

# Make way for mobile health in clinical trials

## Despite patient retention, data quality benefits, regulatory hurdles persist

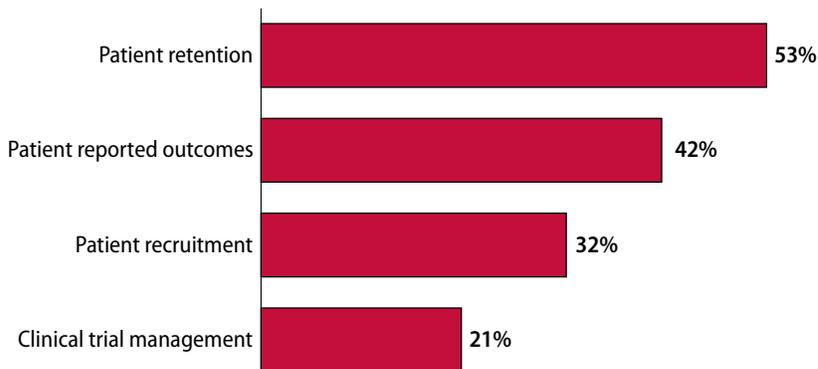
**P**atients can wear watches that monitor heart rates, wireless patches that read blood pressures and headsets that measure brainwaves. Smartphones can be turned into ECG or blood glucose monitors. Clothing embedded with sensors can measure breathing patterns and body temperatures.

As the pharmaceutical industry looks for ways to simplify trials and lower drug development costs, innovators are exploring how to incorporate these and other mobile health, or mHealth, applications into clinical trial designs, which could make it more convenient for patients to participate while also improving the quality of data.

What if a patient could participate in a clinical trial simply by wearing a tee-shirt customized to measure vital signs? What if study volunteers never needed to visit an investigative site? How could a sponsor leverage unstructured data collected from wearable mobile devices for clinical research?

While mHealth applications do have a place in clinical research, adoption levels for using the new wave of sensor-based monitoring devices in trials—once the hype about mHealth apps has settled down—are expected to be low. Many of these apps have the potential to transform patient medical care and allow greater personal control in health management, but regulatory concerns and ques-

### Reasons sponsors are using mobile health apps



Source: Tufts CSDD, 2013 <<http://csdd.tufts.edu>>, N=20 sponsor companies

tions about the benefit the apps can bring to studies most likely will hinder their use in clinical trials.

Tim Davis, CEO and co-founder of Exco InTouch, which provides technology services to the biopharmaceutical industry, said although many mobile health apps are available for the commercial setting, it could be difficult to find a protocol-defined reason to use them to collect data within the constraints of a clinical trial.

"Although some of this stuff may be pretty interesting and look pretty cool, that is not a scientific reason for pulling information through these apps now. It's not going to get ethics approval," said Davis. "The technology should be about making a clinical trial run more effectively, engaging better with patients and getting more accurate data that is more timely and responsive. It's that kind of better-quick-er-more accurate thing we've been striving for in clinical research forever."

### Channel to reach patients

mHealth, just like social media, is viewed by the industry as another major channel for reaching the patient community. According to a recent Tufts Center for the Study of Drug Development (CSDD) report, 75% of biopharmaceutical companies and CROs surveyed last year reported using mobile applications. Survey respondents, who typically used Apple and Android applications as platforms, primarily used mobile apps for patient retention (53%), patient reported outcomes (42%) and patient recruitment (32%). Specifically, mobile technologies are used to promote study opportunities, pre-screen potential patients, remind participants about their study obligations and collect clinical data from volunteers remotely. Companies employ mobile strategies to enhance the clinical trial experience for patients—making participation easier and more con-