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How patient insights are changing trial solutions

Patients have been asking for patient-centric trial solutions for years – the industry just hasn't been listening. That's according to Medidata's Anthony Costello, who was bringing patient feedback into product design long before COVID-19. He tells us what insights pharma has been missing out on and how they can be harnessed to build better solutions.

COVID-19 might have forced the industry to leave behind its reticence around remote and decentralised trials, but according to Anthony Costello, senior vice president of mobile health at Medidata, this reticence wouldn't have existed in the first place had the industry been genuinely listening to patients.

"Patients have not been saying anything new during COVID-19, but the difference is that the industry has woken up and started paying attention," he says.

"Patients have long wanted more and better technology to use in studies so that they don't have to visit sites so often, but the industry has been very reluctant to go in that direction."

The pandemic, he says, has forced many parts of the sector to treat patient-centricity as more than "lip service".

"Until now the industry has been listening to patients in an obligatory way, but not much action has resulted from what those patients are saying. Everyone had the right talking points about how they wanted to design studies that lowered patient burden, but very few clinical trials actually implemented patient-friendly technology and protocol designs.

"A year and a half ago most clinical research teams would have snubbed their nose at the idea that they would cancel site visits and do them via video instead, but now it's what everybody wants to do."

Trial burden is not a new concern for patients – health problems and the necessities of everyday life have always been barriers to participation, and better tools and technologies were already important for reducing these barriers before lockdowns forced industry-wide adoption.

Costello's team at Medidata had been hearing this through the company's Patient Insights Program for some time, and in using these insights to help build trial solutions Costello has seen how impactful the right patient feedback can be.

Patient insights

The Patient Insights Program aims to dig deep into what Medidata can do to make their protocol and technology designs better for patients.

When doing this, Costello says it is important to seek out and engage with as broad a range of patients as possible.

"We bring in everyone from cancer patients that have been on nine or ten clinical trials all the way to patients that have never been on a trial but are concerned about how they work," he says.

The backbone of the programme is patient workshops where the company gathers insights through discussions with patients and industry experts. They then use that input to influence future product design. The workshops are run eight to ten times a year, with each one being focused on a particular theme.

"We go deep into each topic then publish our learnings to the group," says Costello. "Everyone who was there has a chance to digest the findings and possibly revisit them in a future workshop.

"Everything that we learn in the workshops goes directly back into the technology that we're trying to build."

Of course, one challenge of this methodology is that it can produce a huge range of qualitative data.

"It isn't magic – often we'll get as many opinions as we have people in the room," says Costello. "We'll try and get deep engagement on every possible solution, and then it's our job to go away and find a solution that works best.

"We make appropriate trade-offs and build the product as best as we can with all the inputs in mind – but the Insights Program is designed so that we can circle back to the patients that helped us design it once we are ready to launch. We call that a 'patient acceptance test'; the patients will literally sign off that the product is acceptable, in their opinion, to go to market. Any problems they still have are documented and put into roadmaps for future consideration."

Costello says the most important consideration for a patient insights programme like this is to maintain fluidity.

"If we don't get something exactly right the first time, we'll continue developing it using an agile methodology to make it better."

Although in the past Medidata has designed products before bringing in patient insights, or has brought in these insights to improve pre-existing technology, the company has started building software from scratch with patient teams – such as the company's patient portal myMedidata.

Costello says that, in myMedidata's case, this meant spending hours "agonising over" even the simplest functions to make sure they were optimised for patients.

"For example, we spent a lot of time looking at the journey through an account creation screen. That's not something most of us would think about when getting a new piece of software, but patients have to worry about how accounts might link into their health records.

"We asked what we should put on the screen to tell patients how their information is going to be used, and when we should even ask them to create an account. Should it be on the very first screen, where they might not be comfortable yet, or do we guide them through an information screen first? Should you have one information screen or multiple screens? Should those link to other resources to read, or should there be a video instead?"

Similar considerations surrounded how consent forms should be structured, and what font sizes or colour schemes should be used.

"These are all things that matter so much to patients, who might not be experts in technology but are still going to have to look at the software every day for the 18 months they're on a trial. It really is critical to get these things right for them."

The team also sought feedback on how questionnaires, which are a huge part of the software's experience, should be structured.

"It might seem rudimentary, but we find lots of different opinions among patients," Costello says. "Some will want one question per screen in a large font size that's easy to read. Others say that having to go through multiple screens would drive them crazy.

"It also depends on the device you're using – it makes more sense to have one question per screen on a smartphone, for example.

"Sometimes we have to make trade-offs, but we also aim to build software with as much choice and flexibility as possible."

With more and more mobile data capture technologies emerging, a broader goal for the design of myMedidata was to bring multiple functionalities together into a single portal for patients, allowing them to do away with having extra devices or multiple apps with different logins to remember.

"We built myMedidata to be accessible from any kind of device," says Costello. "It also has the same authentication requirements as the rest of the Medidata platform.

"If you're on myMedidata with a single username and password, you can see every feature that you need for that study, and you can also see every other study you've ever done on our platform."

Like with other products, Medidata hopes to continuously roll out updates to myMedidata as more patient feedback comes in.

"We're getting constant feedback right now on what features are important to customers and why," says Costello. "That includes building more registry capabilities to facilitate large COVID-19 trials that are happening."

Although the rest of the industry may have been slow in taking patient insights on board, Costello believes that the pandemic has helped pharma realise what they've been missing out on, and he hopes that these kinds of insights can be filtered into development across the sector.

"Patients are not saying anything different to what they've always said," he says, "but the industry is listening in a very different way now."

About the interviewee

Anthony Costello, senior vice president, patient cloud, Medidata

After beginning his clinical research career at Genentech 20 years ago, Anthony Costello has gone on to co-found several clinical trials technology start-up companies including Nextrials (acquired by PRA Health Sciences) and Mytrus (acquired by Medidata). Over his career, he has focused on disruptive and innovative technology that can simplify clinical trials for patients, sites and sponsors. He has been selected as one of the PharmaVoice Top 100 Most Inspiring People in Clinical Research, has served as chairman of the Board for the Society for Clinical Data Management and is currently a member of the editorial advisory board for Applied Clinical Trials magazine. He is a frequent author and presenter on topics related to the efficient use of technology in clinical research.

About Medidata

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Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences, creating hope for millions of patients by helping to generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimise risk, and optimise outcomes.

About the author

George Underwood is a senior member of the pharmaphorum editorial team, having previously worked at PharmaTimes and prior to this at Pharmafocus. He is a trained journalist, with a degree from Bournemouth University and current specialisms that include R&D, digital and M&A.