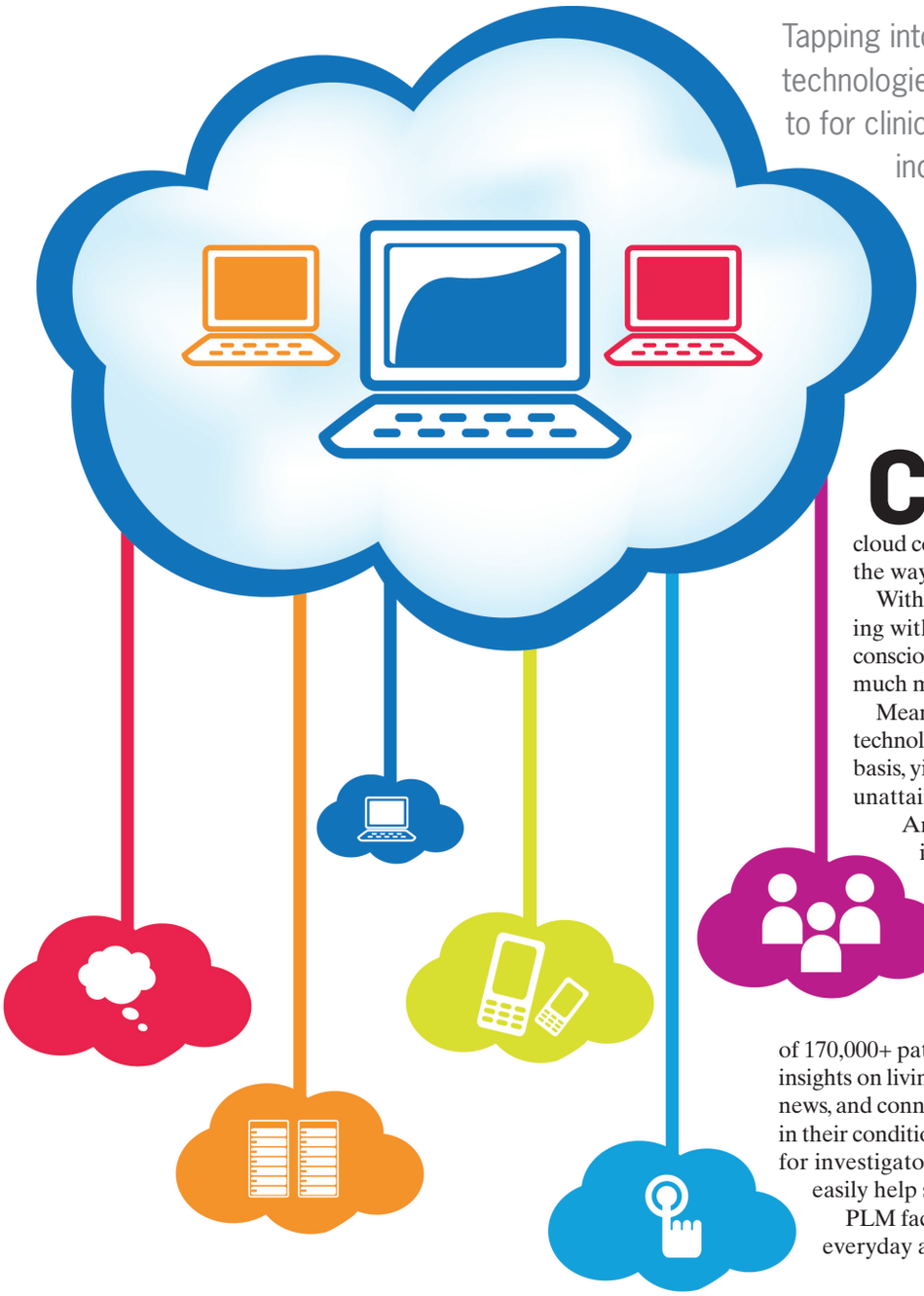
TRIALS & TRIBULATIONS



Tapping into social, mobile or cloud-based technologies may take some getting used to for clinical investigators. But for a drug industry that needs to trim the time and cost of R&D, these approaches may bear a closer look. **Joe Dysart** reports

Clinical researchers are finding that some of the same technology revolutionizing everyday life—social media, mobile computing and cloud computing—is poised to completely transform the way clinical trials are performed.

With social media, clinical researchers are partnering with pre-established social networks of health-conscious patients to recruit those patients for studies much more quickly—and at significantly lower cost.

Meanwhile, those using mobile and remote-sensing technologies are securing data from patients on a 24/7 basis, yielding data sets that heretofore were simply unattainable utilizing conventional methods.

And investigators leaping to the cloud are finding services designed to automate every step of the record-keeping process, freeing them to spend more time on scientific inquiry—and less on paperwork.

At eight-year-old social network PatientsLikeMe, for example, co-founder Jamie Heywood has put together a community of 170,000+ patients who regularly visit his website to trade insights on living with their diseases, pick up the latest health news, and connect with doctors and scientists who specialize in their conditions. "It's difficult for patients to find trials, and for investigators to find patients," Heywood says. "We can easily help solve both these problems."

PLM facilitates those connections by trolling for info everyday about new clinical trials on ClinicalTrials.gov.

ILLUSTRATION: THINKSTOCK

Members with the appropriate conditions are alerted about their eligibility for those new trials. Given that more than 1,500 diseases are represented across the PLM membership, the potential match of patient to trial is enormous. For clinical researchers facing recruitment deadlines, Heywood's firm also offers a paid service, which researchers can use to personally reach out to patients on the social network.

The upshot: Heywood says PLM can shave as much as two months off the typical amount of time it takes a researcher to populate a clinical trial as compared to conventional recruitment methods.

Plus, Heywood says the patients researchers recruited on his social network are among the most ideal for clinical trials. "Our members are already engaged and activated," about their health, he says.

Besides turning the heads of more than a few researchers, Heywood also snagged a $1.9-million grant in February from the Robert Wood Johnson Foundation. He'll use it to create a social-networking platform where patients and researchers can interact to pilot, deploy, share and validate new ways to study diseases.

Meanwhile, over at drug-development firm Transparency Life Sciences, CEO Dr. Tomasz Sablinski is busy re-engineering the way clinical researchers gather data, by evaluating the mobile and/or remote-sensing devices that can be used in a virtual clinical trial.

> "For most people in R&D, it's difficult to change. They're still stuck in the eighties in terms of how they do research."
> — Tomasz Sablinski, TLS

Sablinski says he plans to use the tech to remotely monitor patient vitals in a Q3 study that will evaluate a treatment for multiple sclerosis. Other studies by TLS—and expanded use of other remote-sensing technologies—will follow, he says.

Essentially, by outfitting patients with remote-sensing technology that monitors vitals 24/7, Sablinski says he'll be able to generate much more data for his company—as well as data that he says will be much more accurate.

The remote-sensing tech will also reap savings in time and money for researcher and patient, according to Sablinski. For example, instead of having to drive to a clinical trial office for a mobility test, patients in the MS study will take the test at home using a GPS device.

The technology will enable TLS to secure much more detailed data on patient mobility, Sablinski says, since the GPS device can conceivably be worn continuously by subjects for up to six weeks. Using conventional methods, such as in-office visits, a clinical researcher simply cannot achieve a similar depth of data, Sablinski says.

There is virtually no limit to what researchers can measure with remote sensing, Sablinski adds. Body temperature, breathing, hydration, optometrics—including color recognition—can all be assessed remotely. "There are hundreds of devices available," he says.

The savings—and increased accuracy—in sleep research alone should open minds. "A night at a sleep lab runs $1,500," he notes, and features a subject who is thrust into a foreign environment, riddled with wired sensors, and then encouraged, 'Have a nice sleep now.'" The remote-sensing alternative—the use of a non-intrusive device, attached to a subject who has become accustomed to wearing the technology days before the study begins—seems much more efficient, and much more accurate, Sablinski says.

Finally, new directions in clinical trial data management are afoot at Veeva Systems, which has partnered with Medidata to offer a cloud-based solution that streamlines and automates data management for any clinical trial. The heart of the system is Veeva's Vault eTMF—an electronic Trial Master File application, which enables researchers to quickly file all documents associated with a clinical trial—and check on the status of those docs at any time.

"Clinical researchers are constantly asked for status reports and updates like, 'Where are we with the eTMF?'" says Michael Burton, a director of product strategy at Veeva. "With this technology, everyone can see the same eTMF and the same reports. So researchers don't have to waste their time answering requests for status updates."

The system is also designed to be user-friendly, and guide researchers through the filing process to help ensure all necessary documents are filed accurately, and on time, Burton says.

Progressive clinical researchers believe the efficiencies of cloud computing—pioneered at IT facilities like this IBM behemoth in Southbury, CT—are too significant to ignore

By partnering with Medidata, a cloud services provider, Veeva is able to maintain the Vault eTMF in the cloud. That offers all the efficiencies cloud apps are now famous for—including the ability for Veeva to auto-update its software for clinical researchers.

Medidata also brings its own suite of applications to the partnership that clinical researchers can use, including apps for study and protocol design, trial planning and budgeting, site negotiation, trial management, randomization and trial supply management, medical coding to business analytics, and more, Burton says.

"By providing all the applications from a single vendor—and as part of a shared platform—Medidata can remove many system compatibility issues and data sharing challenges," Burton says.

And all the integration helps automate document filing and maintenance. For example, reports from Medidata's other trial-management tools are all auto-filled into the eTMF, Burton says.

For many clinical researchers, the idea of using the same technology the masses use to stay in touch on Facebook, remind Grandma to take her pill, or back up songs on iTunes, takes some getting used to.

But for Sablinski, the migration is inevitable. "For most people in R&D, it's difficult to change," Sablinski says. "They're still stuck in the eighties in terms of how they do research. We believe technology should drive the process—and will." ■