CXO INSIGHTS

OPTIMIZING CLINICAL TRIAL DECISION-MAKING

A discussion with **Ravi Ramachandran,** VP, Head of Product and Technology, PPD® Digital

Ravi Ramachandran, Vice President and Head of Product and Technology, oversees PPD® Digital's product development and technological innovation initiatives. Having spent most of his working life in the clinical trials space, he started his career developing biomarkers in clinical trials and enabling the provision of centralized expert services for pharmaceutical companies. With the advent of wireless technologies, Ramachandran was an early adopter of digital health technologies, which he leveraged to collect data for optimizing clinical trials. In this interview with Pharma Tech Outlook, Ramachandran discusses the significance of contextual data and the need for technologies that accommodate trial participants, such as sensors and wearable devices, to obtain a more holistic view of their condition during the clinical research process.

How have sensors and wearable devices been used to decentralize clinical trials and reduce the burden on clinical trial participants?

The use of sensors and wearable devices clearly decentralizes clinical trials, minimizes the need for visits to brick-and-mortar clinical sites and allows people to participate in studies from the comfort of their own homes and around their schedule. Having a powerful tool, like a virtual decentralized clinical trial platform accompanied by wearable devices and sensors, facilitates the collection of physiologically relevant endpoint data from participants in a trial. But it is mandatory that an organization maintain a healthy balance between its desire for actionable data and maximizing participant convenience. So, the decentralized platform should provide an easy-to-use, intuitive, low-friction experience for participants while curating the data needed to drive decision-making in clinical trials.

What are some of the factors that are leading to the push toward decentralization of clinical trials?

Digital technologies are not new and have extensive footprints in the pharma industry. With the pandemic, the whole perception of digitization has shifted from nice-to-have to must-have as clinics were hesitant to accept people and many participants were unwilling to visit clinics. Consequently, there was a fundamental need to shift toward virtual and decentralized clinical trials. On top of that, regulatory agencies—the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), for example—were pivoting toward using real-world data for regulatory decisions, drug approvals and new treatment approaches. Remote monitoring also has been gaining massive traction in the industry as it helps to make clinical trials more participant friendly. All these factors are simultaneously steering clinical trials onto the digital bandwagon by reducing participation barriers with advanced decentralized trial technologies. This enables greater involvement in clinical trials and allows people to more easily access innovative therapeutic and treatment regimens.

How do sensors and wearable devices affect the objectivity of data, functions of clinical trials and long-term follow-up studies?

I've had years of experience working with pharma companies and helping them run clinical trials, where we've deployed digital tools—sensors and wearable devices—to precisely assess the individual's day-to-day functions. In addition to that, we use participant-reported outcomes, which is a set of questions used to gather data on an individual's physical condition. Unfortunately, these two models can contradict each other when it comes to a person's data. While participant-reported outcomes can result in positive remarks on an individual's physical condition, information curated by sensors and wearable devices could present a different picture. For example, while a trial participant may self-report that he or she is feeling "fine," the technology may show that the person is moribund, sleeping a lot, etc. While we have to be respectful of the "patient voice," we also should build into the decision-making process the objective data from sensors and wearables.

Another way wearables help is by providing a holistic view of trial participants' lives. For instance, while running a diabetes study, we have to measure the person's glucose level. In a typical clinical trial, we provide individuals with a glucose monitor and measure their glucose level at various intervals to identify variations. But that data, while important, only tells a portion of the story. In order for organizations to arrive at better decisions, they need to contextualize data with additional information like insulin dose intervals, food habits, exercise patterns and more. This can be achieved by providing a wearable along with the glucose monitor. Now, by combining the data from sensors or wearable devices, glucose monitors, and participant-reported outcomes, sponsors can better understand how a single data point reflects an individual's condition.

Ravi Ramachandran

> **Having a powerful tool, like a virtual decentralized clinical trial platform supported by wearable devices and sensors, facilitates the collection of physiologically relevant endpoint data from participants in a clinical trial**

How will the data obtained enable better decision-making?

Historically, during clinical studies, individuals are brought to a clinic to assess basic information (such as height, weight), collect samples and even to ask them a set of questions on their physical condition. Furthermore, sensor and wearable device technology has made it possible for example to obtain ECGs from the participant's home. Instead of a 12-lead ECG machine that is used in a typical clinical study, organizations now have six-lead portable ECG devices that provide similar data and a better participant experience. Having a virtual platform along with sensors and wearable devices, organizations can get data almost every second as opposed to a few data collection points with conventional clinical visit models. In addition, with decentralized capabilities, organizations are able to better understand how trial participants behave in the real world in the comfort of their homes. This helps generate more accurate and reliable data of their lived experience, which can enable making better decisions. Further, the exponential increase in data availability enables them to make better-informed decisions by providing a more holistic view into participants' conditions throughout the trial period.

Could you talk about the differences related to the application of these devices for patients in clinical trials?

Sensors and wearable devices are creating a massive difference in the way clinical trials and related processes are being conducted. Primarily, they can add value to clinical trial data by providing a better and more contextualized holistic idea of the participant's basic parameters, such as temperature, heart rate, respiratory rate and more. They also can enhance information on the person's quality of life, where their energy expenditure, sleep pattern, sleep quality and such are measured. Another aspect these technologies excel at is measuring the gait—not just the number of steps, but also the movement pattern, such as single, double-stance time, postural sway, gait stability, stride length and more. These rich datasets provide organizations with valuable insights into the participant's neuromuscular condition.