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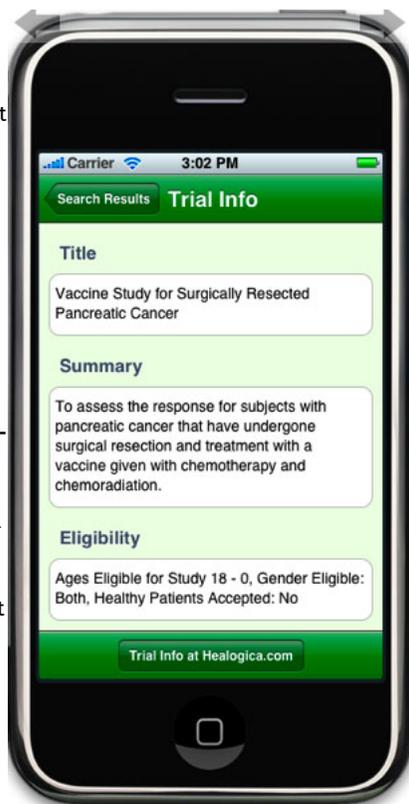
The year for mobile-enabled clinical trials: 2013 or 2030?

By **Jonah Comstock** (/content/jonah-comstock) | November 20, 2012

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Clinical trials are a clear area where mobile engagement and big data have serious potential, but it's still a largely untapped use case. There have been a lot of stories recently about the opportunities in that space, but also on the challenges companies have encountered in implementing them. At least one abandoned study and one failed company can attest to those.

Paulo Machado, CEO of Health Innovation Partners, a digital health consulting firm, says that mobile could cut both the time and the money it takes to do a clinical trial in half. Machado made that claim in an interview with **Life Science Leader** (<http://www.lifescienceleader.com/magazine/current-issue-3/item/4347-mhealth-could-cut-clinical-trial-time-and-money-in-half>) this month, for an article that also featured Craig Lipset, Pfizer's head of clinical innovation and the brains behind the first attempted (and, tellingly, abandoned) venture into mobile-enabled, entirely remote clinical trials. Lipset said that mobile has the capacity to revolutionize every step of the clinical trial process: recruitment, data capture, and analyzing study data.



The now-defunct Healogica app.

Pfizer's study, a clinical trial involving an overactive bladder treatment launched in the summer of 2011, was poised to be the first clinical trial that patients could participate in remotely, with even the drugs delivered to the patients by mail. Previously, Pfizer had conducted a traditional trial on the same drug, Detrol LA. The pilot was focused on testing the online method itself and on promoting patient engagement in the research.

"This is the first randomized clinical trial under an IND [Investigational New Drug] whereby patients can participate entirely from home — without requiring proximity to an investigator site," Lipset said **at the time** (<http://www.thinksciencenow.com/blog-post/virtual-clinical-trials-to-improve-patient-participation-and-access/>). "The participatory, patient-centered model will create new opportunities for patients to access clinical trials. As partners in research, patients will have access not only to all study results but also to their own clinical data, to be made available via personal health records. Patients can then use this data to manage their own health and wellness, including sharing this data with their treating physicians."



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Pfizer announced a year later that they were discontinuing the trial, however, citing a lack of participation. Lipset **told Pharamlot** (<http://www.pharmalot.com/2012/03/pfizer-social-media-its-clinical-trial-lipset-explains/>) at the time that though social media channels from Facebook to Craigslist were successful in getting people to the website, the number of those visitors who actually signed up for the clinical trial was too low, possibly because patients didn't trust online sources enough to deliver the necessary personal information. Lipset said **on the Pfizer blog** (<http://www.thinksciencenow.com/blog-post/talk-about-it-apply-what-worked-fix-what-didnt%E2%80%99t/>) that the failure might have been due to trying too many new innovations at once. According to the LSL story, Pfizer is going to try that trial again in 2013, tweaking its approach based on lessons from the initial experiment.

Pfizer's venture is not the only indication that the mobile-enabled clinical trial's time has come. MedCityNews **reported today** (<http://medcitynews.com/2012/11/4-ways-to-source-big-data-for-better-clinical-trial-recruitment-and-improving-public-health/>) that two of the four finalists in the Sanofi Collaborate Activate Innovation challenge deal with clinical trials. The Sanofi challenge seeks ideas for increasing patient engagement in healthcare. One finalist, Kim McCleary from **Partnering to End Pain** (<http://collaborateactivate.com/blog/partnering-to-end-pain/>), suggested using smartphones to get sufferers of chronic pain to answer questions about their health, generating data that could improve clinical trials. Another, Sharon Terry of Genetic Alliance, proposed the creation of a **Registry for All Diseases** (<http://collaborateactivate.com/blog/registries-for-all-diseases/>) that would create a patient-driven, crowd-sourced database for research into different diseases.

It's not just individual companies tackling these problems; larger companies are also partnering to effect changes in how clinical trials are done. **The New York Times reported** (<http://www.nytimes.com/2012/09/20/health/drug-makers-in-joint-effort-to-streamline-research.html>) last month that 10 pharmaceutical companies, including Pfizer and Machado's former company AstraZeneca, have banded together to start a nonprofit called TransCelerate BioPharma, which will focus on improving the efficiency of clinical trials for the whole pharmaceutical business. Although TransCelerate's initial goals aren't mobile-focused, they could pave the way for mobile engagement in the future. One goal is to create a shared Internet portal for clients to communicate with drug companies and another is to adopt a standardized data format for clinical trial recruiting, both of which will make data easier to manage in any format.

In an **interview with MobiHealthNews** ([/19102/epocrates-finally-launches-native-ipad-app/](http://19102/epocrates-finally-launches-native-ipad-app/)) last week, Andy Hurd, the CEO of clinical mobile software provider Epocrates, mentioned his company's intention to leverage its existing software and user base to help doctors match patients with clinical trials. Rather than using the Internet as a new recruiting vector, one of the pitfalls of Pfizer's venture, Hurd's approach would use a mobile infrastructure to enhance an existing channel — doctors recommending trials to their patients.

"Our surveying has demonstrated that physicians have a strong desire, upwards of 80 percent, to connect patients with clinical trials. But at a practical level the numbers that actually do are significantly lower than that because it's a pretty arduous and clumsy process, in terms of actually identifying where trials are and identifying if there's a fit," Hurd told MobiHealthNews. "We're able to identify and alert a pulmonologist in Raleigh, NC, as an example, of the two or three clinical trials that might be available to them. And as they're seeing patients they're able to get an alert that there's a fit to a clinical trial for that patient."

Much of the tech already exists for a truly mobile-driven clinical trial. Mytrus, one of the firms involved in the Pfizer trial, produces an iPad app for distributing **clinical trial informed consent forms** (<http://www.mytrus.com/news/article/20120912-ucsf>). Also, earlier this year, Exco InTouch, which was also involved in that trial, **partnered with Vodafone** (<http://www.excointouch.com/news-and-events/blog/2012/6/26/vodafone-and-exco-intouch-partner-to-develop-a-patient-reported-/>) to announce a system that will allow patients in a clinical trial to easily report data via mobile phone.

The pieces may be falling into place, but, Machado and Lipset told LSL, it will still be some years before they come together. Machado predicted it would be 2030 before we saw completely digitized clinical trials, partly because it will take that long to develop a digital ecosystem they can thrive in.

A case in point is Healogica, a clinical trial app maker MobiHealthNews wrote about in 2009. Healogica closed in May 2010, selling their software to the Michael J. Fox Foundation. Healogica told **CenterWatch News** (<http://www.centerwatch.com/news-online/article/838/healogica-to-close-plans-to-sell-trial-matchmaking-technology>) that the app faced some of the same problems that Lipset reported running into with the Pfizer trial: Even qualified patients were hesitant to sign up for a clinical trial online. When the company tried to turn the business to the pharmaceutical side, founders said they were met with a rigid system that couldn't accommodate mobile innovation.

"Pharma companies are facing huge pressure to get patients involved, and there is a huge number of patients out there who could qualify for clinical trials," co-founder Jean-Luc Neptune told CenterWatch at the time. "There's a big demand and a big supply. The big problem that exists in this industry is that the mechanism for connecting patients to trials is very inefficient. There is this regulatory paralysis that exists in the pharmaceutical industry, and people are literally afraid to make decisions. I can't tell you how many times we talked to somebody and they've said 'Hey, I've got to talk to my lawyer, and I've got to talk to my in-house counsel.' This is a huge space, and hopefully, in the next few years, we'll actually be able to move forward."

On the other hand, **competitors** ([/3653/clinical-trial-app-choices-expensive-for-charity-or-in-the-making/](#)) **Stopwatch Media** (<http://www.iphoneclinicaltrials.com/>) and **TrialX** (<http://trialx.com/>) are still in business, as are a handful of other clinical trial-related startups such as **goBalto** (<http://www.gobalto.com/>), which is aimed at facilitating clinical trials for startups and **TrialReach** (www.trialreach.com), a UK-based clinical trial search site that doesn't appear to include a mobile component.

Whether the 2030 marker is on point or not, it seems clear that timing is key for these technologies. All eyes will be on Pfizer next year, as it takes its 2013 mulligan for the REMOTE clinical trial.

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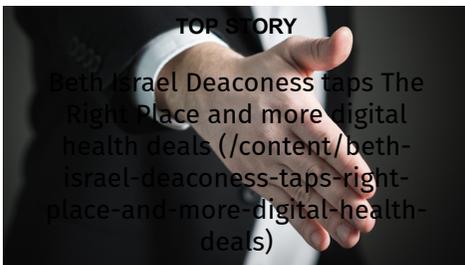
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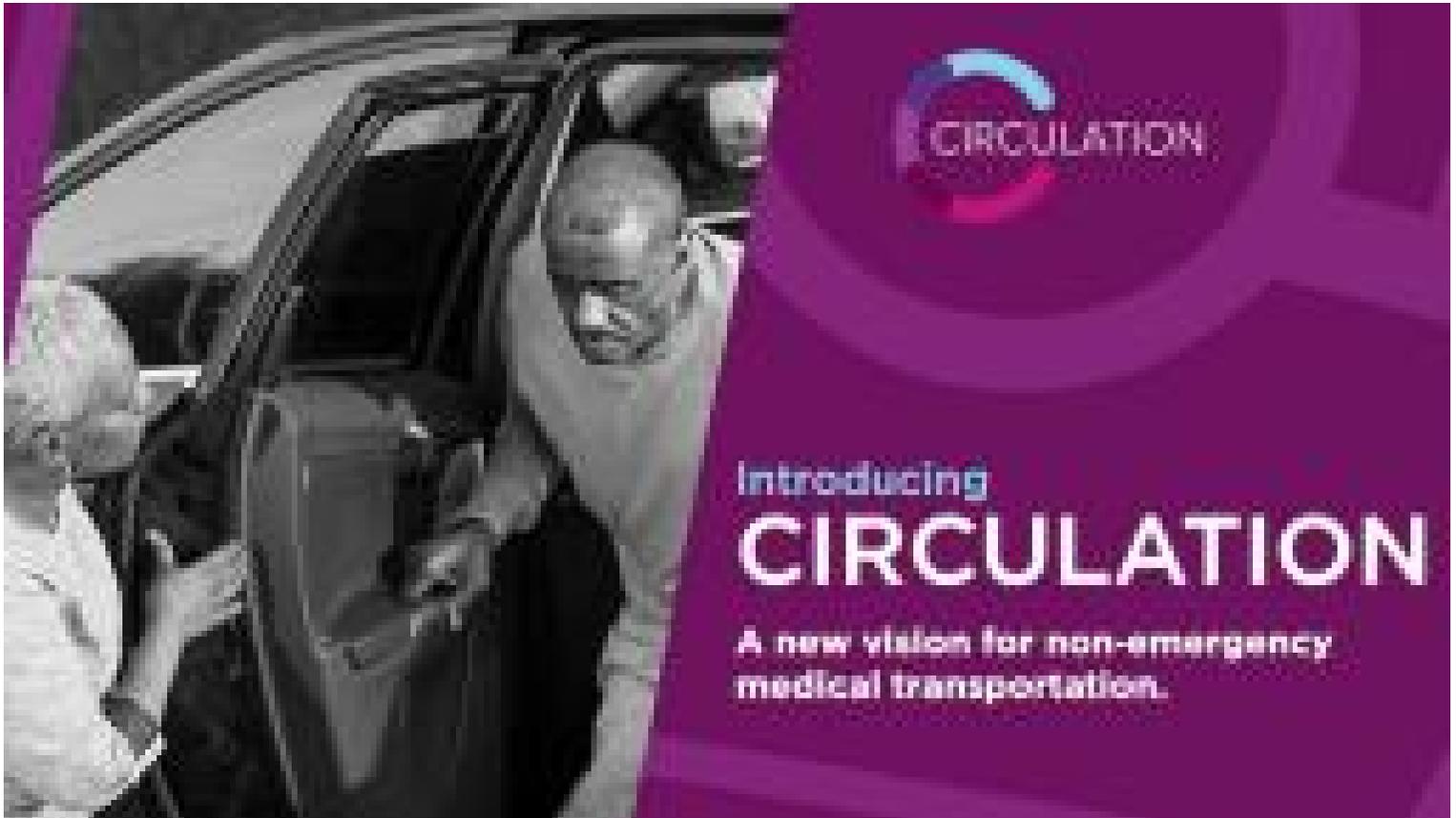
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