Clinical Minds Transcript: How Do We Keep Clinical Trial Patients Safe in the Pandemic?

Dan Poppy: Welcome to Clinical Minds, presented by Medidata. I'm Dan Poppy.

You may have noticed there's a bit of attention—just a little—on clinical development at the moment, as the world races for treatments and vaccines for COVID-19. Much has been said about how governments are responding to the pandemic. It could be the defining feature of administrations around the world, but there's the government response at the executive level, and then there's the government response at the regulator level, which receives a lot less attention.

In the U.S., the Food and Drug Administration, the FDA, oversees clinical development to make sure patients are protected, not just for the drugs on market, but for the clinical trials used for the next generation of drugs. And despite the intense focus on COVID-19 treatments and vaccines, there's still a lot of clinical trials going on for all sorts of diseases. So, how are governments making sure patients in clinical trials are safe, while also making sure we keep developing new treatments?

Today we're speaking with Ari Feldman, vice president of global compliance and strategy at Medidata, to walk us through the government response. Ari and his team recently published a great resource about regulatory impact on clinical trials, so make sure to check it out at medidata.com if you want to learn more.

Hi, Ari Feldman. Thanks for being here.

Ari Feldman: Hey, Dan. How are you? Pleasure to be here.

Dan Poppy: We're happy to have you. In our last episode we walked through what clinical trials are, but we didn't really talk about how they are overseen by the government to keep the public safe. So, you and I are in the U.S. How does the government oversee clinical trials?

Overseeing the whole process are the regulatory agencies. And really what they're after is clinical trial conduct. And the regulators are looking at clinical trials based in accordance with International Council of Harmonisation, or ICH, guidelines for Good Clinical Practice. These are well-published, well-known guidelines for how to conduct a clinical trial.

There are both national and local regulatory bodies. So, for example, the Food and Drug Administration in the U.S.; the Pharmaceutical and Medical Device Agency [sic], or the PMDA, in Japan; the Medicines and Healthcare products Regulatory Agency, or the MHRA in the U.K.; the European Medicines Agency in Europe; and the National Medicinal Products Administration in China.

Dan Poppy: So, right now we're dealing with the COVID-19 pandemic. COVID-19 is really throwing a wrench in how things have been done in clinical development. How is FDA and others, how are they responding to COVID-19 in terms of clinical trials?

Ari Feldman: Yeah, the FDA, no different than many of the other global agencies, have come out with emergency guidance.

And what we've seen is, since the original guidance was issued on March 18, 2020 it's been followed by several amendments to account for various responses to questions from the industry, webinars and Q&As that they've had. This guidance encapsulates both COVID trials, non-COVID trials, new trials, ongoing trials. Underlying all of this we believe, and what we see, is that this—that the agency has adapted a very pragmatic approach, but most importantly, has kept patient safety in the forefront.

Dan Poppy: And when you say "guidance," what does that mean for people who—we hear a lot of discussion of the government mandates put out and that sort of thing. What is guidance in the world of regulatory oversight?

Ari Feldman: So, guidance documents are just that. They're not prescriptive approaches to how clinical trials should be conducted. They're a framework for ensuring that when you're creating a clinical trial, that it's going through certain checks and balances and that patient safety—you're not unnecessarily risking someone's life for development and for the advancement of science.

An example of guidance would be related to medicinal product. Typically what we're used to seeing is that a patient would have to go to a site to get the medicinal product associated with the clinical trial.

In the times of COVID that might not be practical. And if someone's on a clinical trial for a life-threatening illness, we wouldn't want to risk their participation in the clinical trial simply because they can't get to the clinic. In this example, we've seen pragmatic guidance to how, perhaps, that medicinal product might be sent to the patient who might be in quarantine.

Dan Poppy: So, how are we seeing this agency response play out in terms of its impact on patients and then researchers?

Ari Feldman: Consenting of a patient. You and I have both been to doctors, just sort of a routine. And you know when you go to the doctor they give you this clipboard, and you look at this thing and it's got lots of writing. And at the bottom it says, "Sign here," and then you flip to the next page and it says, "Sign here." There's a bunch of that. And those are various consents that—

Dan Poppy: I don't think I've ever read those from top to bottom.

Ari Feldman: I don't know how many people have read them, but those are consents that are required to be obtained for various different areas, whether it's for privacy, whether it's for insurance billing, whether it's for interventions. And for many years technology providers have been advocating for the use of electronic consent. That is you get that on your mobile phone, you get that on a tablet, you review it and you sign it.

So, here's an example where, through this COVID-19 guidance, we've seen the FDA as a trailblazer, and most of the global regulatory bodies following suit. Electronic informed in the times of COVID, patients might not be able to get to that site, electronic informed consent is now acceptable.

Another example might be patient tracking. It's important throughout the life of a clinical trial to understand how a patient's reacting to the medication, how they're feeling on a regular basis. Historically you would be required to maybe go into a clinic and give that information to a professional who would simply write it down and you'd go on your merry way. And what we're seeing is remote patient tracking, where the regulatory authorities have given the ability for patients to more readily provide this information, and researchers to more readily receive this information.

Dan Poppy: So, when are we getting a vaccine or a treatment for COVID-19?

Ari Feldman: Well, I can say that as of May 15, 2020, as it relates to COVID, according to the World Health Organization there were north of 110 vaccine candidates in preclinical development, and 8 that were in clinical trials. That's a huge number, seeing as though clinical trials and clinical trial approvals normally take many years. And what we're hearing is the approvals to proceed are happening at light speed.

So, I think that the regulatory response in relation to what's happening in the world today has been incredible. And what we're seeing from a regulatory response for both patients and researchers, is that there are long overdue accelerations to advancing the clinical science, while still maintaining the patient safety—a concern that has long been out there in the industry and has, frankly, been a barrier to the adoption of technology. And this approach is absolutely incredible.

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

Ari Feldman: Pleasure to be here. Thank you.

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. We listen. And we'll see you next time. Thanks.