden of participation, such efforts are largely designed to enhance patient engagement before, during, and after the study.

While the challenges surrounding patient access, retention, and engagement are not new, surmounting these requires new approaches to trial design and administration. Already, some sponsors and CROs are incorporating patient input into study design to align clinical endpoints with patients' priorities for health outcomes. On the legislative front, citizens and lawmakers in several US states are seeking to pass 'right to try' laws intended to enhance access to experimental drugs, especially for terminally ill patients. Nonetheless, such initiatives will not be sufficient unless they are accompanied by efforts that improve the patient experience.

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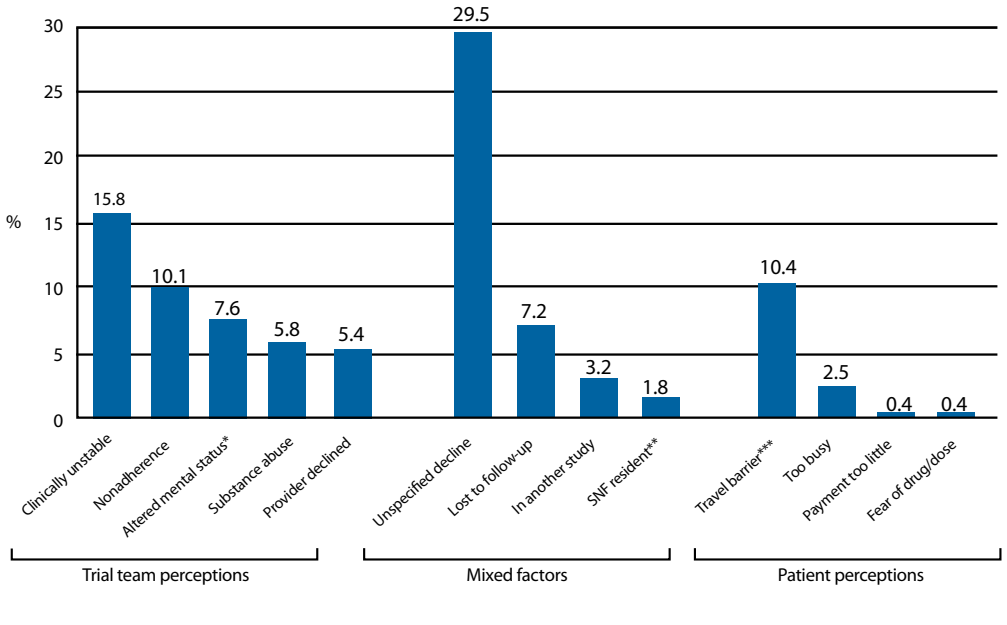
Transportation Resolutions

Historically, transportation costs have constituted a very small portion of clinical trial expenses. However, when patients lack reliable transportation, this can lead to no-shows and dropouts, which significantly impact study costs and results (1). A National Research Council report identified inadequate transportation as a major contributor to a 30% dropout rate in Phase 3 trials, noting that the problem worsened over the course of lengthy trials (1,2). Factors such as travel distance and intensive trial-related testing schedules are often cited as barriers to participation, especially among patients considered for lengthier trials and the elderly, as well as for those with challenging disease profiles for whom transportation can be very difficult (3).

Their reputational issues notwithstanding, disruptive innovators such as Uber and Lyft have created a fundamental shift in the transportation industry, reinventing how we think about providing services. By decentralising the business infrastructure, reducing overhead costs, and making transportation more convenient, these companies have revolutionised the way many consumers get around. Furthermore, they may offer a model for upgrading patient transportation options to improve trial participation and patient retention. Indeed, ride-sharing companies are pursuing partnerships that offer patients the convenience of prepaid and prescheduled solutions, potentially removing a major impediment.

A recent survey of approximately 430 clinical trial sites in the US revealed that 44% of these sites offer free transportation assistance to trial enrollees, and 32% of sites that offer these services use ride-sharing companies (4).

Such services include the recently launched Circulation – an independent ride-booking service that uses Uber's technology, enabling management of trial participants' rides to study centres via real-time tracking of patient location and allowing patients to interact with the system via text messaging (1,5). Similarly, a pilot programme of Concierge – a joint venture of Lyft and National MedTrans that provides non-emergency medical transportation rides – reportedly yielded a 30% average wait-time reduction, a 32% reduction in costs, and



Source: Marrtin SS

* Including dementia and delirium ** Skilled nursing facility *** Travel distance and transportation barriers

Figure 1: Distribution of 278 subjects: Primary reasons for not participating in a cardiovascular clinical trial

an 80% improvement in patient satisfaction between May and June 2016 (6).

Enhancing Patient-Centricity

Transportation barriers are just one of the many reasons that patients do not participate in clinical trials or drop out once enrolled (Figure 1) (3). Addressing other elements of trial participation can yield incremental improvements that may enhance patient engagement, shorten enrolment timelines, minimise attrition, and improve patient retention and adherence to trial protocols.

One approach is to make clinical research more patient-centric through the implementation of remote or site-less trials, also known as direct-to-patient clinical studies. This approach puts individuals, rather than sites, at the centre of the research process, enabling them to self-enrol and participate without visiting a traditional study site. Patient burden is further reduced through use of remote and electronic data capturing technologies, allowing patients across many geographic areas to submit data to a central study coordination centre. These technologies also permit researchers to collect and analyse data and conduct long-term follow-ups, while facilitating consistency checking, data completeness, and detection and monitoring of errors and protocol violations (7).

Site-less trials are increasingly viewed as a means to attract a broader, more diverse patient population – one that is increasingly comfortable using data collection technologies. When supplemented by services that allow at-home participation (eg home nursing and telemedicine), site-less trials may also facilitate recruitment and retention of patients who are generally inclined to participate in clinical research, but loathe enduring the hassle of frequent visits to distant sites. This model is considered especially suitable for trials involving patients with neurodegenerative conditions, such as Parkinson's, Huntington's, and Alzheimer's disease, and may enable greater participation of geriatric and paediatric patients, as well as those residing in remote locations (8).

Remote Monitoring

Wider adoption of the site-less model may be fuelled by the use of wearable sensors that can remotely measure physiological indicators, such as activity levels, sleep, blood pressure, heart rate, electro encephalograms and cardiographs, weight, and blood glucose. When adequate security measures are in place, use of wearable technologies in the home setting can enable real-time transmission, collection, and monitoring of data through deployment of compliance dashboards that track parameters affecting patient safety, data quality/variability, and engagement.

De-identified data collected through mobile devices, integrated with the full patient dataset, can yield more objective information with a more transparent audit trail than that offered by traditional outcome assessment instruments, potentially improving data quality, reducing patient burden, and enhancing patient engagement (9). Remote monitoring can also facilitate provision of informed consent and verification of critical source data – eg laboratory and radiology reports and adverse events – and objective endpoints (10).

Leveraging Technology

Although the site-less model holds great promise, it is still in its infancy and may not entirely replace the traditional site, within which transformative direct-to-patient opportunities abound. Elligo Health Research, through its Goes Direct™ approach, aims to remove barriers to patient participation and retention by targeting the 97% of physicians and patients who do not currently participate in clinical research. Using electronic health records and other health data, Elligo identifies candidates for clinical studies and provides their physicians with the requisite personnel, processes, technology, and infrastructure for conducting studies in their own clinics. Thus, the Elligo model allows patients to participate in research with their own physician at a site that is close to home (11).

ThreeWire, a specialist in clinical trial recruitment and direct-to-patient marketing, offers a variety of technology-enabled services to improve patient enrolment and retention. The company deploys Enrollment Assistants™ at selected sites to enhance enrolment and further supports patients with offerings such as Community Health Talks and a Patient Interaction Center®, which is designed to facilitate screening and follow-up while optimising the patient experience (12).

Clinical Trial Design

A logical extension of the patient-centricity movement is to involve patients in clinical trial design. PatientsLikeMe, which bills itself as "the world's largest personalized health network," is used by more than 500,000 individuals to find new treatment options and share information about more than 2,700 conditions. Members have generated 40 million data points to create "one of the largest repositories of patient-reported, cross-condition data available today," information that informs clinical trial design and "help[s] the healthcare industry better understand the patient experience" (13).

Similarly, the European Patients' Academy on Therapeutic Innovation (EUPATI) is a public-private partnership that provides training and educational resources to enhance patients' and advocates' understanding of drug R&D, as well as helping them become more actively involved in clinical development. With its database of patient experts, EUPATI facilitates patient collaborations with academic and industry researchers, regulatory authorities and ethics committees, and has trained a cadre of patient advocates who have participated in "patient involvement activities" across the R&D continuum, including all phases of preclinical and clinical trials, regulatory approval and post-approval activities (14).

Such services are particularly well-suited for rare disease communities and can also be extremely valuable to patients with more common conditions. For example, patients with kidney disease who require dialysis three times a week or often suffer from diabetes, heart disease, or other comorbidities, have specific needs that must be accommodated within a trial protocol. Involving patients in trial design and engaging a CRO with an understanding of clinical care specialising in kidney disease trials can be critical to driving patient enrolment in these studies.

Transforming and streamlining clinical trials will not be simple or instantaneous. However, adopting new patient-centric models can help the industry take steps to address the bottlenecks in clinical development by accelerating enrolment and improving patient retention. As new solutions continue to emerge, the industry must keep developing and exchanging ideas so that patients can be better connected to clinical research that advances medical understanding and improves treatment outcomes.

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About the author

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