Getting the Most out of Wearable Technology in Clinical Research

The pharmaceutical industry continues to face a deeply entrenched set of challenges as companies develop new medical products – including declining clinical trial patient enrolment and retention rates. Fortunately, there are a growing number of innovative technologies with the potential to address this problem.

By capturing continuous data from patients via mobile wearable technology, clinical trial sponsors may be able to reduce the burden of frequent site visits, which could improve patient dropout rates and overall clinical trial efficiencies. How sponsors, regulators, solution providers, and other stakeholders manage this opportunity could go a long way to deciding the shape of clinical trials in the years to come.

Changing the Paradigm

Today's widespread adoption of smartphones has supported the development of digital consumer technologies that have the potential to disrupt the traditional approaches pharmaceutical companies take to data collection during clinical studies. Wearable activity trackers are at the forefront of this new paradigm – in fact, IMI (a European public-private partnership) is launching a multi-year project in which wearables are measuring walking activity in everyday life to measure real-world walking speed as a validated clinical outcome.[1] And, the breadth of data types that can be collected using such devices has expanded beyond step counts to include sleep metrics and heart-rate readouts.

These and other advancements in mobile health (mHealth) technology are changing paradigms in pharmaceutical research by offering significant improvements in patient recruitment, engagement and data collection. But, these possibilities need to be balanced against practical use within clinical trials, and integration with electronic clinical outcome assessment (eCOA) data. By overlaying wearable data streams with eCOA data, e.g., symptom frequency and occurrence, and quality of life, captured by the patient on handheld and/or web interfaces, sponsors are starting to get a complete picture of the patient experience during clinical development.

Making Sense of Wearable Technology

Until recently, the worlds of drug development and consumer technology were unconnected. Innovation came from within pharma companies and specialist vendors. That changed with the emergence of wearable devices such as Fitbits and ResearchKit – Apple's mobile research framework. Each of these solutions has contributed to trial sponsors recognising the consumer technology sector as a source of innovations that can improve clinical trials.

With so many mHealth devices now available, knowing which technologies to bring into clinical trials and in what context is now an important skill. Such knowledge will help sponsors convert technological advances into tangible improvements in clinical trials; specifically by enabling a shift from periodic to continuous data collection, but the pharmaceutical industry will need the support of regulators if it is to fully realise the potential of digital health.

Ideally, this will occur soon, as the FDA is generally open to working with innovative digital health companies in the consumer space, as evidenced by the recent formation of a pre-certification pilot programme under its Digital Health Innovation Action Plan.[2] Coupled with the ePRO Consortium's recent findings that support the appropriate use of wearables in study protocols[3] – which aligns with the agency's development of new mHealth guidelines in response to the 21st Century Cures Act – this may be enough to nudge the agency into the development of more clear regulatory guidance.

The emergence of wearables provides clinical trial sponsors with the means to generate unprecedented amounts of data on the lives of patients between site visits. This should be a boon for clinical trials, but it also creates new challenges that can be easily overcome when sponsors consider the implications of the data they hope to leverage from these innovations. Here we present some of the scientific and operational factors trial sponsors must consider before including these technological innovations in clinical development.

Scientific Considerations of Wearable Technology

Data from wearable devices can best serve the scientific objectives of a trial when they are:[4]

- **Fit for purpose.** Trial sponsors should let the decision to use wearable data be driven by their ability to support the trial's endpoints (or serve as independent endpoints themselves), rather than letting the choice of data collection technology drive the scientific questions of the trial.
- **In context.** Data about sleep patterns, activity level, and physiological measures such as heart rate are only meaningful if the context in which the data collected is known. Integration of wearable technology with eCOA enables the real-time capture of context surrounding a clinical event.
- **Accurate and validated.** Data from wearables that were originally created for commercial use may not be subject to the same standards of accuracy as medical devices vetted by the FDA. However, when data are to be used to support

endpoints, an appropriate level of evidence of data validity and reliability is required to confirm that the device provides the required level of measurement accuracy and precision. Efforts are underway to validate wearable or smartphone data with existing COAs, including an app developed by Roche that uses smartphone sensor data to measure symptoms of Parkinson's disease and attempts to predict patient scores on the Unified Parkinson's Disease Rating Scale (UPDRS).[5]

Operational Considerations of Wearable Technology

Beyond the scientific considerations of wearable devices, there are several operational aspects a trial team needs to consider when adding a wearable into the protocol, including:[4]

Study Goals

Prior to looking at any devices, sponsors need to determine what data are needed. There are hundreds of wearables on the market but sponsors can quickly narrow the scope by knowing exactly what data they want to collect and for how long they want to collect it. An important consideration is if the data will be submitted to regulatory agencies, and if any regulatory precedent has been established for their use in clinical research.

Wearable Selection

When people refer to wearables they often mean activity meters, but the wave of innovation in wearables means there are options beyond just activity, including many that have multiple sensors. For example, Vital Connect has a wearable patch that collects single-lead ECG, heart rate, RR interval, respiratory rate, temperature, body posture, fall detection and activity including steps. Next-generation wearables are likely to include connected clothing and true wearables such as tattoo-like health monitors.[6]

Patient Experience

Part of the patient-centric movement in clinical trials is to understand the impact that trial requirements have on a participant's life. This is especially important for wearable technology, as an uncomfortable device or one that requires extensive setup can lead to loss of data and non-compliance. To be successful, wearables must be simple to use and integrate seamlessly into everyday life.

Data Retrieval

Data from some wearables can be quite extensive, so it's important to understand the level of data required, and define useful collection intervals. Collecting a data point for every step may be more than needed; an alternative might be steps per minute or per day, so a consumer device may be sufficient. However, if the data are to support a key claim for submission, a clinically validated device that reports full raw data sets is essential.

Encouraging Change in a Risk-Averse Industry

Faced with a highly regulated and risk-averse environment, drug developers have traditionally been wary of adopting new technologies and ways of working. They typically need to see compelling evidence that the use of new technologies will not have detrimental effects on their data. When running expensive, multi-year trials, fear that data will be compromised acts as a brake on the uptake of innovation.

This puts the onus on regulators to provide clarity and on advocates of innovation to show how new products can live up to the industry's demands.

But, in the long run, it will be up to pharma to define their needs in order to extract value from consumer wearable devices in their clinical research strategies. By working with device manufacturers, other industry providers and consortia, trial sponsors can generate the evidence that regulators need to support adoption of these innovative technologies while demonstrating to the industry that the tools are a low-risk way to improve clinical research.

Conclusion

While there are risks to making changes, inaction carries its own dangers. Companies that leverage new data collection technologies and ways of working will be rewarded with clinical trials capable of generating broader, more continuous data sets while reducing the burden trial participation places on patients and investigators by lessening the need for site visits. Having a plan that addresses the scientific and operational considerations of these new technologies and optimises the integration of data sources such as eCOA will lead to a smoother rollout, a higher likelihood of success, and potentially significant efficiency improvements during new drug research and development.

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