Improving DCT Technologies for Efficient and Personalized Delivery

Clinical research execution is rapidly moving out of the clinic into a range of novel decentralized trial settings. Scores of different approaches are emerging that promise to bring trials to patients with more convenience and choice.

If the future vision for clinical research is focused on open, flexible, and personalized execution, there are significant operational challenges to solve before decentralized research can be delivered in a cost-effective and efficient way.

A recent Tufts CSDD study identified a host of specific challenges that drug developers routinely face in the implementation of DCTs. This article explores potential solutions based on best practices and novel trends for many of those challenges related to data and technology.

Technology that Prioritizes the Patient

While clinical trial technology has earned a reputation for prioritizing the needs of the pharma buyer at the expense of the end users, there are many promising signs of improvement with current data capture and patient engagement solutions, as consumer practices influence technology design.

Start with Protocol Design to Select the Right Technology

Technology can either be a major help or a hindrance in reducing patient burden if not integrated into the protocol. During DCT protocol design, key questions that should be considered upfront include: What are the experiences a patient is willing to go through and how can you do it more effectively? If it's a question of follow-up assessments, telehealth may not always be the right option. With some conditions and patient populations, home nursing may work better. Similarly, mobile app alarms often help with medication or assessment adherence, but are not ideal for all conditions, especially those involving debilitating headaches or similar ailments. Patient feedback, through a combination of surveys, roundtables or in-depth interviews should always inform technology selection.

Essential Design Practices for Technology

DCT solution developers are increasingly adopting conceptual design practices to gain deeper insight into how human characteristics impact technology. A first step is the discipline of practicing empathy in design thinking, which involves in-depth research, journey mapping, and even role play. Mapping the emotional journey is foundational to uncover opportunities that clarify and simplify user experiences. "Exploring and capturing immersive patient experiences take time and resources, but it's our job to make clinical trial technology easy, accessible, and enjoyable," said Mike Hughes, Chief Product Officer, YPrime. Organizations such as Life in a Day provide role play and theater techniques to reflect the reality of daily life with chronic conditions and can be a valuable resource for product designers.

Integrated UX

Consumer trends from every software-reliant industry clearly indicate that users want single, holistic experiences and high-quality interactions. "One app that easily integrates all data sources across different providers and automates the data flow through the
whole process is the holy grail for a unified patient experience in a clinical trial," added Hughes. Delivering an integrated experience for patients throughout a clinical trial requires moving away from point solutions, leveraging existing workflows, and integrating with other core clinical trial data systems to simplify data flow and help accelerate clinical trial timelines.

UX Design Tips from Neuroscience Research

The most modern experience design techniques incorporate neuroscience-based techniques to explore user interactions with technology on a deeper level, based on the brain's preference for patterns and lazy decision making. Advances in eye tracking, biosensors, electroencephalography have unlocked a host of new insights into users' on-screen behavior. Essential UX neuroscience-based design considerations include:

- Clean and simple interface designs that prioritize minimalist aesthetics and information
- Visual cues that indicate the next step
- Information organization that places key information in F or E patterns
- Color and contrast to guide the eye to important elements or understate other information
- Enhanced visualization such as providing the user with the ability to view animations that guide the user through every task required in a clinical trial assessment
- Shorter content that incorporates chunking to improve the user's ability to process and remember

As with so many things, these new methods are most effective when used in combination with UX research and traditional methodologies for a deep dive into user behavior and needs.

User Support

One unintended consequence of DCT adoption is the investigator site inevitably becoming a helpdesk for patients, which can result in negative user experiences for patients and sites, who already face severe staffing challenges. While it's critical to provide robust logistical and technical support for patient engagement and compliance, companies like Current Health are taking it to the next level of experience. Following their 2021 acquisition by BestBuy, the remote home care provider is now exploring uses of the Geek Squad model from their parent company to support sensor use in the home for elderly patients, with plans to expand into chronic disease, post-hospital care and eventually into acute care.

Data governance

Based on research conducted by Tufts CSDD, the average Phase III clinical trial conducted ten years ago collected approximately one million data points. Data volumes today are more than three times that amount. This trend will accelerate rapidly with DCT adoption predicts Saama Technologies, who recently presented on next generation clinical data management and programming at the DPHARM 2022 conference. Their analyses concluded that over 60% of current clinical trials have more than 10 million data points.

The way data are collected and stored presents an even greater challenge, because there is a vast array of fragmented data in different formats that don't talk to each other. As the variety of technologies that support a DCT continues to increase – from eConsent, eCOA, EDC, labs and biosensors and other data sources, so does the risk of duplication, error, and inefficiency.

That is why a solid data governance strategy is critical to manage the increasing volumes of data and also the rising complexity associated with expanding data sources, which often challenge the integrity of data and clarity of ownership.

Data governance is a framework that enables organizations to get the most of out their data. Within clinical research, data governance identifies data collection strategies, defines standards for use and processes for data management, and explains methods for data integration. A well-managed clinical trial data framework will contain standardized data management processes, centralized collaboration tools, open standards to promote flexible, scalable processes, and data retrieval mechanisms that enable fast access. The four pillars of data governance include data quality, acquisition, integration, and consumption.

Data standards

Consistent data standards are foundational to ensure quality and efficiency. A standards-driven approach enhances the value of data ensuring data are easily stored, aggregated, and quickly retrieved for use and re-use; to support internal decision making, regulatory and reimbursement strategies, and good product stewardship among many other potential uses.

The full potential of artificial intelligence (AI) cannot be achieved without widespread adoption of data standards. With data standards, AI can accelerate adoption of a more comprehensive virtual clinical trial, through a greater reliance on virtual assistants, adherence tools, as well as remote monitoring and data collection solutions that don't require face-to-face administration and oversight.

On a broader level, adoption of common data formats will significantly shorten overall development timelines and reduce redundancy of siloed efforts. Organizations such as CDISC and Transcelerate are working to improve integration and support greater interoperability in clinical research.

Collaboration is an Essential Operating Component

For the last decade, a host of concerns about new burdens introduced by expanded data sources and technology solutions have been well-documented. "These trends aren't inherently negative," declared Shawn Blackburn, YPrime CEO. "Technology enables many benefits across speed, precision and quality and more data gives us richer insights. But fragmented technology solutions create more challenges for sponsors, CROs and their research partners. The era of DCTs - and the intersection of digital transformation with patient experience in trial delivery takes this complexity to a new level. Much of the future success depends on cross-functional collaboration to reduce redundancy and create efficiencies." The future of decentralized research in an on-demand, consumer-driven space requires new approaches to collaboration among sponsors, sites and CROs, technology providers, and specialty logistics alongside advocacy groups, caregivers, and patients.

Management consultant leaders Deloitte and Accenture have written extensively about the evolution of partnership strategies, away from transactional models to growth engines as a call to action for large providers to move out of their comfort zone to successfully step up innovation. Within clinical research, effective partnership now involves long-term collaboration that requires early pipeline engagement, co-creation, and joint investment to extend capabilities and accelerate innovation on a therapeutic, indication, or portfolio level to create more complete solutions to meet patients' needs and deliver better outcomes. "Collaboration is particularly critical for technology in this space. There is rising interest in co-investment from sponsors and CROs looking to create unique solutions on top of standard platform offerings," added Blackburn.

As patient demands intensify, digital transformation will connect the siloed clinical research ecosystem and enable much-needed efficiency to streamline trial execution. In the near-term, data standards through open platforms are urgently needed to encourage broad participation and reap the benefits of AI and big data analytics.

Partnership models still need to mature, aided by the rapid growth of DCT solutions and data collection technologies. Looking forward, the gains of the past three years can provide the impetus to advance the potential for transformative change. As more organizations look to increase adoption of DCTs, the ability to develop a collaborative ecosystem to deliver a personalized, end-to-end solution will be essential for success.