Wear it on Your Sleeve — How Sensors and Wearables Help Drive Richer Insights on Intervention Effects

"I didn't sleep well last night." It's a phrase we've all heard, and unfortunately said, hundreds if not thousands of times. For some of us, the phrase instantly invokes the struggles to fall asleep, tossing and turning throughout the night. For others it means constantly waking up, gaining only an hour or two here or there in between frustrating bouts of staring at the ceiling or counting sheep. For you the reader, it may mean something entirely different, something unique only to you. Regardless, the phrase itself remains unchanged, even if our own experiences vary.

This ambiguity can be a challenge for clinical trials. Clinical outcome assessments (COAs) are a valuable approach to assessing symptoms and functioning in a systematic and clinically validated manner, using clinician interviews or asking patients to chronicle their symptoms in diaries. However, the rapidly growing development of micro-sensors in the personal health and wellness industry provides insight into new data that can be hugely informative about intervention effects in clinical research. Sensors and wearables present the clinical trials industry a golden opportunity — the ability to collect objective data to supplement patient self-reports which may in some circumstances provide increased sensitivity to detect subtle changes and reduce ambiguity.

Charting New Territory

Simply put, sensors and wearables allow us to capture and measure data that can be used to assess, define, and categorize a patient's functioning in a way that was never available before. In some cases, this may represent a superior way to capture clinical endpoint data compared to existing methods. Returning to our example of sleep assessment, wrist-worn accelerometers with validated algorithms can provide objective measures of important sleep parameters such as total sleep time, wake after sleep onset and sleep efficiency; facilitating their objective assessment in large populations outside sleep clinics.

In other cases, using a sensor may enable the measurement of a construct that has not been possible before. In oncology treatment, for example, patients during cycles of chemotherapy experience drug-related side effects that can be debilitating and difficult to manage. These symptoms are difficult to measure as when at their peak in the first week or two into a treatment cycle, patients are often too unwell to interact with tools designed to capture their self-reports. By the time patients return for the next cycle of treatment, this acute side-effect phase has often passed and yet this is the only time often considered practical to collect patient-reported outcomes data. A commonly used instrument to collect information about adverse events, the PRO-CTCAE, for example, asks patients to identify and grade events over the previous seven days, which may miss the magnitude of effects experienced in the early part of the treatment cycle.

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More recently, however, the use of a wrist-worn accelerometer worn passively by the patient following chemotherapy has been seen to provide valuable insights into the effects of treatment on patient functioning by providing a picture of their sleep and activity profile and recovery after each treatment cycle.

In addition, the use of wearables and sensors affords the opportunity to capture data more frequently than might be possible via scheduled clinic visits. This can provide richer and more informative insights. For example, measuring tremor or gait freezing in Parkinson's patients can provide a more informative picture of these symptoms and side effects than a monthly clinician assessment — a day on which the symptoms may be absent. Their use also opens the door to greater leverage of telemedicine techniques within clinical trials, facilitating superior monitoring of patients outside clinic visits, and potentially making participation more convenient by reducing the number of times a patient needs to physically attend clinic. Measuring in the home environment can eliminate white coat effects, such as sometimes seen in the measurement of blood pressure, and may provide a more insightful picture of patient functioning compared with in-clinic tests — for example measuring elected free-living activity compared to a treadmill test performed at clinic.

Taking Patient Analysis to the Next Level

With wearables sponsors, CROs, and research institutions now have new ways to understand, quantify, and categorize patients and their experiences and to inspect and analyze data quicker than ever before, enabling swift analysis and identification of trends, while offering the ability to outreach and intervene as needed.

To help harness this potential, at Signant Health, we recently partnered with ActiGraph to integrate their latest line of activity and sleep monitoring devices within our TrialMax eCOA solution. The integration was designed to simplify the use of multiple technologies for sites and patients and improve endpoint quality. Simplified workflows for sites makes enrolling patients for both eCOA and ActiGraph is streamlined and frictionless — all implemented through the TrialMax interface. Data-driven notifications notify patients when to wear the device and remind them if they have not worn the device for the requested number of hours during a day — aiming to limit missing and ineligible data and drive endpoint quality. Integrated reporting enables sponsors and sites to review eCOA and activity/sleep data together and inspect ePRO and wearable device compliance to enable proactive monitoring.

As sensors and wearables continue to gain ground with consumers, consider exploring the insights that they can provide to your next study. While this may be seen as a relatively new area for clinical trials, as an industry we understand how to select fit-for-purpose devices and how to develop and validate clinical endpoints we derive from their data — so there is nothing to lose sleep about. PV

Signant Health *(formerly CRF Health and Bracket) provides solutions that simplify every step of the patient journey to make it easier for people to participate in, and for sites and study teams to run, clinical trials. Signant unites eCOA, eConsent, Patient Engagement, IRT, Clinical Supplies and Endpoint Quality into the industry's most comprehensive patient-centric suite — an evolution built on more than 20 years of proven clinical research technology.*

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