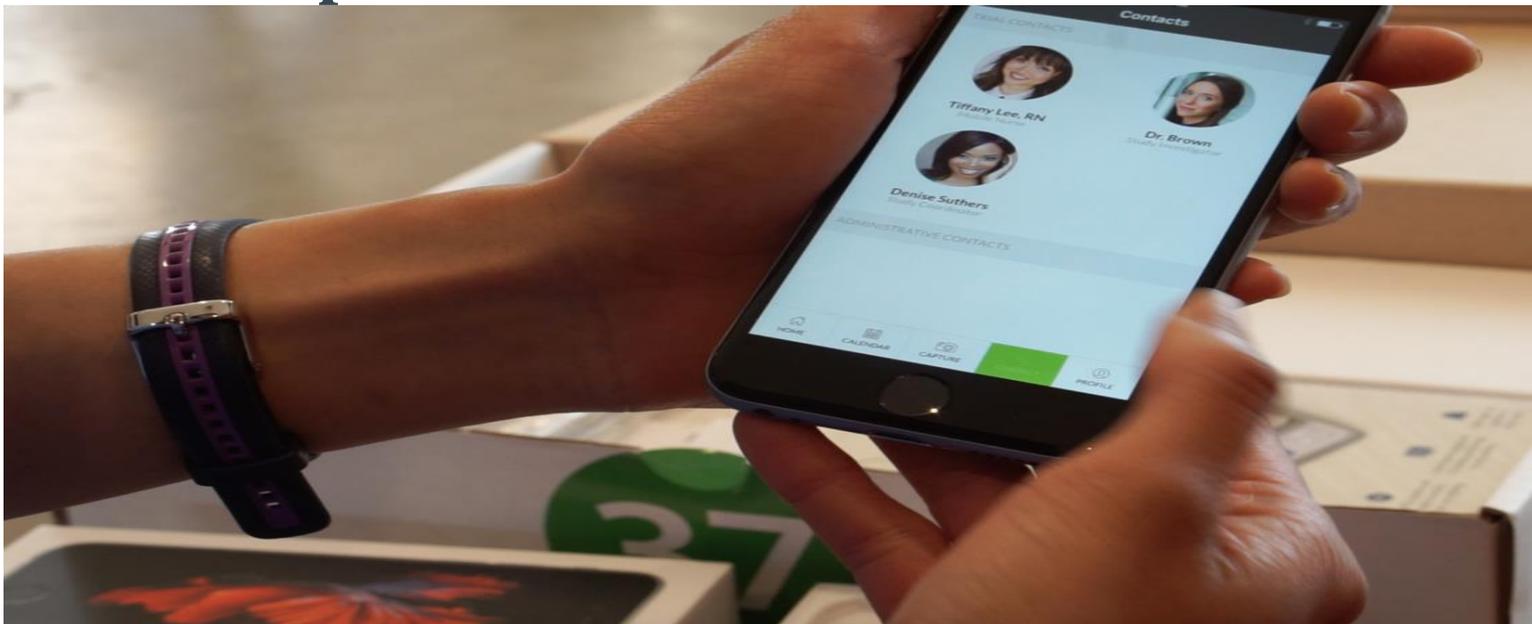


March 1

Science 37 and Sanofi Introduce a New Partnership



Without clinical trials, new medicine may never make it from the research lab to patients in need. These carefully designed studies can provide important data that include proper dosage, benefit to patients, and potential side effects.

There is a growing challenge, however, in finding appropriate participants, especially for treatments that target highly specific conditions affecting narrower patient populations. Right now, there are more than 40,000 clinical studies recruiting patients in the U.S. alone, with some requiring thousands of participants, each of whom must meet precise criteria to join. So it's not surprising that 80% of these important studies are delayed due to recruitment problems, according to a study by the [Center for Information and Study on Clinical Research Participation \(CISCRP\)](#).

Unfortunately, those delays mean it can take longer for innovative new medicines to be studied and approved, leaving patients to wait years for new treatment options. To tackle this growing problem, Sanofi is taking a digital approach to clinical trials, partnering with [Science 37](#), a clinical research services and technology company based in California.

Leveraging mobile technology and telemedicine capabilities, this new approach will allow Sanofi to develop "site-less" or decentralized clinical trials that are more patient friendly: easier for them to access, and eliminating many of the common impediments to participation. Using digital technologies to streamline finding and retaining participants for the entire length of a study has the potential to reduce the time required for a typical trial by at least 30%, according to Science 37.

Traditional Clinical Trial Challenges and Opportunities



OF CLINICAL TRIALS DELAYED DUE TO ENROLLMENT

Lamberti, "State of Clinical Trials Industry"



OF SITES FAIL TO MEET ENROLLMENT GOALS

Tufts CSDD 2013 Study



OF PATIENTS SOMEWHAT WILLING OR WILLING TO PARTICIPATE

CISCRP 2013 Survey



OF PATIENTS LIVE MORE THAN 2 HOURS FROM CLINICAL SITES

Roche Internal Review of Trials

"How do we best serve the patient?"

We see the opportunity to serve all patients, regardless of where they live, their gender or race, by bringing cutting-edge treatments.

A Radical New Approach To Clinical Trials



Science37.com

"After years invested in the lab on an innovative treatment, the clinical trials are where we finally obtain and analyze the relevant data that will let us understand how well a new treatment will benefit patients," said Lionel Bascles, Global Head of Clinical Sciences and Operations of Sanofi. "With digital clinical trials we can get and analyze the data on how a new medicine works in the real world a lot sooner, which means patients get the medicines they need sooner."

Going digital also eliminates a number of other hurdles to patient participation, including the most significant: geography.

Most people are eager to participate in relevant trials – 87% of patients want to do so, the CISCRP study found. Yet, 70% of potential participants live more than two hours away from the nearest study center. Because most clinical trials require patients to travel to those centers for regular tests and observations, sometimes several times each week for the duration of the trial, this distance is another challenge to patient access.

Science 37's approach allows patients to be monitored and report to researchers via an Apple iPhone equipped with the company's NORA[®] technology. Qualified study participants are provided with the phone, a data plan and any other sensors or connected devices needed for the trial, along with the medicines being researched. Participants can reach study staff at any time via the mobile device, while also remaining under the care of their local health care professionals. Mobile nurses are also sent to the participant's home to provide services like blood draws when needed, and nearby hospitals or clinics are engaged for scans or other tests that require specialized equipment.

The patient's data are sent securely to researchers who can immediately access information that would otherwise have to be collected by medical personnel through face-to-face interactions at study centers. This platform can also remind patients to take their study medications at the proper time, and let researchers know if participants are adhering to the study requirements.

"Our decentralized clinical trial model addresses critical shortcomings of traditional clinical trials, such as enrolling and retaining appropriate patients. Whether you live near a major research institution, or in a remote area, we make participation possible," said Noah Craft, CEO of Science 37. "By utilizing a patient's home in lieu of a physical trial site, we remove the burden of travel for those too sick or remote and provide access to qualified individuals who want to volunteer for a study but cannot because of geographic limitations."

The Science 37 platform will also help engage patients who would normally not participate in clinical trials, "so our data will much more closely track the diversity of the population," Bascles said. "In addition to reducing the burden for patients, decentralized clinical trials are far more likely to keep patients engaged for the full length of the trial, increasing the relevance and the acceptability of the data by regulators."

Sanofi's agreement with Science 37 covers use of its Metasite[™] model and NORA technology across the U.S. with plans to expand internationally in the future. By eliminating months of searching for patients and long travel time to study sites, virtual clinical trials could reduce total trial time by as much as two years.

Partnering with Science 37 is the most recent strengthening of the relationship with Sanofi, which began last October when Sanofi's venture capital fund, [Sanofi-Genzyme BioVentures](#), made a minority investment in Science 37.

"Science 37 has a great track record, and they are smart and forward-thinking about developing the science around clinical trials that leverage digital technologies," said Heather Bell, Global Head of Digital and Analytics for Sanofi. "As part of the scope of our digital strategy, we have expanded the scope of the venture fund to include digital investments, and Science 37 was our first investment since that change and we're very excited about it."

