Clinical Minds: What is the Data Telling Us?

Dan Poppy: You're listening to Clinical Minds presented by Medidata. I'm Dan Poppy. When you think about the science of new drug development, what do you think about? Maybe biochemistry or pharmacology, but what about data science?

Dan Poppy: Yes, there are numbers in science, that's not hard to believe. But there's also science in the numbers, and data science plays a major role in how we develop new drugs and how we understand disease. And that's true for the COVID-19 pandemic as well.

Dan Poppy: Today, we're speaking with Fareed Melhem about what data is telling us about COVID-19, and how data is being used to combat the challenges of a pandemic. Fareed leads Acorn AI Labs, a collaboration space for researchers to bring together data and technology to solve drug development's biggest problems. Fareed Melhem, thanks so much for joining us.

Fareed Melhem: Thanks. Great to be here.

Dan Poppy: First, what is data science exactly?

Fareed Melhem: Data science is really just the process of using data to make better decisions. So as data available to us grows and it's been growing quite rapidly, we need to be able to use more advanced methods to acquire that data, to link that data, to clean that data, and to model that data. But at the end of the day, it's really about making better decisions and developing better insights to help us with the way we do run clinical trials.

Dan Poppy: You and your team have been sharing data trends about clinical development during COVID-19, which people can find at medidata.com. What is the data telling us about COVID-19's impact on clinical trials?

Fareed Melhem: First of all, the impact of COVID-19 has been immense. So we've done analysis of trials currently running on our platform, and we've seen an upwards of 80% drop in new subject enrollment. And so what that means is that trials are really struggling to get new patients into their sites and into their trials.

Fareed Melhem: We've also seen a similar drop, so 30% or more drop, in patient visits for ongoing trials, meaning that even if the patient was already enrolled in a trial, they are having trouble getting to their sites to do their regularly scheduled visits. And so both of those are really obviously causing a lot of challenges for clinical trials, both in terms of trying to get the number of patients in that we need, but also to make sure that we're collecting the data on patients for those who are already enrolled.

Dan Poppy: And what does this mean for research being done today?

Fareed Melhem: Well, it means that we need to rethink how we're going to work with those trials that are ongoing right now, or that were scheduled to start up. So most sponsors have either slowed down or stopped enrollment of new trials. And then for the trials that are ongoing, we're working on ensuring that we are getting the right data in for those trials.

Fareed Melhem: Some of that can be done with virtual solutions. So trying to capture data from patients at their homes, use telehealth visits and other methods, and some of that may have to be done by extending the length of these trials.

Dan Poppy: You mentioned these data trends were pooled from your platform, where is this data coming from exactly?

Fareed Melhem: Medidata runs thousands and thousands of trials on our platform every year. So we currently have about 6,000 live trials running on the platform, and that data is the data that we're using to try to measure some of the impact of COVID-19. So we are looking across therapeutic areas, across different indications and across countries, to measure not just the overall impact, but what is the impact country by country and what is the impact therapeutic area by therapeutic area?

Dan Poppy: So Acorn AI is the advanced analytics arm of Medidata, and you mentioned the live trials, but it's also built on data from, I think something like 20,000 trials and patient data from more than six million trial participants. How are you able to use this data to help today's trials?

Fareed Melhem: As we think about coming out of COVID, and it's not going to be a quick recovery, it's going to be many months and probably multiple year sort of recovery trajectory, that data is going to be very useful to do a few different things. The first is really starting to chart what does that recovery look like?

Fareed Melhem: We can start to think about what do recovery curves look like country by country? How do we plan for trial restarts? Even going down to individual site levels and understanding which sites are starting to come back online and which ones aren't. We start to see some signs of recovery, which are positive, but we're still a long ways away.

Fareed Melhem: And that's really going to be a really important use of that live trial data. The historic data is also quite important in identifying potential sites to go to, but also in starting to leverage some of that historic data for our ongoing trials. And so thinking about something like a synthetic control arm.

Fareed Melhem: And basically what a synthetic control arm is, is using historic patient data to supplement the data for ongoing trials. So think of it something like this, most trials have an experimental group and a control group. And the experimental group gets the drug or the therapy that we're testing, and the control group gets either a placebo or standard of care.

Fareed Melhem: And they're really the baseline against which we compare the effect of the experimental drug. Now we have to, in trials, usually enroll a whole bunch of patients into the trial who end up in that control group, don't get the benefit of the experimental drug, but still have to go through the whole process. So that's not great for patients. It also is quite expensive and it delays the timeline of trials.

Fareed Melhem: And a synthetic control is basically, at its simplest form saying, "Well, we already in our database have data on a lot of patients who have gone through trials in a control arm on that same standard of care or placebo, let's use their data and set the baseline using that and compare that to the experimental control."

Dan Poppy: And this is something that you think can be useful during COVID-19?

Fareed Melhem: Yeah, absolutely. Especially as we think about data disruptions that we're seeing, because of missed visits because of inability to conduct trials in the same way that they were planned to be conducted. One approach is to either extend or collect more data on an ongoing basis for those trials as we come through COVID, but that can certainly be supplemented with some of this synthetic control data to try to make that easier, to try to reduce the number of new patients you have to recruit. To try to supplement some of the signal that you're seeing from the data you have and see how robust it is with additional data.

Dan Poppy: In this series we've been talking about clinical trials and how important they are for new drug development, something like synthetic control, how do we know it's good? How do we know that we can use it? Why don't we just run a trial the way that we used to?

Fareed Melhem: So we've done a lot of testing around the synthetic control data and the synthetic control arms that we developed for exactly that reason, to make sure that they are robust and that they do match what a real patient population would look like.

Fareed Melhem: And so we've published work with Friends of Cancer Research on exactly that topic a couple of times, but the reason to do it is simply because it significantly reduces patient burden, so it makes trials a lot easier for patients, it reduces cost, and it reduces timelines.

Fareed Melhem: And so drugs get to market faster, they get into patient's hands faster. There's really a myriad of reasons to do it, and I think that we will see increasingly companies move in that direction, and regulators accept that data.

Dan Poppy: You mentioned that we're starting to see some positive trends in the clinical trial data. What can you tell us about what those trends are showing us about clinical trials now?

Fareed Melhem: In countries where the lockdown status was eased earlier, countries like China, like Korea, like Italy, and even places like Australia, we have seen an uptick in clinical trial activity, both in terms of visit volume, as well as in terms of subjects being accrued.

Fareed Melhem: And that is looking like it's taking roughly six weeks. So somewhere between four and eight weeks, we'll call it six weeks on average, to get back to 50% of what the pre-COVID baseline was once those restrictions are eased. Now that's different from therapeutic area to therapeutic area. Some are recovering faster.

Fareed Melhem: So oncology is recovering a bit faster, and some are recovering quite a bit slower. So things like cardiovascular trials are recovering more slowly. But what we are doing is tracking that on a country by country basis and looking at what are the indicators that actually help us start to identify when we're expecting an uptick in country and site level performance.

Fareed Melhem: We're looking at things like peak in the COVID case rate. You mentioned the lockdown status, and so we're looking at lockdown severity and when that's easing and what follows on that. And all of this is to really start to develop a picture of what does the next six months, what does the next 12 months look like as we come out of this?

Dan Poppy: You mentioned differences between oncology and cardiovascular. Are there any indicators that you've been able to identify that may suggest why we're seeing different rates of clinical trial participation between cancer and cardiovascular and others?

Fareed Melhem: So it probably has to do with how critical the trial is for the patient involved and how eager they are to get back into it. So some of this is driven by sites reopening and accepting patients again.

Fareed Melhem: But the flip side of that is that patients have to be willing to go out, to go to a health center, to enroll in a trial or rejoin a trial. And so you can imagine that there might be a difference in a patient willing to do that if that patient is receiving treatment for their cancer, versus if they're in a long-term study for some of these other diseases where disease progression might be much slower.

Dan Poppy: And this maybe is a little bit different than the types of research that people think of when they think of clinical trials, clinical trials happen at a hospital, and maybe they seem a little bit removed from everyday life, but in your world, everyday life and clinical trials are pretty interconnected, yeah?

Fareed Melhem: Yeah. We think about clinical trials every single day, for sure. But it's a bit disconnected from most people's lives, certainly, but for the patients in the clinical trials, it's obviously critical.

Fareed Melhem: And so a lot of the work that we do and that we're doing with sponsors is trying to get those clinical trials back going in some form to support those patients. Because for some a clinical trial can be kind of a lifeline. It's a hope for a lot of these diseases that are quite terrible.

Dan Poppy: Fareed, thanks so much for joining us.

Fareed Melhem: Thank you.

Dan Poppy: If you want to learn more, Fareed and his team published the paper on COVID-19's impact on clinical trials, and you can find it at medidata.com. This has been Clinical Minds presented by Medidata. We're planning out our next season, so drop a note at podcast@medidata.com, and let us know what you want to hear about. We would love that, and we'll see you next time. Okay. Bye.