The new wave of innovation in clinical trials

Why adopting new technologies is no longer a choice but a necessity for pharmaceutical companies running clinical trials
Contributors to this paper

This paper is an analysis of a discussion lead by group of innovators gathered at Patient Centered Clinical Trials 2015 in a bid to identify and uncover challenges associated with industry-wide patient-centered technology adoption. The consortium of digital health innovators included:

- **Fabio Gratton**, Founder, Alchemy Factory, Co-founder & CEO, CureClick
- **Abbe Steel**, Founder & CEO, HealthiVibe
- **Tyler Trueg**, Director of Clinical Product, TrialReach
- **Sean Vassilaros**, Partner and COO, Thread Research
- **Mike Solomon**, Head of Healthcare, Google
- **Joseph Kim**, Senior Advisor, Clinical Innovation, Eli Lilly and Company

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What are the innovations that are transforming the medical research landscape? Technology has the power to reshape our understanding of the delivery of healthcare and the impact it can have on patients’ lives. We know that 30 billion Google searches every day are related to healthcare. Patients are hungry for knowledge, and are keen to play an enhanced role during their clinical trial participation.

Wearables, algorithms, and out-of-the-box strategies have the power to disrupt every aspect of the clinical trial industry. These technologies will have a wide-ranging impact – from trial design and data capture to community outreach and patient recruitment. The digital pioneers spearheading these endeavors have a unique understanding of technology and its role in achieving better health outcomes.

Fabio Gratton, Co-founder and CEO, CureClick acted as panel host, and he began by admitting that sometimes tech innovators in the health space can sometimes get “drunk on our technowizardry” and lose sight of the real goals.

Gratton told the audience to think of patient centricity as “more than a poster you put in your hallways… think about what it is you are going to do when you get back to work… change will only happen on our watch.”

Technology is enabling patient centricity but must be used effectively; according to Gratton, it is still quite innovative to engage and listen to patients but he emphasized to the delegates that it is important for companies to use what various innovators have developed as an actual product – and not just a mere survey tool.

“We get this data and have codified it and structured it in a way that people have no excuse but to listen to patients – previously that has been lacking because people have a difficult time knowing how to listen.”

Tyler Trueg, Director of Clinical Product, TrialReach, previously worked with the Patients 2 Trials consortium, a group using technology to match patients to trials, via their health records. According to Trueg, it didn’t make sense for this type of tool to live in the industry; he memorably described it as being like “building a Subaru but selling it on chevy.com”.

“The bias is there and it was not the most patient-centric approach.”

The approach of TrialReach involves structuring eligibility criteria for every clinical trial that is ongoing globally; this is then fed into a patient-facing application, where they answer questions and hopefully find the trial that is the right match for them.

“We are taking the messy data from clinicaltrials.gov and other places, and making it very quick and easy so they can find a trial for them,” he explained.

Simple issues such as synonyms and syntax can make this information extremely difficult to elucidate, making finding the right trial a headache for patients.

“For example, Smart Patients found that there are over a thousand ways to represent pregnancy on clinicaltrials.gov, something that should be pretty easy and straightforward to represent. We found out there are hundreds of ways to say type 2 diabetes, which is shocking. The organizing of the words, the order of the letters, was making it really complicated to make any sense of it.”
Truem said TrialReach took a “brute force” approach to tackling these inherent problems by structuring all the eligibility criteria.

“What that does for us is that we can then do some pretty clever things by turning out a statement of an eligibility criteria into a question such as ‘do you have type 2 diabetes?’”

This can be normalized, as Truem explains; essentially that question is answered for every trial the exclusion criteria applies to. A few questions like this can quickly reduce a list of hundreds of potential trials to just a handful.

Where it gets interesting for the pharmaceutical industry, Truem explains, is that the information captured regarding patients can be used when planning future trials. In its earlier days, TrialReach found that overly onerous eligibility criteria made recruitment for some trials almost impossible.

“You cannot save a trial if it is designed for a patient that doesn’t exist, and that happens all the time. We would get called when the companies were struggling – they were blowing their marketing budgets but couldn’t find the unicorn patient they were looking for. Now we are finding things out like what eligibility criteria consistently fail – so that unicorn patients begins to move away. We feed all this back to the industry, and tell them this is what’s working and this is definitely what’s not. If we really want to move the needle on this and make trials more efficient, better search tools won’t do it but finding out the insights on these tools will give us a chance to redesign the trials upfront.”

Searching for the answers

Mike Solomon, Head of Healthcare, Google told the audience that “one out of every 20 Google searches is for health-related issues”.

“At 2am, you will see spikes for all sorts of disease searches – it’s that time when we finally sit down and at the end of our day and pick up our smartphone.”

Despite being simply known as a search engine, Solomon explained that Google is very much focused on the health aspect of its operation.
“The real play here is preventive medicine, as so much of what we do is reactive — we know more about how our cars are running than how our bodies are functioning.”

He gave the example of Google’s Project Iris; this is a smart contact lens that Google have developed and commercialized with Novartis’ eye care division Alcon.

“This is a contact lens that type 2 diabetics can wear, and which monitors blood glucose from your tears. What that does is give continuous monitoring instead of pricking your finger five times a day to get your blood glucose.”

Unsurprisingly, the nanotechnology involved in this landmark innovation is “incredible”, and its potential uses are myriad, said Solomon.

“It’s got a radio frequency, it’s got a power source, and it’s got a chip, all in a contact lens that can sit on my pinky. But take a step back and this is a platform... what else could your ocular fluid tell you about your body? I think we are going to have a future where there are miniaturized devices and wearables that are really going to help us and when you tether this back to clinical trials, this really gets interesting because so much of what makes a successful clinical trial is getting the right data and that’s what connects these two universes.”

When a wearable is unbearable

Abbe Steel, Founder & CEO, HealthiVibe explained that HealthiVibe gathers patient insights and feedback that ultimately help with clinical trial design; the advent of wearable technologies has made this possible.

“Individuals are using technology more and companies are trying to bring new approaches and wearable technologies into clinical trials more and more. What we do involves gathering feedback from patients about their disease and their lifestyle, and the barriers they have and how caregivers affect all of that, as well as treatment choices and switching — all the thing related to their illness but also we want to learn and better understand how they use and will use various technologies as part of their participation in the study,” she said.

This could include wearing a Fitbit or using an e-PRO, and HealthiVibe’s role is to see how these different wearables intersect with the everyday life of the patient, as well as the part they play in the clinic setting.
While pharmaceutical companies are increasingly eager to introduce wearables to their clinical trials, sometimes it’s easier said than done. Steel gave an example of a recent project, whereby HealthiVibe was running advisory boards to specifically look at the wearable fitness tracker FitBit and its use in a clinical trial.

“What we learned with this population that, for various reasons, Fitbit is just not going to work – it’s a patient population with some really severe dermatology issues, many of them said they don’t want to wear anything, or that something containing plastic will irritate them. There are other ways to collect the same data with perhaps a clip-on, however.”

While patients wanted to see the data the FitBit could collect for them, it became clear that it was unfeasible; yet, as Steel explains, the trial sponsors thought that the FitBit would be the unique selling point for the trial, as every participant would get a free one.

Gratton highlighted the importance of learning if something makes sense for the patient, for the trial and for the population, “because otherwise technologies can just get in the way”.

“A lot of companies have the idea that they will innovate and use these cool things but maybe it isn’t the right thing for these patients or this trial.”

**Acceleration through information**

The power of accelerating trial recruitment has been largely untapped by the industry and the data that companies like Google have is “mind-blowing”, Gratton continued.

Solomon explained that when Google first began to explore trial recruitment, they looked at how pharmaceutical companies were going about it; what they found was that their use of traditional print media to advertise trials was costly and inefficient.

“Companies would say ‘We have been at this four months and it has cost us $3,000 to get one person signed up and we need 10,’” he said.

Google engaged in “smart targeting” – by narrowing the focus of the search to patients living within three to five miles of where the trial is going to be fielded.

“We thought, let’s go big and powerful – let’s really try to comb this three mile or so area and see can we get to the people that really matter and see if they are raising their hands. Using this approach, the remaining nine trial participants were found within 10 days. That’s how quickly we were able to do this, and at a fraction of the cost – south of a hundred dollars per candidate,” Solomon outlined.

Google is now using that case study to show other pharmaceutical companies what they are capable of.

“It’s less about the advertising and more about we want to help the industry get these clinical trials fielded quickly. We think if we can help with that, the outcomes are going to happen more quickly too. For us, it always comes back to outcomes and how can we use our expertise and tools to achieve that.”

**Designing a study to design a study**

Thread Research have been involved in developing a study for University of California, San Francisco, who wanted to investigate the unique health problems within the LGBTQ community, but weren’t sure what the end goal should be.
Sean Vassilaros, Partner and COO, explained that Thread Research, using the Apple Watch and Research Kit, created the first longitudinal LGBTQ study platform. Within that platform, a Reddit-style community was also built where members could anonymously recommend various topics and subjects relating to their health that they found important – these could then be voted up or down, based on their popularity within that community.

“This was really one of the first opportunities to democratize the study process. The opportunity to hear patients have a voice and knowing that they are going to have the opportunity to craft studies, and help and create true outcomes for that community is so humbling and amazing to see.”

The PRIDE study launched in June and within two weeks, 14,000 people had enrolled in the study. Within a couple of months, the community aspect of it had identified 30,000 topics of importance – Vassilaros admitted the scale of the response took them by surprise.

“We thought it would take six months to have enough data to craft a real study but within a month we were ready – with the way the system is set up, this registry can last a long, long time – we are looking at a 30-year registry. This real data can have a real impact on this community.”

Gratton concluded by saying that without people from industry adopting, piloting and testing these new disruptive technologies, positive changes will not occur.

“We are here representing all the start-ups to remind you that you need to do these pilots, you need to trust the technology and the way they are going. This is not being done in vain – it’s being done because we need to build that time machine so one day in the future we can look back and know we did the right thing.”

The meteoric rise of mobile

Joseph Kim, Senior Advisor, Clinical Innovation, Eli Lilly and Company, was also at the meeting and he examined the impact that the rise of mobile technology has had on how patients search for health-related topics.

Kim began by informing attendees that clinical research is “not a scientific experience”. It is, he believes, a consumer experience that delivers scientific value.

“How do I know that? Because it’s your sister that participates, it’s your son that participates, it’s your father. These aren’t animals in a cage, these are everyday people,” he said.
Some 42 per cent of the world’s population have access to the internet, around three billion people. Penetration will reach 100% within a couple of years, said Kim.

“When people are on the internet, they gain this ability to do things they couldn’t before, and when they gain new abilities, they start to do things differently, especially in relation to healthcare, and when their behavior changes their expectations change and that’s when they start to demand more transparency and more convenience.”

Its users are now increasingly accessing it with a mobile device and one-third of all web pages are now coming through a mobile phone – this will reach 50 per cent in 2016, Kim predicted.

“Mobile internet will soon be the only internet, the desktop version will soon be irrelevant. Sixty-five per cent of Americans now own a smartphone. Sixty-two per cent of those smartphone owners will use their smartphones to look up medical information.”

Many of these are smartphone dependent, with no access to desktop – this opens up new possibilities in research with regard to diversity. “These will be lower-income, younger people,” explained Kim.

The importance of being mobile-friendly

Mobile is starting to dominate Google, too – in the US and nine other countries, more searches happen on a mobile phone than on desktop, and Google has recently changed the rules for its paid search campaigns.

“Search campaigns now need to be mobile-friendly. The quality of your mobile experience will affect how your mobile ad gets displayed and how you pay for it. If your website is subpar that your mobile ad links to, then you will pay more and you may not be seen at all. If you have a really good mobile experience that you click into, then you will pay less and be ranked higher on page search.”

What makes a site mobile-unfriendly? For example, using software that can’t be used on mobile, such as Flash, or having readable text without zooming. The content should also fit on one page, and links should be far enough apart that you don’t accidentally click something you don’t want to, Kim outlined.

Mobile users are more discerning on Google, with 61 per cent of mobile users saying they quickly move to another site if they don’t find it easy to use and navigate. Google has now established 25 principles of mobile site design to help companies build consumer-friendly mobile sites – principles that the pharmaceutical industry should be aware of, according to Kim.

He explained that Eli Lilly kept all these in mind as they developed their newly-minted Lilly TrialGuide; knowing it had to be mobile-friendly, the text and links were designed to be easy to read on mobile, and the call-to-action is kept front and center, staying on screen as people navigate the site.

“But this doesn’t mean we jam it down people’s throats, we allow people to continue scrolling as it is there.”

Google has a tool that allows anyone to test whether a site is mobile-friendly, and Kim urged attendees from pharmaceutical companies to go away and check if their company site fits the criteria.

“Go away and look at your site and if it’s not mobile-friendly, you should be changing it tomorrow. This is too big and too important – it affects search and it affects social. If you want to raise awareness and connect people to research, you will never succeed as well as others without being mobile.”
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