



First Medidata-Sponsored Clinical Trial ASSESSES CAPABILITY OF MHEALTH TOOLS

► **Trending Now:** *New study explores potential for providing patients with mobile health tools in a clinical trial setting.*

MEDIDATA, a leading global provider of cloud-based solutions for clinical research in life sciences, has completed MOVE-2014, a behavioral study it sponsored to test whether mobile health (mHealth) devices and tools could be used to drive better health outcomes in overweight adults with type 2 diabetes. The pilot open-label clinical trial is part of Medidata's ongoing efforts to explore the challenges and opportunities associated with the adoption of mobile sensors, wearables, and apps in clinical trials.

MOVE-2014 study participants exhibited high compliance with charging and using the mobile devices, which included wearable activity trackers and smartphones. The study also showed that quantifiable, objective data, such as movement levels and sleep patterns, from the activity trackers and subjective, patient-reported diary data collected via smartphones could be securely pulled into the Medidata Clinical Cloud platform and be seamlessly integrated with other clinical trial information.

"The successful completion of MOVE-2014 reinforces what we at Medidata have discovered through a number of recent initiatives: mobile health solutions can be used to further clinical research in a reliable, secure and regulatory-compliant way," says Glen de Vries, Medidata's president. "Our goal was to show that mHealth tools can be incorporated into the highly structured world of clinical trials, providing a more holistic view of disease progression and patient response to therapy."



Glen de Vries

ZS Analytics and Veeva CRM Partner to Help Coordinate Multichannel Marketing and Sales Interactions



Matt Wallach

As pharmaceutical companies deploy more and more multichannel marketing and sales strategies to reach time-pressed physicians who leverage digital technology, a new challenge has emerged: how to thoughtfully coordinate the myriad sales and marketing activities in a way that creates a memorable customer experience and effective physician engagement.

Marketing firm ZS and cloud-based software provider Veeva Systems have joined forces to help orchestrate pharmaceutical companies' sales and marketing interactions.

The new solution helps companies orchestrate the optimal mix of rep and multichannel marketing activity based on physician preferences. The Veeva CRM platform informs sales representatives

of all multichannel interactions, and ZS's AffinityMonitor provides physician affinity for various channels and marketing offers. ZS's Suggestions Engine solution then provides guidance for the reps/ next best action.

The new tool includes a data-driven analytical engine that evaluates relevant sales and marketing data, shares physician affinities, and then recommends the next best action for sales reps. ZS also provides overall program and change management to drive adoption and implementation success for clients.

"The current move toward true multichannel marketing and sales requires a broad approach that encompasses new technology, processes, and training," says Matt Wallach, Veeva co-founder and president. "Together, ZS and Veeva are working together to make multichannel a reality for our customers."

BBK Worldwide Launches Live Streaming Video App

BBK Worldwide has launched My Research Mate,

Updates

MedNet Solutions has released the latest version of its iMedNet eClinical technology platform, which is being made available to all iMedNet customers. iMedNet is a cloud-based and fully unified eClinical system that can be used for any type of research initiative anywhere around the world.

The 2015 Feature 1 Release provides many new capabilities that focus on making clinical research more efficient than ever, such as a new configurable, algorithm-driven risk-based monitoring module as well as the ability make to MedDRA and WHO drug auto coding even easier.

Oracle Health Sciences InForm Cloud Service 6.1

the latest release of the data capture and management platform, provides trial sponsors and CROs with a complete, integrated solution designed to accelerate trial timelines, lower costs, deliver higher data quality, and reduce risk. This latest release supports more precise, risk-based monitoring; provides a single location for defining and managing study administrative data; and streamlines management and validation of in-place, protocol amendments.

Additionally, Oracle has released Oracle Argus Standard Edition 8.0, Oracle Argus Enterprise Edition 8.0, and Oracle Argus Safety Japan 8.0 for sponsors and manufacturers of pharmaceuticals, medical devices, and vaccines, as well as CROs and health authorities. The extensive pharmacovigilance platform is designed to help safety organizations comply with new reporting regulations and enable them to maintain or increase compliance, gain actionable insights into their data, and lower their total cost of ownership.

(c) PharmaLinx LLC. Rights do not include promotional use. For distribution or printing rights, contact mw@pharmaVOICE.com

Updates

Parexel International has launched the next generation of its risk-based monitoring tool Perceptive MyTrials, a data-driven monitoring (DDM) solution. DDM now further enables clients to perform cross-study analysis of quality, risk, and monitoring work effort by combining analytics, reporting, and monitoring activity into a single cohesive solution. The enhancements increase a drug developer's ability to demonstrate appropriate oversight and control of site-related risk, quality, and performance while simplifying monitoring governance and execution.

PRA Health Sciences has released its new Predictivv platform, a fully integrated solution for designing, planning, and optimizing the management of global clinical studies. Designed around a unified platform that harmonizes data, processes, and people across every aspect of a clinical study, Predictivv enables adaptive intelligence and decision support for the ever-increasing complexities of the clinical development process. The platform brings together a series of clinical study applications representing the foundation of a true end-to-end clinical development process. Predictivv combines data input and continuous feedback from across the spectrum of the trial process, empowering decision support intelligence throughout the entire clinical lifecycle.

Quintiles' Infosario technology platform is now available with mobile access to critical clinical trial information. Using the mobile app, key stakeholders in the drug development process can conveniently access site start-up, recruitment, and compliance information as well as status updates on data queries and project milestones. The Infosario One mobile app can be personalized with different filters so users can quickly see precisely what's most important to them.

a live streaming video app platform developed to educate consumers about treatment options and available clinical research studies, and the importance of clinical research more broadly. The app is intended to offer an enhanced experience through live video interactions with researchers, thought leaders, advocacy groups, and even other patients and caregivers.

"mHealth for clinical research continues to evolve quickly as we work as an industry to ensure that patients have greater access to study information — where, when and how they need it," says Joan Bachenheimer, founding principal of BBK Worldwide. "Consider the person exhibiting symptoms of early Alzheimer's disease, most likely fearful and wishing to deny his or her worries. Investigational treatments are showing promise in delaying the devastating progression of the disease, but are most effective when provided to the patients early on in their disease progression."

Quintiles and Quest Diagnostics Launch Lab Services Organization

Quintiles and Quest Diagnostics have launched Q2 Solutions, a new combined clinical trials laboratory services organization. Q2 Solutions brings together the clinical trials laboratory operations of the two parent organizations to provide biopharmaceutical customers with the diverse capabilities and end-to-end services required in the rapidly evolving biopharmaceutical industry.

"Q2 Solutions harnesses the complementary strengths, expertise, and scale of two industry leaders," says Tom Pike, CEO, Quintiles. "This new organization is built upon the strong foundation of its parent companies and provides customers with access to an innovative, progressive and responsive partner with the quality focus, global experience, and deep medical expertise integral to drug development."

Steve Rusckowski, president and CEO of Quest Diagnostics, adds that clinical laboratory services are central to advances in genomics, precision medicine, and drug development. Q2 Solutions is well-positioned to generate significant advances in these areas to benefit biopharmaceutical customers and patients.

ICON Launches Firecrest Patient Portal to Enhance Education around Informed Consent

ICON, a global provider of drug development solutions and services to the pharmaceutical, biotechnology, and medical device industries, has launched Firecrest Patient Portal. This portal enables patients to view clinical trial information and is specifically designed to enhance the patients' understanding of treatment before consenting to participate at an investigator site.

The Patient Portal solution is a component of ICON's new informatics hub designed to enhance the engagement of patient populations in the development process and is in line with ICH E6 guidance, which recommends patients receive ample time to review consent materials and ask follow-up questions.

"The opportunity for education about the trial, before a face-to-face meeting with their doctor, helps patients make truly informed decisions about participation," says Frances Abeton, VP, Firecrest at ICON. "Improved patient comprehension of a trial can reflect positively in patients' relationships with investigators and subsequently lead to better recruitment and retention rates."

The Firecrest Patient Portal is a centralized solution for patients, investigators, and study staff, making it easier for all involved to interact and stay informed. Patients can find active trials, complete pre-screening questionnaires, and select a convenient study location.

PPD and HealthCore Collaborate to Deliver Enhanced Pre- and Postapproval Research Services

Pharmaceutical Product Development (PPD) and HealthCore have established a collaboration that enables both companies to further expand their services in the pre- and postapproval research market with the aim of helping biopharmaceutical clients demonstrate more quickly and cost-effectively how their products will perform and benefit patients in the real world.

The collaboration allows life-sciences companies to engage in one contract with combined services from PPD and HealthCore that has the potential to cover product research in both pre- and post-approval settings.

Both PPD and HealthCore can provide biopharmaceutical companies analyses of medical claims data and electronic health records necessary to understand the use and impact of their products and to design appropriate pragmatic clinical trials that address payers' needs.

Mosio Launches Two-Way Text Messaging Platform

Mosio has created a suite of text message-based clinical trial tools designed to improve study enrollment and patient retention success, tailored specifically to the varying needs of research sites, CROs, sponsors, and patient recruitment firms.

Mosio's Web-based mobile messaging software services designed to enhance trial recruitment and retention range from targeted plans for PIs and study sites to capabilities for CROs and fully customizable solutions for integration into study platforms of study sponsors, patient recruitment firms, and trial technology enterprises. 