Clinical Minds Transcript: What do Virtual Clinical Trials Look Like?

Dan Poppy: Welcome to Clinical Minds presented by Medidata. I'm Dan Poppy. As COVID-19 spread it put a major strain on healthcare facilities, but it also heavily impacted clinical research. The number of patients entering clinical trials declined pretty dramatically, especially as countries tighten laws and guidelines restricting the public's movement outside of their homes.

There have been several challenges facing clinical trials during the COVID-19 pandemic, but a main priority for researchers is to reconsider what a clinical trial looks like when trial volunteers are stuck at home or just unwilling to leave home.

Today, we're speaking with Anthony Costello, Senior Vice President of Mobile Health at Medidata, a frequent author and presenter on the use of technology in clinical research, to talk about what research looks like now and where it's headed. Anthony Costello, thanks so much for joining us.

Anthony Costello: Hey, thanks a lot for having me, Dan. I'm excited to be here.

Dan Poppy: First, what is mobile health, exactly, when we're talking about clinical research? I track my steps on my phone. Are we talking about the same thing?

Anthony Costello: We are. We are, but it's bigger than that. What we consider the mobile health components are any tool or technology or data-enabling capability that is used directly by a patient.

The patient cloud team or the mobile health team at Medidata builds apps and other types of tools that patients use directly on a study to provide their own information or to have access to their own information. So something like the wearable sensor that you were talking about could be included in that, but we also have products for doing direct data entry over phones or tablets or even computers, in many cases, where a patient might be between site visits and needs to provide information for the clinical research protocol.

Dan Poppy: So I mentioned at the top, stay-at-home orders and just general unease about travel within the public, it really changes how we think about where we want to be when it comes to clinical research. How is mobile technology shaping our approach to clinical research?

Anthony Costello: It's really changed dramatically in the last few months. So I think I like to look at this as a marathon to get the clinical research industry to restructure itself around patient centricity, patient-facing applications, and things that really bring the burden down for patients who are participating in these kinds of trials.

And if you look over the last few years, there's definitely been movement in our industry towards more patient-centered capabilities and patient-centered protocol designs, but that's just been hyper-accelerated over the last few months because of COVID.

But enter the COVID pandemic, and many of those same customers that might have been on a path or a slow path, now they're on a super-fast sprint path to deal with site disruptions and protocol disruptions caused by a pandemic where many patients won't leave their house because they're having health concerns at home with their family or they're afraid to go to a site where they might pick up exposure to COVID, or the sites themselves are so swamped with COVID cases that they literally are unable to keep up with the visit pattern they would normally have for patients on a clinical trial.

So mobile technology becomes the whole story. It's literally the difference, in some cases, between the study failing because it can't collect any data at a site visit versus the study succeeding because they found a way, operationally, to migrate that data capture outside of a site to the patients at home using the kind of mobile capabilities we're talking about.

Dan Poppy: So I know my doctor now offers a virtual consultation so I don't have to go to the doctor's office. Are we talking about the same thing here?

Anthony Costello: In some ways, yeah. Let's say the patient goes in every eight weeks, they talk about what's been going on, have they had any adverse events, have they taken any medications, what are their vital signs, are they taking the drug regularly, have they missed any doses, that's the kind of stuff that gets discussed with a typical clinical trial patient every periodic site visit. So if those visits just don't happen at all and no data gets captured, that's a significant hit to the protocol.

But if you take that eight-week visit and you turn it into a telemedicine consultation where the same questions can be asked and the same data captured where the patient can enter their own headaches or their own medications, or maybe even we ping them every day and remind them about something that they normally would have been reminded of by the site but now we can find ways to keep them on task during quarantine, all of these approaches are being used now on studies that are suffering from the effects of the COVID pandemic on site visits.

But you can easily see how just enabling a few simple capabilities like that could keep a study on track and could keep the data capture coming in for those patients so you don't have the kind of disruption that just ruins a whole protocol.

Dan Poppy: This pandemic, in some ways, as you said, has really accelerated the adoption of some of this technology. What happens when the pandemic ends? Do we go back to the way things were done?

Anthony Costello: You know, we don't know. I've got my own personal theories on that, and I think you could probably, if you ask 10 people in our industry, you'd get 10 answers. But I think one thing is clear. Regulators have really shown a lot more willingness during this timeframe to quickly adopt new methods and consider what I would call out-of-the-box thinking on how to keep things afloat during this very challenging time, so I think that's part one.

The other piece of that is that sponsors have not just a willingness to consider new ways of doing this, but they are seeing it as a way to survive. If we're going through a mode here where we might be on and off quarantine for the next couple years, let's say, that's going to be on and off significant disruptions to studies that cost hundreds of millions of dollars to run, and you can't just throw the whole thing away and start over, right?

So the combination of regulatory willingness to speed things up in our industry and sponsor willingness to look for a way to, let's call it, COVID-proof some of their capabilities around these ongoing trials, it's horrible that a pandemic has to make these sorts of changes in our industry, but I think we will see some of these things last beyond just the first wave of the pandemic and lead us into just a much, much better system for collecting data from patients and running these trials more efficiently.

Dan Poppy: What does all this technology mean for the patient experience?

Anthony Costello: If you're in a life or death oncology situation where the clinical trial is your last hope and you can't go to that site visit because of quarantine or because the site's been retooled around a different disease, then obviously that's an almost unimaginable position for a patient to be in. And the kind of tools and capabilities that we can offer to maybe just help a little bit in that kind of situation could mean a lot to that patient and to the possibility of that research being completed on time.

But there's lots of clinical trial scenarios that are not necessarily life and death. There are patients who want to improve their own disease condition, they want to help science, they want to help other people that they know in their community that want to get better from this disease.

And those kind of patients suffer all the time from badly-designed protocols that are very burdensome on patients, very expensive for patients, don't consider patients at all in the way the protocol's built or the way the site visit schedule works, and don't offer any kind of mobile health capabilities where patients might avoid the life disruption that is caused when you have to go in for these site visits over and over and over again for the life of the study.

So I think our mission at Medidata is to build better patient tools for every study and to bring down patient burden in every kind of study scenario no matter how... It could be a healthy

volunteer Phase I trial, it could be a life or death Phase III oncology situation. We want to lower the burden on patients in all of those cases.

But when you kick that into the realm of COVID-19 quarantine, I think those kinds of tools make an even bigger impact. We've been on this path before COVID-19, and we will continue on this path after COVID-19, considering patients and what's important and critical for patients before anything else.

Dan Poppy: In the midst of this pandemic, Medidata launched myMedidata, which is a patient portal that allows patients to more fully participate in clinical trials. Can you tell us a little bit about what this looks like for patients?

Anthony Costello: Traditionally, Medidata and many of our competitors as well, have offered mobile health tools as a series of different apps.

So we built myMedidata as a single platform for patients to collapse all of those different types of features that they might find today on three or four or five different apps into a single app. They'll have one login. They'll keep that login for life. And maybe most importantly, they'll continue to have access to myMedidata when those studies close and lock and go away, so that as a patient who participated in each of those trials, they'll be able to have longitudinal lifetime access to all of the information that they've previously provided and all the studies that they've been on.

So we see this as an important step for our sponsors to consolidate vendors into a single platform.

But again, everything that we're doing is circling back to, how do we help patients get through these studies more easily, and how do we help them partner with us to provide the research data and information as fast as possible? And we see myMedidata as just a huge step in that direction.

Dan Poppy: You also announced a COVID-19 symptom tracker. So what does that do, and how do you expect that to be used by researchers?

Anthony Costello: The idea behind the symptom tracker is that if patients are not able or not willing to go to site visits right now because of the pandemic quarantines, as we talked about before, this is a tool our customers can use to reach out to those patients remotely and get some information about their COVID status. So it's meant to be an offering that patients not going to site visits will fill out periodically, and we send them reminders about when to do it.

Dan Poppy: And do you expect this to be used not just for COVID trials? This could be used for any type of trial?

Anthony Costello: Oh yeah. This is really not even a tool with a lot of value on a COVID trial, because on a COVID trial, you know everybody's got COVID, and you're finding clever ways to stay in communication with those patients anyway.

This is for your average, run-of-the-mill, non-COVID trial in the 200 other disease areas that we're studying where patients just, for whatever reason, for months at a time, may not be going into the sites to comply with the visit schedule because they're stuck on quarantine.

Dan Poppy: Data privacy is obviously a huge concern for everyone. How do you ensure that I don't enter into the tracker that I have a runny nose and then immediately get ads for Kleenex on Instagram a few minutes later?

Anthony Costello: Well we will not share that data with Kleenex or any other home-based products that might want to market to you. The data that we're collecting on myMedidata for COVID screening, it literally is pushed directly into the Rave database. It's under all the same restrictions and privacy rules that all other Rave data are for those customers.

Dan Poppy: And what is Rave, for people who aren't necessarily in the clinical trial space?

Anthony Costello: Rave is Medidata's primary electronic data capture tool, and it's used on 60-plus percent of the world's clinical trials as a technology that sites who are seeing these patients will enter the data related to the clinical research study.

Dan Poppy: Anthony, thanks so much for joining us. Stay safe, and we can't wait to hear how the COVID tracker works in the field. Maybe we can get you back on the show to give us an update.

Anthony Costello: Yeah. Thanks very much for having me. I'd love to come back. There's a lot of great topics related to patients and patient technology in our industry right now, and I think we're all going to find out in the next few months what kind of lasting effect this COVID pandemic is going to have on the way we do research. So looking forward to discussing that.

Dan Poppy: This has been Clinical Minds presented by Medidata. If you haven't yet, make sure to subscribe wherever you get your podcasts. Let us know what you think of the show. Let us know what you want us to talk about on the show. We love that, and we listen, and we'll see you next time. Bye.