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Connected Devices Experts Discuss Clinical Trial Device Selection In Upcoming Webinar

by Elizabeth Orr

As decentralized clinical trials become more common, trial sponsors are adopting digital health devices to track patient data in remote settings. Two connected devices specialists talked to MTI about device selection, including light shed on the topic by a recent draft FDA guidance document.

The growing number of decentralized trials with remote patient participation makes the role of digital health technologies and connected devices in collecting patient data increasingly important. While a recent *draft guidance document from the U.S. Food and Drug Administration* provides some practical information on factors that sponsors and investigators should consider in selecting connected devices, the topic of remote data capture remains new and worthy of discussion, two connected devices experts told *Medtech Insight*.

Jessica Ekey, director of connected devices strategic solutions at health care analytics and technology consulting firm IQVIA, and Jen Ohme, strategy solutions lead in IQVIA's connected devices division, spoke to us in advance of a 14 June webinar, *Choosing the Right Device For Your Trial: A Consideration of FDA's Digital Health Technologies Draft Guidance*. The event is co-sponsored by IQVIA and *Medtech Insight* sister publication *Pink Sheet*.

During the 10 June interview, the IQVIA leaders discussed the benefits of connected devices in a clinical trial context. For example, collecting data directly from sensors worn by patients, such as via a wearable patch, helps provide a complete and accurate picture of clinical outcome measures, Ekey said. The use of patient-worn devices in a remote setting provides better data about how a patient is doing day-to-day, rather than only when they're visiting the trial site.

"You get a holistic viewpoint," Ohme said. "It's not just at one time point; you're seeing the actual patient's overall lifestyle and how that relates to their disease progression or improvements."

Ohme also said connected devices on remote trials help to serve health equity goals by allowing a broader range of patients to participate, such as those who don't live near trial sites. Additionally, collecting data remotely lessens the burden on patients by reducing how much time they need to spend manually recording data. It also opens trials to patients who may not be able to record data themselves due to age or other limitations, she said.

Guidance On Selecting A Device

What device is most appropriate for a given clinical trial will depend on the trial's clinical endpoints, Ekey said. The endpoint determines what digital measurements sponsors should track, which in turn directs device selection. For example, researchers who want to look at how a treatment being studied affects patients' heart rhythm as a safety endpoint would need to use a connected device that captures ECG data.

"We will work with a sponsor to determine, based on trial design and clinical endpoints, what type of device [the sponsor] can select and deploy in order to ensure that they're capturing the data needed to measure and support required endpoints," Ekey said.

> *"The FDA has created a practical guide to help sponsors and investigators who are looking at decentralized trials or hybrid trials navigate the incorporation of digital health tools." -- Jessica Ekey*

The recent FDA draft guidance may add clarity to the issue by discussing best practices in the growing field, Ekey and Ohme said.

"Especially with increased public safety precautions during the COVID-19 pandemic, more sponsors considered conducting studies remotely" in order to navigate local restrictions and to minimize patients' exposure to the virus, Ekey said. "The FDA has created a practical guide to help sponsors and investigators who are looking at decentralized trials or hybrid trials navigate the incorporation of digital health tools."

Ohme also noted that the guidance document explains how trial sponsors can balance remote device selection with other equal-priority factors in the design of trial data collection requirements.

"You don't need to think of [remote devices] differently, but you do need to think of it and you need to think of it in all the same ways," she said. "Just like when you're thinking about your

other data sources, it needs to be clear in the protocol, it needs to be in the informed consent documents, and it needs to be handled in monitoring and statistical analysis plans."

Registration for the 14 June webinar is still open at the link above.