The Shift Towards Digital Technology for Clinical Research

Remote patient participation and trial monitoring can avoid the high risk of hospital visits

In the wake of COVID-19, running clinical trials in patients' own homes became a reality. The US and Europe were quick to adopt this approach, with roughly 45% of clinical trials in progress during the pandemic moving to digital platforms.

However," Japan has lagged," says Motohide Nishi, Vice President of Japan Professional Services, Medidata, a Dassault Systèmes company. " But there are ways to accelerate and optimize technology strategies for remote patient participation monitoring," says Nishi.

"Today's clinical research and development requires digital technology, tools, and strategy. Now more than ever, we must prepare clinical operations to respond rapidly, handle problems flexibly, and choose the best tools.

Tool selection depends on ease of use, speed of implementation, usability of the data source, scalability, and cost. "Our overarching aim is to reduce the burden on patients and sites, and we support that by creating a seamless data flow," he adds.

A number of lessons from the pandemic can inform future trials, says Nishi.

1. Adopt Decentralized clinical trials (DCT) to enable a rapid response

“We must be prepared to handle future issues promptly,” says Nishi. He recommends sponsors move to virtualize operations where practical, and devise a long-term strategy. Centralizing the data is vital for ease of use, just-in-time access, remote data collection, and data availability.

Sponsors need to review the usability and scalability of data in their system and select the best and most cost-effective tool for their studies. Accumulating the know-how to execute clinical trials virtually can take time. However, it’s important to be prepared for the future.

2. Adopt digital recruitment and patient consent strategies for inclusive clinical trial participation

For a clinical trial to be viable, it needs to recruit enough patients and obtain the patients’ consent for participation. “A long-term digital strategy helps us complete trials in progress now and start new ones,” says Nishi. Of primary concern is recruitment and enrollment: new enrollment has actually fallen 79% during the past 12 months, since the pandemic began. Also, for Japan, he emphasizes, “patients in regional areas should be able to participate, and they need digital tools to do so.” However, supplying patients with tools is not enough to carry out a clinical trial virtually. Adjusting workflow for the process from recruitment to enrollment are essential. “The key is to enable patients who do not live near city centers to participate”, Mr. Nishi stresses.

Medidata eConsent, allows patients to sign up for clinical trials on mobile devices or the web, to learn the potential risks of a study, and to watch short videos to understand other aspects of the study. Its use in Japan is limited now but interest is growing because patients benefit from not having to leave their homes for site visits. With this solution, the patients can communicate with their clinician using video chat. In partly or mostly decentralized trials, the patient experience can begin with a virtual meeting with their clinician. This virtual experience also enables more interactions.

3. Leverage wearable devices to ensure patient safety and to decrease their burden

Once patients are enrolled and participating, sponsors must ensure the safety of patients. Investigators need to deal with any adverse events as soon as they occur. By using wearable sensors, it allows them to identify something "unusual" earlier, and to review real-time data collected from patients using the devices. Wearable sensors may even increase patient engagement, Nishi says, because they can collect objective data automatically, and could lead to decreased site visits and reduced patient burden.

4. Allow patients to report their PRO data through mobile devices to ensure trial integrity

Medidata has an electronic Clinical Outcomes Assessment (eCOA) solution, used in more than 900 clinical trials across 70 countries in more than 100 languages. Patients or caregivers can enter data remotely through an application on their mobile device.

Medidata developed its patient portal, myMedidata, which includes eConsent and eCOA, providing patients easy access to this functionality. Here, patients can consent to the clinical trial online, see virtual visit scheduling, and confirm all other activities online. Once the trial is completed, the patients can access their own data from myMedidata.

With all the data in one place, the investigator can support patients as well as monitor patient safety and data quality.

5. Facilitate remote monitoring of site data to assess risk

Access to the site data and documentation remotely provides continuous access to critical documents and data, improving the monitoring of safety and data quality. Nishi says, “By implementing continuous remote monitoring, clinicians can assess risk and make adjustments to the trial in real-time, enabling clinical trials to run smoothly.” As one would expect, remote monitoring had explosive growth during the pandemic.

Medidata solutions to facilitate a timely and efficient technology implementation

The Medidata Clinical Cloud, a unified life sciences platform, comprises multiple solutions supporting end-to-end drug development. As the only unified technology platform dedicated to clinical research, the Medidata Clinical Cloud addresses the holistic research process from start to finish. This platform helps life science and medical device organizations cut development costs, mitigate risks, and deliver treatments and devices to market faster. The Medidata Clinical Cloud works seamlessly with existing systems and can easily support small Phase I studies through large global programs.

Lessons learned from the COVID-19 pandemic

Nishi stresses how much the pandemic has changed our lives and livelihoods. We began to realize that we did not have enough experience working in a virtual world. It was not only implementing digital strategies or just using platforms. We also had to rethink how to turn manual tasks into automatic processes and collect reliable data in real-time.

“How do we create an end-to-end platform to increase the productivity of drug development? There are so many different systems to integrate. There’s hospital system data, lifestyle data, and clinical data. Is there a future when all of these will be integrated?” says one pharmaceutical executive participated in a Reuters Events: Pharma Japan session on the subject.

Nishi answered, “There is a future, a bright one”, yet “We must ensure patient safety and usability of patient data first of all and need to cooperate and work all together with those who are involved in clinical development -- pharmaceutical companies, academia, and government.”

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