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Parexel brings a new patient sensor platform to market

By Marilyn Fenichel

Parexel International, a global biopharmaceutical service provider based in Boston, recently launched Perceptive My Trials Analytics Platform, a tool designed to securely collect and store data from patients wearing medical devices and participating in clinical trials. The system has the capacity to collect data from six wearable devices or sensors measuring lung capacity, pulse, blood glucose levels, body weight and activity levels—essential information for many trials.

While gathering data from personal devices is not yet the principal way information is collected during clinical trials, the practice is gaining momentum. One of the main advantages of this approach is that it makes the clinical trial experience much easier for patients.

"In the past, patients were expected to go on-site for assessments during clinical trials," said Xavier Flinois, president of Parexel Informatics. "This could potentially reduce the burden on trial participants and sites, as well as decrease trial costs."

Paul L. Greene, Ph.D., senior vice president, clinical development—CNS, at INC Research in Raleigh, North Carolina, added that for pediatric subjects, the difference is transformative. "When parents don't have to bring the child participating in the study, along with their other children, to a doctor's office on a regular basis, they are more apt to enroll in the study," Greene said. "The process is much less disruptive and more patient-friendly."

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Data from wearable devices has another advantage—it can be collected more often. "Frequent collection of this data can provide meaningful insights into a study subject's behavior and health outside of visits, supporting better compliance and real-time user feedback," noted Flinois.

Samuel Volchenboum, M.D., director of the Center for Research Informatics at the University of Chicago and chief science officer for Litmus Health, a company based in Austin, Texas, which launched its platform for collecting data from wearable devices in 2016, concurred, observing that "continuously measuring outcomes in multiple dimensions leads to faster, more efficient pipelines. The result is better research, improved decision-making and faster analyses of incoming data."

In addition to being easier to collect, the data are considerably more objective. Volchenboum pointed out that data gathered with a pen and paper or on an archaic online data entry system often are highly subjective. "If we're trying to track information about sleep, it typically comes from a survey two weeks after the fact," said Volchenboum. "That information is susceptible to errors and misrepresentation."

Of course, there are disadvantages to collecting data from wearable devices. For one thing, the data from home-based devices may not be as accurate as those from site-based equipment. To overcome this barrier, the team at Parexel collaborates with scientists and therapeutic area experts to ensure the accuracy and reliability of the data.

Justin Johnson, founder and CEO of Biotaware, a company based in the U.K. that also has a data-collecting platform, added that it is crucial to monitor the devices to make sure they are working properly. "Our system enables that kind of monitoring, along with checking that patients are wearing a device that is charged and connected to the Internet or a smartphone as needed," he said.

While the industry continues to develop solutions to overcome barriers, they are also starting to use this technology in the real world. Parexel has its processes in place and is working with its partners to collect trial data. Since May 2016, Litmus has been collaborating with David Rubin, M.D., a gastroenterologist from the University of Chicago, on a pilot study using the Litmus platform to measure quality of life among patients with inflammatory bowel disease, Crohn's disease

and ulcerative colitis. By wearing a Fitbit and downloading a Litmus app from iOS or the Android store, patients supply data on their sleep, pain levels, activity, diet and bowel habits. The app serves as a clearinghouse for the data, collecting it and sending it back to the platform.

"The pilot seeks to obtain more reliable data upon which to base clinical decisions," explained Daphne Kis, CEO of Litmus. "We're still collecting data but hope to publish our findings later this year."

Although the use of these devices for clinical trials is still in its early days, most experts in the field predict that they are the wave of the future and will eventually dominate the field. At this point, there are few regulatory obstacles; in fact, according to Parexel's Flinois, the **FDA** has expressed cautious optimism about the application of sensors and wearables in clinical trials. They are waiting for drug companies to present them with data they can evaluate.

Most experts agree, too, that collecting data in this way is more comprehensive, opening the door to learning about a drug's impact on quality of life, an endpoint often neglected in today's environment. "We can find out if the medication will help you live longer, but not necessarily better," said Kis. "By collecting, integrating, analyzing and presenting data to pharma in an actionable way, we help researchers discern their trial population's quality of life remotely, thus speeding up the drug development process."

Equally important, however, is that this approach benefits patients. "Our offering is a formal movement toward patient-centricity," said Flinois. "These trial designs reduce the burden on patients and sites, leading to decreased costs and more investment in alternative data sources in the industry."