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Shimmer launches Verisense wearable sensor platform for clinical trials

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Verisense was designed specifically to improve data quality in clinical trials, while reducing burden on sponsors, sites and participants

Shimmer, a global leader in wearable technology for research applications, has announced the launch of Verisense, its next-generation wearable sensor platform designed from the ground up to meet the needs of clinical trial sponsors, sites and participants. This new technology will be unveiled at the SCOPE Summit for Clinical Ops Executives.

“There is a growing demand from pharmaceutical companies, regulators and payers to factor real-world data (RWD) into healthcare decision making. They want to ensure that new therapies, especially those for chronic conditions, deliver objective improvements to participants’ health and quality of life. That requires access to real-world participant data and has spurred the rapid growth in wearable technologies to measure objective quality of life indicators, such as activity levels and sleep patterns,” said Geoff Gill, president of Shimmer Americas.

The US Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD, stated on Dec. 6, 2018 that leveraging RWD to improve regulatory decisions is a key strategic priority for the FDA. He also unveiled the FDA’s new strategic framework to advance use of real-world evidence (RWE) to support development of drugs and biologics. “RWD and RWE can be especially useful for postmarket monitoring of the safety of products during their use in real world settings,” said Dr. Gottlieb. He added that FDA has “new drug applications under review [in the oncology setting] where RWD and RWE are helping to inform our ongoing evaluation as one component of the total complement of information that we’re evaluating.”

“But an effective clinical trial solution has to meet very specific requirements, such as providing access to raw participant data and purpose-built management tools, while placing the minimum burden on sponsors, sites and participants. This can’t be done by simply repurposing consumer wearable devices or other current devices. We started by systematically understanding the needs of sponsors, sites, and participants, then designed Verisense from the ground up to meet those needs,” added Mr. Gill. “The initial feedback from customers has been overwhelmingly positive. Starting in March, customers are planning to use Verisense in trials for Alzheimer’s disease, Parkinson’s disease, cancer-related fatigue, and stroke.”

Verisense is a comprehensive and flexible solution for reliably capturing accurate and complete biometric data. Verisense is launching with the Verisense IMU sensor, a general-purpose Inertial Measurement Unit (IMU). Worn on the wrist, it can monitor activity and sleep seamlessly. In addition, it can be used for any IMU application with up to seven sensors worn on different parts of a participant’s body, making it invaluable for studying complex musculoskeletal or neurological conditions, such as dystonia or epilepsy. Furthermore, researchers can draw on a wealth of published data and established metrics from more than a decade of research using Shimmer devices.

The Verisense platform provides complete clinical trial sponsor support. Sponsors gain access to all the raw participant data; they are uploaded to a secure site and can be transferred to an electronic data capture system automatically to ensure data integrity. Built-in algorithms provide validated metrics. A monitoring dashboard shows the status of all the sites at a glance, and provides the ability to drill down to every sensor in the study.

From the site perspective, Verisense requires just a five-minute setup to initiate data collection and participant follow up if the system alerts them to a critical issue.

The Verisense platform places the minimum burden on participants. After putting the base station near their bed, or in another location that they visit every day, all they need to do is wear the sensor. It can even be worn in the shower or bath. The Verisense battery lasts for up to six months and the data transfer is completely automatic. The Verisense sensor can be inserted into a wide variety of cradles, ensuring that it meets all style and functional requirements.