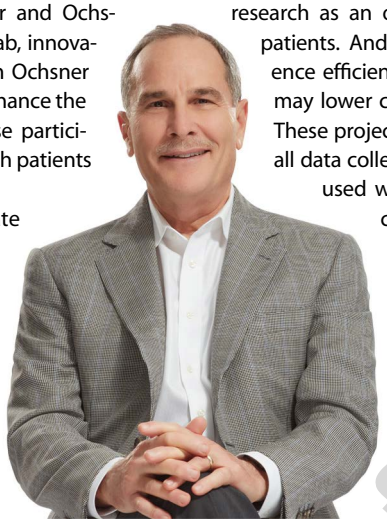
Ochsner Health System and Pfizer Partner to DEVELOP INNOVATIVE MODELS FOR CLINICAL TRIALS

▶ *Trend Watch: Technologies Continue to Enhance Clinical Trial Experience and Efficiency*

Ochsner Health System, Louisiana's largest nonprofit academic healthcare system, and Pfizer have entered into a multi-year strategic alliance to develop innovative models for clinical trials. Through this partnership, Pfizer and Ochsner — through its innovation lab, innovationOchsner, in partnership with Ochsner Research — explores ways to enhance the clinical trial experience and ease participation in clinical research for both patients and healthcare professionals.

The alliance aims to create faster, improved access and connectivity to clinical trials for patients, with the ultimate goal of better experiences and outcomes. Participating patients will have the opportunity to test new digital tools designed to make the clinical trial experience more inclusive and enjoyable. Participating clinicians will benefit from reduced manual data entry as a result of direct data system integration and automated study conduct tools, freeing up time and work to allow them to offer clinical research as an option to a broader range of patients. And research groups will experience efficiencies from interoperability that may lower costs while increasing capacity. These projects are designed to ensure that all data collected is secure and will only be used with patient consent, as in any clinical trial.



We are relentless about using the latest breakthroughs in science and technology to solve some of the toughest healthcare challenges.

Dr. Richard Milani
Ochsner Health

Ingestible Microneedle Can Inject INSULIN INTO STOMACH LINING

A team of investigators from Harvard-affiliated Brigham and Women's Hospital, MIT, and Novo Nordisk has pioneered a new approach that brings closer to the clinic an oral formulation of insulin that can be swallowed rather than injected. With funding and in collaboration with scientists from Novo Nordisk, the team has developed an ingestible microneedle that can inject insulin into the stomach lining in a large animal model. Results are published in Science.

About the size of a pea, the SOMA houses a needle made of insulin and its injection is controlled by a spring held in place by a sugar disc. The sugar disc allows the humidity in the stomach to serve as the trigger of the micro-injection, and the solid insulin needle enables delivery of a sufficient dose of the drug. Its size and material makeup are similar to previously approved FDA ingestible devices.

The pill, which has already been tested on pigs, features a mechanism that makes sure that after swallowing, its injection needle is positioned against the wall of the stomach. The needle is protruded to hold onto the stomach and to access the blood vasculature within the stomach. Insulin is then pushed through to deliver therapy, all without the patient having to do more than simply swallow the pill.

Once the insulin is released, the amount of which can be customized for different patients, the pill detaches from the stomach and leaves the body along with the rest of the excrement. The pill consists of a biodegradable polymer and small steel parts, so there's little fear of side effects from the pill itself. While it has been developed for insulin delivery, the pill may also end up being effective for delivering other protein-based drugs.

Astellas and WiserCare Collaborate to Improve PATIENT EXPERIENCE

Doug Noland, head of patient experience, executive director, Astellas US

Astellas US and WiserCare, a company that develops healthcare decision-support solutions, are collaborating on improving patient experience by eliciting and integrating patient feedback to improve patient communication and shared decision-making tools.

The project examines how patients learn about their disease states or conditions, including their options for treatment and tests various approaches to communicating the risks and benefits of these options. By integrating patient feedback to different communication designs and delivery methods, Astellas and WiserCare aim to reduce patient anxiety about and increase satisfaction with their decisions, to improve adherence to care plans, and improve the overall care experience.

This 12-month initiative examines patient decision-making for DCIS (ductal carcinoma in situ), localized prostate cancer, menopause, and mild-to-moderate depression.

For menopause, the collaboration will include additional patient interviews to develop a robust understanding of patient treatment decision factors.

The project uses WiserCare's online interactive approach to shared decision-making. Patients use WiserCare independently, resulting in patient and care team reports that prepare the patient and care teams for a more focused, satisfying visit.

"Astellas seeks unique and innovative external collaborations to deliver value beyond traditional pathways," says Doug Noland, head of patient experience, executive director, Astellas US. "We feel there is great potential to better help patients navigate the hundreds of decisions they make during their journey, and we are eager to collaborate with WiserCare on this important work."

The project is expected to be complete in January 2020.

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KEYNOTE SPEAKERS

ContinuousNext: Mindset & Language of Digital Business
Irving Tyler, Gartner

Insights (R)evolution: AI and Intelligent Augmentation Opportunities for Healthcare Insights & Analytics
David Gutelius, The Data Guild

Global Healthcare Trends Impacting our Industry
Brian Corvino, DRG Consulting

Industry Leaders POV: The Evolving Insights Role
Nicole Engel, Medtronic
Debbie Kenworthy, Johnson & Johnson
Additional panelist TBA

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- Paul Gorman, Vice President of Intellus Worldwide and Senior Manager, Market Research at Sanofi

"By forming Intellus, we've kept the best of both worlds—the broader perspective of an international membership in PBIRG and the rich educational content of PMRG. We're now evolving into something even greater as a combined organization, with initiatives such as our work to impact policy around adverse event reporting and our efforts to help researchers navigate emerging challenges with high-tech tools that traditionally have sat outside the researcher role."

- Lynn Ricker, President of Intellus Worldwide and Principal and Founder of Knowvanta

Shimmer Introduces Verisense WEARABLE SENSOR PLATFORM FOR CLINICAL TRIALS

Shimmer, a global leader in wearable technology for research applications, has launched Verisense, its next-generation wearable sensor platform designed from the ground up to meet the needs of clinical trial sponsors, sites, and participants.

Verisense is a comprehensive and flexible solution for reliably capturing accurate and complete biometric data. The Verisense IMU sensor, a general-purpose inertial measurement unit (IMU), worn on the wrist, 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.

Starting in March, customers are planning to use Verisense in trials for Alzheimer's disease, Parkinson's disease, cancer-related fatigue, and stroke.

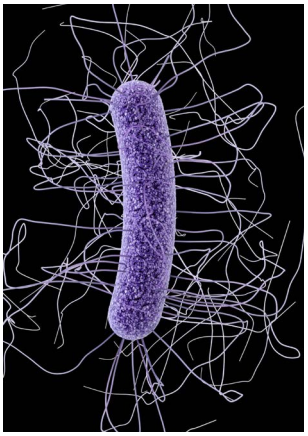
The Verisense platform provides complete clinical trial sponsor support. Sponsors gain access to all of the raw participant data; they are uploaded to a secure site and can be transferred to an electronic data capture system automatically to ensure data integrity. Built-in algorithms provide validated 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.

"There is a growing demand from pharmaceutical companies, regulators, and payers to factor real-world data into healthcare decision making," says Geoff Gill, president of Shimmer Americas. "They want to ensure that new therapies, especially those for chronic conditions, deliver objective improvements to participants' health and quality of life. This 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."

Microrobots Take Minutes TO DETECT C. DIFF IN STOOL SAMPLES

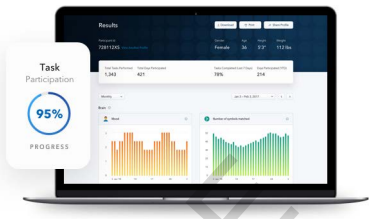


Researchers at Chinese University of Hong Kong (CUHK) have developed fluorescent microrobots that can spot *Clostridium difficile* (C. diff) in a stool sample within a matter of minutes without relying on expensive laboratory equipment.

The technology relies on fungi spore-inspired microrobots that feature fluorescent functionalized carbon nanodots. When the microrobots encounter toxins produced by C. diff, the brightness of the fluorescence changes, something that can be detected with digital photo equipment.

The process is accelerated by the shape and structure of the microrobots, which spread throughout a diluted stool sample and quickly come in contact with as much as the present toxins as possible. This "active" process also helps to detect low concentrations of toxins, according to the researchers.

Additionally, because the microrobots have iron-based nanoparticles in their structure, they can be manipulated by an external magnetic field and gathered together for best visualization.



Genentech Smartphone App Helps MS Patients MONITOR ILLNESS

Biotechnology company Genentech, a subsidiary of multinational pharmaceutical/diagnostics company Roche Holdings AG, has developed a smartphone app that enables patients with multiple sclerosis (MS) to monitor and track their illness in real-time and provide data and insight to their doctors.

Clinical laboratories may be able to help in the collection, storing, analysis, and reporting of the data obtained by the app.

Genentech's "Floodlight" mobile app, which can be downloaded for free from Apple's iTunes app store, is part of Floodlight Open, a global MS study that hopes to "understand the effects of MS on mental and physical functioning in a real-world setting."

There are currently more than 400 MS patients using the Floodlight app. Genentech hopes to enroll 10,000 patients in the program within the next five years. Among the current Floodlight users, there is a 76.5% adherence to the active tests and an 83.2% adherence to passive monitoring, such as walking and mobility throughout the day.

When questioned about their satisfaction with the app, study participants gave it a good to excellent rating of a 73.3 average out of 100 possible points.

Floodlight enables MS patients with smartphones to monitor the progression of their illness by measuring mobility, hand motor function, and cognition. These three domains are key for both MS patients and care providers, because they help clarify both disease status and response to treatment. Its passive self-monitoring also helps patients understand fluctuations in their condition.

People using the app can choose to automatically share their personal information with their physicians via a private ID number.

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