

On ‘cloud 9’ with new mobile health app

Medidata, GSK evaluate impact of cloud-based tech on engagement, data quality and efficiencies in clinical trials

BY LORI LESKO

NEW YORK—Aimed at offering high-tech solutions toward faster, more reliable diagnoses and treatments in the future, life-sciences company Medidata Solutions joined hands with global pharma giant GlaxoSmithKline (GSK) to evaluate the impact of mobile health (mHealth) devices linked to smartphones and cloud-based technologies on patients in clinical trials. The method development project trial run with GSK was deemed a success, Medidata announced Nov. 6.

Furthermore, the combined effort demonstrates the capacity for technology to accele-

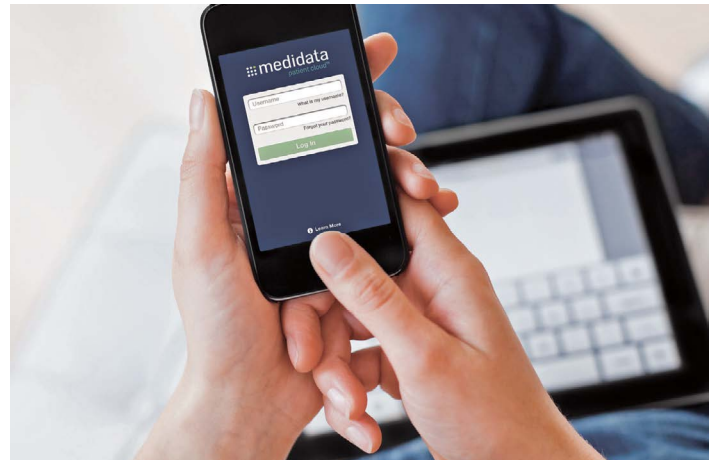
form. The Medidata Clinical Cloud captured all the data, mapping mobile health data to the clinical record.

Speaking on the collaboration with GSK, Kara Dennis, Medidata chief of staff, tells *DDNews*: “We were thrilled with the way the system was able to collect and send a huge amount of data.”

As chief of staff, Dennis oversees Medidata’s priority strategic initiatives to advance clinical trials and accelerate internal efforts.

Medidata’s cloud-based program has “tremendous potential for providing a better level of insight in clinical studies than ever before, tracking the progression of diseases and being an accurate predictor of adverse events,” Dennis says. Medidata’s program is “a very promising, very important development in clinical research.”

“We plan to pursue follow-up trials,” Dennis adds. “There is still work to be done.”



A mobile app on a smartphone is read by the Medidata Patient Cloud for patient-reported outcomes offered as part of Medidata’s technology platform.



“We were thrilled with the way the system was able to collect and send a huge amount of data,” notes Kara Dennis, Medidata chief of staff, of the joint project with GSK to evaluate the impact of mobile health devices linked to smartphones and cloud-based technologies on patients in clinical trials.

rate innovation in drug development and makes a strong case for cross-industry collaboration between technology and life sciences, Medidata stated.

The joint pilot project was administered at GSK’s Human Performance Lab where, over a five-day period, six participants wore two devices: the Vital Connect’s HealthPatch MD, placed on the chest, and ActiGraph’s wGT3X-BT Monitor, placed on the wrist. The devices continuously measured vital signs, electrocardiogram data and activity levels. Such devices can also potentially monitor stress levels, diabetes signs, sleep patterns and more.

A mobile app on a smartphone, given to all participants, was read by the Medidata Patient Cloud, for patient-reported outcomes offered as part of Medidata’s technology plat-

Pairing mobile health and cloud-based technologies streamlines the data collection, management and analysis process, as well as reduces site visits. Other key benefits of combining these technologies include streamlined routine procedures and real-time, continuous insight into large volumes of secure and analysis-ready data.

Medidata intends to use the technology infrastructure developed for this initiative as a model to enable new Phase 1 through Phase 4 mHealth clinical trials, which the company will be supporting for clients over the coming months.

The collaborative project with GSK demonstrated that mHealth technologies have the power to comprehensively collect large volumes of objective data that is reliable, secure and analysis-ready and that provides real-time, continuous insight into the well-being of patients, according to the company.

Medidata collected more than 18 million data points on activity and vital signs per participant per day. All of the data collected was audited and is compliant with FDA regulations. Additionally, the effort indicated that mobile devices can support the long-term goal of lessening the burden on patients participating in studies by streamlining routine procedures, eliminating unnecessary ones and reducing visits to clinical trial sites.

“Working with GSK on this initiative has provided us with an exciting opportunity to show how technology can be used to enhance patient engagement and accelerate the pace

of innovation in drug development,” said Glen de Vries, Medidata’s president. “We gathered data on an unprecedented scale. This is an extraordinary level of in-life, real-time patient instrumentation for clinical trials, which will create new disciplines and new opportunities for life-science companies.”

“Seamlessly integrating data from HealthPatch MD into clinical records through the Medidata Clinical Cloud opens up new possibilities to measure biometrics from heart rate to skin temperature,” added Dr. Nersi Nazari, Vital Connect’s chairman and CEO. “The availability of continuous, clinical-grade health data provides important

demonstrations of using mobile devices in a compliant, effective and safe way. We believe these breakthroughs over time will help to alleviate any concerns about regulatory compliance and data quality, much like the early days of the Internet and electronic data capture.”

Medidata is a global provider of cloud-based solutions for clinical research in life sciences, aiming to transform clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud is intended to increase productivity and quality for the clinical testing of medical treatments, from study design and

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opportunities to analyze results in real time to quickly identify potential safety concerns and adjust a trial based on preliminary evidence.”

Medidata’s data science team is working with GSK to leverage the data from the project and turn it into insight that can be used to conduct faster and more patient-centric clinical research.

“When it comes to mHealth, there is one aspect everyone agrees on: the technology is here now,” de Vries stated. “Breakthroughs in mHealth adoption can come from clear

planning through execution, management and reporting.

Vital Connect is a Silicon Valley-based company founded in 2011 with the goal of developing the newest generation of technologies that help address some of the most challenging healthcare issues in the world today. Vital Connect creates wireless, wearable biosensors that are small, powerful and capable of capturing clinical-grade biometric measurements in a continuous, configurable and unobtrusive manner. ■

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The Vital Connect’s HealthPatch MD is placed on the chest to measure vital signs, electrocardiogram data and activity levels.