Enhancing Decentralized Clinical Trials Through Advanced Digital Platforms

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The Shifting Paradigm In Clinical Trials

For the past several years there has been an increasing shift in the clinical trial industry from studies conducted in hospital or clinic settings to decentralized clinical trials (DCTs) conducted in the patient's home. The convenience and flexibility of DCTs have been shown to reduce or eliminate the need to travel to a specific site, boosting patient engagement and optimizing the trial experience. Retaining patients and keeping them actively engaged in a trial is a key issue in centralized studies, and MRN's focus on in-home decentralized services addresses the problem by bringing a patient-centric approach to clinical trials.

Enter The Advanced Digital Platform

The central goal of DCTs is to ease the patient burden and maximize participation — and innovations in digital platforms and technology offer an entirely new level of empowerment and engagement in implementing a decentralized trial. The interrelationship between an advanced digital platform and a DCT creates a product and service offering that integrates and unites software tools and technologies with smart devices, enabling patients and staff to remotely communicate trial data and information from the home setting. In addition, by meeting the regulatory and data privacy requirements in a clinical trial, a digital platform potentially offers a regulatory compliant solution to collecting the data mandated in the trial protocol. Given the powerful innovation of digital technology platforms, a tremendous opportunity now exists through the use of mobile technologies to transform the way decentralized clinical trials are designed and implemented. Yet, innovation is hard.

Challenges To Adoption

Gaps In Awareness And Application Of Technology

In March 2019, Scott Gottlieb, MD, former commissioner of the Food and Drug Administration (FDA), announced the modernization of clinical trials as an agency-wide priority, emphasizing that such innovations can help patients gain earlier access to important new therapeutic options through the use of mobile technologies and innovations in trial designs. In his statement, however, he also noted that there is "continued reluctance among sponsors and clinical research organizations to adopt innovative approaches to trial design." Some of the hesitancy on the part of the clinical trial industry can be attributed to a major awareness gap of the possibilities an advanced digital technology platform can provide to a DCT. Another challenge to widespread adoption has been global clinical trial regulations that have not kept pace with the rapid growth of digital tools and technologies.

Data Privacy Concerns

Data privacy and the sharing of personal data is another major hurdle facing the adoption of a digital platform. Some of the significant privacy challenges include:

- Understanding and complying with changing data privacy mandates and regulations for each country, especially the U.S. patient protection requirements
- Confirming patient identities — ensuring that the patient recording the data in the mobile device is the actual patient
- Tracking the delivery of the medication and verifying that the patient has actually received the correct drug and has taken it as prescribed by the study protocol.

As digital platforms and DCTs continue to move forward and evolve, privacy considerations will require innovative solutions to address these concerns. One recent approach to patient confidentiality initiated by hospitals during telemedicine visits is to blur out a patient's face during the assessment process, so that the information is accessed without visual identification of the person. Newer software designs that protect patient privacy are also constantly being explored and developed.

Addressing Information Overload

Another barrier to adoption has been the plethora of complex information and acronyms used to describe platforms and digital technology. Keeping current with these terms can be overwhelming, requiring a new

level of education and understanding. While advanced digital technology offers remarkable innovations for DCT design and implementation, the ability to fully master and apply this information — coupled with the myriad regulatory and data privacy mandates — creates additional barriers to the universal acceptance and use of digital platforms in DCTs. Working with decentralized trial experts such as MRN can move the clinical trial industry past many of these operational and technological hurdles and begin to incorporate advanced digital technology into clinical trial design.

COVID And The Digital Leap Forward

In spite of the many challenges to the adoption of advanced digital platforms and technologies, the impact of COVID-19 has been a major catalyst in driving the use of technology in the DCT environment. Even prior to the pandemic, hospital systems were embracing digital technology to streamline processes and eliminate unnecessary paperwork. Hospitals have pioneered the use of telemedicine for patient assessments and follow-ups, online appointment requests, and electronic patient registration, providing convenient and readily accessible patient information and communication via the internet and mobile devices.

The arrival of COVID dramatically moved the clinical trial industry toward decentralized trials since patients could no longer travel to sites. At the same time, this use of this technology also flowed into the clinical trial ecosystem, which is central to MRN's decentralized in-home services. While barriers still exist, digital technologies are transforming the way clinical trials are designed and implemented in a myriad of ways.

Mobile Technology For Remote Data Collection

In a traditional trial, data would be generated at the site, initially on paper, and then inputted into an electronic health record (EHR) or an electronic medical record (EMR) system. The use of an advanced digital platform now enables the capture of patient data at the DCT site. Healthcare professionals (HCPs) making home visits to administer the trial drug, draw blood or perform wellness checks can use digital technology in which the visit report forms (VRFs) are accessed via a mobile app on an iPad and then connected digitally to the EHR or EMR system. The use of iPads by MRN's HCPs has reduced the burden of paper-based forms that can now be completed on a smartphone or tablet through the iPad connection. Providing an iPad to the HCP also ensures that the data collection processes are more compliant with the data management and privacy requirements of the trial protocol, truly taking advantage of the powerful benefits of a digital platform.

eConsent

Telemedicine technology can also provide patient consent using electronic, or "eConsent technology" via a mobile device. If the patient has a question, they can use the advanced platform to set up a telemedicine call to facilitate the consenting process. Telemedicine can be further enabled through the use of the iPad's image capture, increasing the connectivity of the devices for data monitoring.

Direct Data Capture And ePRO

Direct data capture (DDC) refers to the ability to capture data directly from patients at the time of the home visit and have that data stored onto a digital platform. Another tool for capturing patient data, is electronic patient-reported outcomes (ePRO) software, systems that enable patients to report their symptoms and other health-related information through a mobile device, such as a smartphone or tablet. An ePRO system can also generate appointment reminders, questionnaires, and other validated instruments within the ePRO platform to help maintain patient compliance and engagement. With MRN's focus on patient centricity in clinical trial design, the ability to collect patient data electronically through the use of smart devices and wearable devices — plus having that data available as part of the study anywhere, anytime — can benefit both the patient experience as well as the continuing quality of the data.

Advancing The Era Of Digital Clinical Trials

Another boon to the advancement of digital platforms — including the ability to address many of the challenges — has been the rise of various stakeholder organizations that are actively collaborating in moving

decentralized trials forward. As a founding member of the Decentralized Trials Research Alliance, MRN is focused on the adoption of patient-centric decentralized clinical trials, as well as advocating for the value of advanced digital platforms in accelerating patient access to innovative medicines, particularly in those areas where there's the greatest medical or social need.

Despite the pandemic, MRN has averaged more than 1,600 home trial visits per month, bringing more trials into the decentralized clinical trial environment and enhancing their capabilities and services. Whether it's virtual patient visits using telemedicine services or a hybrid deployment model, MRN's focus is on bringing the study and support services to the patient. Advanced digital platforms can further enable these services by making DCTs faster and more efficient in bringing technological and therapeutic innovations to the patient-participants.

Ultimately, MRN's digital health strategy and mission is to assist CROs and sponsors in the development of successful decentralized trials by being sensitive to the needs of the patient, as well as the site, through the integration of advanced digital platforms with patient-centric Home Trial Support services.

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