TRIAL BLAZING

Running clinical trials remains one of Big Pharma's biggest headaches. But thanks to canny use of social media, gamification techniques and even text messages, CROs have revitalized and revolutionized the process. **Barbara Peck** explains

For the pharmaceutical industry, clinical trials remain the most necessary of necessary evils. The process has traditionally proven excruciatingly slow and costly, not to mention fruitless: of the experimental drugs reaching human clinical trials, as few as 5% ultimately receive FDA approval.

It's a common refrain, then, that there's much to be gained in finding faster, more efficient ways to test new drugs. And armed with the best of what social media and technology have to offer, clinical research organizations (CROs) have started to make headway.

As always, subject recruitment remains atop the list of stubborn problems. John Lewis, SVP, policy & public affairs for the Association of Clinical Research Organizations (ACRO), points out that as the protocols and eligibility requirements for clinical trials have become more complex in recent years, locating subjects is harder than ever.

In the old days, patients might learn about a clinical trial from their doctor, hear a radio ad or spot a poster in the subway. Those old-school approaches weren't always effective. Craig Lipset, head of clinical innovation at Pfizer, explains that physicians have generally had little incentive to refer the patients they're treating into trials – except for the patients the doctor couldn't control, such as those who didn't fill their prescriptions or heed medical advice. Those patients, Lipset admits, are precisely the ones he doesn't want in his own trials.

The obvious solution is to raise public awareness of clinical trials. "We need to make people more aware of the opportunities and we need to provide enough information so they'll know if they qualify," Lewis explains.

Online patient communities continue to provide invaluable sources of subjects for clinical trials. The Michael J. Fox Foundation, for example, runs the Fox Trial Finder to locate volunteers for clinical trials of Parkinson's disease treatments. According to the site, more than 37,000 people have stepped up to date.

While some CROs work with existing online communities to find patients for clinical trials, others have started their own groups for that very purpose. Jonathan Commons, VP of digital strategy and solutions at Quintiles, calls it the direct-to-patient model, meaning they recruit patients without the use of physician sites. Quintiles does this through mobile ads, video ads, social media sites and its own patient communities.

The largest of these, Mediguard, bills itself as "medication monitoring made simple," offering "easy-to-understand health information, safety alerts and recalls and drug interactions." Some 2.6 million patients around the world have voluntarily registered with Mediguard and posted lists of the medications they take. Not incidentally, such information provides Quintiles with a huge pool of potential subjects for clinical trials.

More targeted patient communities include Quintiles' IAmMoreThanLupus Facebook group, with some 37,000 users. The site is fully transparent about motive: A statement on the home page reads, "Quintiles created this community to introduce research opportunities to those affected by Lupus. It's also a place where people dealing with lupus, and those who support them, can get information and make connections."

How's the direct-to-patient model working? At last year's annual meeting of the Drug Information Association, Quintiles reported that it had taken only 18 weeks to enroll 1,000 patients for a rheumatoid arthritis research project.

CROs are getting more help than they once did. The U.S. National Institutes of Health does its bit to inform the public about clinical trials. Anyone who consults ClinicalTrials.gov will find plenty of slots to be filled: The site currently lists 178,250 studies, in all 50 states and 187 countries.

ACRO also supports the 21st Century Cures Initiative, a bipartisan government project established earlier this year that counts among its goals speeding up the expensive, time-consuming process of developing new medical treatments. After six months of roundtables and hearings, the group is expected to propose draft legislation in January that could shake up the existing system by streamlining clinical trials.

New uses for "old" technology

CROs are also deploying "old" technology in new ways, with Annex Clinical president and chief scientific officer Moe Alsumidaie noting that text messaging works better than email as a recruiting tool. According to Alsumidaie, while we read only 22% of the emails we receive, we read 98% of the text messages. Not only that, 90% of those texts are read within three minutes of receipt.

In a blog post, Alsumidaie described a vaccine clinical trial run by Kansas-based Johnson County Clin-Trials. The company had only a small window for enrolling patients and they'd found that patients weren't responding to email blasts. So they asked Mosio, a company that develops "mobile solutions for clinical trials," to run a text-messaging campaign to recruit and enroll patients.

In eight weeks, 1,541 text messages (notifying recipients that they "may be eligible for a clinical trial") netted 795 potential subjects and ultimately 265 trial participants. According to the research team, the calls started minutes after the texts went out—and the response was five times what they'd gotten from email. The Mosio approach isn't just for recruitment: Text messaging can also help research teams retain subjects, since the Mosio system shows when a less-engaged patient is at risk of dropping out and needs special attention.

CROs have similarly grown their presence on patients' tablets—which, compared with the notebook diaries of yore, make data capture a breeze. Steve Horohonich, chief technical officer at Cognitive Research Corporation, notes that portability makes tablets especially handy. Investigators can administer tests in different settings, such as a clinic exam room; a desktop is no longer required.

Tablets also make it easier to monitor adherence. A decade ago, patients would make diary entries to record when they took their medication. Then came pill bottles with electronic sensors that signaled whenever the cap was opened. Now patients need only click a box on the tablet screen. The ease of use has struck a chord with patients suffering from schizophrenia, dementia and Alzheimer's, among other illnesses.

Not surprisingly, wearables (Fitbits and the like) have proven invaluable in clinical trials. Though marketed primarily as fitness aids, these devices can collect data for medical studies, such as the time between tremors for a Parkinson's patient or the activity levels of a post-stroke patient.

Commons, however, cautions that Fitbits are not medical devices and haven't been validated by the FDA. Also, they work almost too well: they collect a huge amount of data that must then be sifted through to find test-relevant information. What's more, if the data collected reveals incipient health issues, such as a risk of heart attack, who's responsible for disclosing this information to the patient? To avoid these issues, Quintiles is seeking ways to incorporate FDA-regulated medical devices, such as glucometers,

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—John Lewis, ACRO

and to use those devices for Web-based electronic data capture.

Finally, the need to assess cognitive ability in clinical trials is being addressed in a number of ways. Gamification improves compliance by making it fun (at least in theory) to report data. A mobile app tracks the trial's activities and creates a video-game journey to keep subjects engaged.

In March, Pfizer began conducting a clinical trial using a video-game app developed by Akili Interactive Labs. "Project: EVO" counts as its mission identifying people at high risk for Alzheimer's disease; the "brain-training" app can track movements in milliseconds. According to Lipset, Akili has high hopes for "EVO," not just as a diagnostic tool but also for assessing and treating Alzheimer's symptoms. The software is currently being used in clinical studies for ADHD, autism, depression and traumatic brain injury – and Akili is seeking FDA approval.

Using milestones to motivate

TrialNetworks, on the other hand, uses gamification techniques to motivate a clinical trial's research team. Sites and individuals can earn badges when they hit project milestones (say, 10 patients screened). Investigators can see how their sites rank on key metrics and watch them climb the leaderboard, all in the name of friendly competition.

Indeed, the use of centralized systems to gather electronic data is already having far-reaching effects on the industry. During a trial, doctors and investigators can analyze data in real time as it comes in, without having to spend weeks poring over paper charts. Similarly, researchers can quickly adapt trial design and address safety issues on the fly. As Lewis points out, this real-time monitoring is reducing the time and cost of clinical trials and helping to establish better metrics. ■