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Expert View: Wearable Technology And The FDA Adoption Curve

The US FDA recently announced that it will carefully consider the value of mobile technology in clinical research. By and large, the process of testing and approving new drugs and therapies has remained unchanged for the past 50 years. Today, data collected in everyday devices like smartphones and wearable fitness trackers could make clinical trials safer for patients and provide meaningful data to the FDA, write Barbara Elashoff and Glen de Vries of Medidata Solutions.

Mobile technology is already shaping the way we think about personal health. Smartphones and activity trackers are now loaded with features such as step counting, sleep monitoring and pill reminder apps. These simple tools are helping millions of people take a more active role in monitoring their own health.

Responding to rapid advances in mobile technology, the FDA requested stakeholder input to help them evaluate how mobile devices can impact clinical research. Specifically, the FDA is interested in feedback on any technology that enables "remote observation." This includes devices spanning realms of mHealth, telehealth and wearable sensors – everything from push notifications on your smartphone, to tiny, tattoo-like electronics worn on the skin. Feedback was due in late December, and the FDA is currently reviewing ideas and recommendations from more than 35 stakeholders.

Today, almost every patient has a smartphone, but any health-related data the phone collects is ignored in research studies. That's because many of the devices available today were designed for the consumer market and need to be utilized correctly for a highly-regulated healthcare setting. Data will need to be collected with reliable, consistent, secure and privacy-protecting methods, but the transition won't take place overnight.

Glen de Vries

Contemporary examples show us that new technologies need to be vetted and there is an adoption curve before they are integrated into the mainstream framework of medical research. Theranos, a blood-diagnostics company, is in the midst of responding to scrutiny around its technology, while direct-to-consumer DNA company 23andme is just now getting past information barriers.

But the opportunities for remote monitoring far outweigh the challenges that lie ahead, because when used appropriately, technology is a valuable tool for clinical development. Data collected remotely can be used to augment, rather than replace, current validated tests. Even when used as a secondary outcome, remote monitoring data could offer additional insights on a new treatment, improve patient health, and might even impact the FDA's approval decision.

"Many folks in the traditional pharmaceutical and device space growl about FDA regulation, but in my opinion, the FDA provides a unique 'stamp of approval' for mobile technologies that have proven their worth," said John Hixson, Assistant Professor of Neurology at the University of California San Francisco School of Medicine and the San Francisco VA Medical Center, and an advocate for mobile health.

Remote monitoring is likely to make its debut collecting information for a primary outcome in diseases that are currently difficult to measure precisely. For example, some medical conditions such as rheumatoid arthritis or muscular dystrophy are often evaluated based on a patient's mobility with a "six-minute walk test." If a new treatment is working, presumably the patient will be able to walk further within six minutes. But this test is rife with problems; mainly, six minutes offers a tiny snapshot of a patient's everyday life. A better way to measure mobility would be to use a wearable device that is worn by the patient 24/7.

Another immediate impact of remote monitoring will be an overhaul of a commonly used tool called "patient reported outcomes" (PROs), essentially surveys that measure quality-of-life. For example, drugs for fibromyalgia, a chronic pain condition, are approved based on the results of a survey that quantifies each patient's self-reported pain level (from one to 10), and any recollection of instances in which pain got in the way of basic tasks like grocery shopping or cooking. The problem with data reported through PROs is that pain is subjective and thus difficult to quantify. With mHealth, we can improve on PROs by asking patients to rate their pain sensations instantly, or directly measure how pain medications change behavior.

FDA officials have publicly recognized the problems with traditional measurements like

PROs and six-minute walk tests. While they were once the best tools available, today we can do better, using technologies that already exist. Many doctors agree updating the clinical trial process will lead to better health for patients.

"The clinical trial community has been slow to adopt mobile data collection technology largely due to inertia and a fear of the unknown," said Hixson. "While it is true that some technologies still require proper validation, there is nothing preventing more mature mobile solutions and wearables from being integrated in parallel with the traditional data collection strategies."

In fact, according to Hixson, the FDA has been quite vocal in expressing its support for these forward-thinking solutions. "Engaging with the FDA early in the investigative process and setting clear expectations for trial design and outcomes measures is the right step forward," Hixson continued. By requesting stakeholder input, the agency is sending a strong message: it will not stand in the way of life sciences companies who want to incorporate these new wearables, apps and sensors into studies. In fact, the agency is now doing everything it can to encourage the life sciences industry to adopt new technologies that enable patients to take a more active part in clinical research. Some of the key issues being targeted by the FDA include improving patient engagement and participation in clinical trials, and the integrity of study data collected.


Barbara Elashoff

The path forward lies in focusing on individual experience to drive innovation in medicine with the goal of improving outcomes, adherence and quality of life for patients. By their very nature, wearable devices are a positive disruptive force collecting real-time, objective data. And, with time, they can offer the same integrity and rigor as other clinical trial data, and be easily embedded in future studies.

With continued support from the FDA, mHealth and wearable sensors in clinical research will become standard practice in the drug development process. And we'll be able to ensure patients – not just their diseases – are at the center of innovation, helping to bring treatments to the market in a way that's faster, less expensive and adequately addresses the everyday challenges of those who need them most.

Barbara Elashoff and Glen de Vries, Medidata Solutions

Barbara Elashoff is the product manager for risk-based monitoring at Medidata. Prior to her current role, she was the founder and CEO of Patient Profiles, LLC, which was recently acquired by Medidata. She was also a statistical reviewer at the FDA in the Division of Pulmonary and Allergy Drug Products division. Glen de Vries is the president and co-founder of Medidata.