Clinical Minds Transcript: When Will We Get the Vaccine?

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

This is a podcast about clinical development, how drugs go from a lab, to testing in humans, to your local pharmacy. Our goal is to share what's happening in the world of clinical research today and the technology and ideas that are transforming it and why this matters for patients, which is all of us. We want this to be relevant to those developing new drugs, but we also want it to be interesting to everyone else because interesting is better than not interesting. So, let's just jump right in.

The global race for COVID-19 treatments is really putting a spotlight on how new drugs and vaccines reach patients. Early reports suggest that a COVID-19 vaccine could be available sometime next year, which for some seems incredibly far away, and yet most drugs take ten years or more to be approved.

Today I'm speaking with Alicia Staley, a three-time cancer survivor, a patient advocate, and Medidata's senior director of patient engagement. Alicia has been in clinical trials herself, but she also thinks a lot about the patient experience in clinical trials and how to make it better. We'll be talking with her about why it takes so long for drugs and vaccines to reach patients, what clinical trials are, and why they're so important. Think of this as Clinical Trials 101. Alicia Staley, thanks so much for joining us.

Okay, so, researchers discover a promising experimental drug or vaccine. What comes first?

Alicia Staley: Well, typically in the drug development process or vaccine development you're going to have to move your research through a number of phases. And that can extend over a number of years, but each phase will work on testing some aspect of that drug or vaccine. You know, you'll begin to test to make sure that the drug or vaccine is even safe to introduce to a patient.

You know, and then as you move into further stages, you'll start to get into answering questions around what the proper dosing would be. Is it really effective? What kind of side effects are we looking at? Is that the kind of outcome that we want for patients?

And then even further in the phasing is does the drug really work in the way that we want it to? Does it eradicate a virus or does it take care of an illness? And that's typically how researchers try to set up these questions and answer them in all these different phases of a clinical trial.

Dan Poppy: So, in the news right now people are reading about phase I trials for COVID vaccines and treatments. What happens in a phase I trial?

Alicia Staley: In a phase I trial you're testing the drug or the vaccine on healthy volunteers that have stepped forward to say that they're willing to be participants in clinical research, to make sure that this vaccine or medicine that they're developing is safe. There's about 15 to 20

volunteers, participants in a trial in this phase. Sometimes it gets up to about a hundred, but a very small amount of people participating in that phase I trial.

Dan Poppy: And these still last several months, right?

Alicia Staley: Absolutely. This is a very hard process to say, "Oh, it's only going to take a month," or, "It's only going to take two months." The amount of time that you can remain in each phase is really unique to the trial and what you're trying to test. You know, everyone's hearing in the news that we could have a vaccine, you know, within months. And I get a little worried when I hear conversations like that because I don't want us to rush through any of these phases for the sake of getting something to market in a very quick way, so we have to make sure that we're balancing the extreme need for a vaccine with safety, scientific method, and these processes that have worked so well for so long.

Dan Poppy: And the variation in time is because we need to fully understand how the drug is working, right?

Alicia Staley: Absolutely. So, each phase really has to answer a series of questions, and in phase I you're asking questions around safety and dosing.

Dan Poppy: And then things go well in phase I, hopefully, and you move on to a phase II trial. What's a phase II trial?

Alicia Staley: A phase II trial really continues to assess the efficacy of the drug or vaccine, and really begins to sort of quantify or document side effects in a larger segment of the population. So, you're going to have anywhere from 100 to maybe 500 patients in a phase II study.

You're asking questions. Again, is the drug working? Is it effective? Is it efficient in what we're trying to do here? At this point you're not checking to see if the drug is actually taking care of the virus. You're really still trying to determine safety and dosing.

Dan Poppy: So, we get through a phase II trial. There's a better understanding of a patient's response to treatment, but that's still not enough to bring it to market?

Alicia Staley: That's right. We still need to go through one more phase, and that's phase III. So, really, in a phase III trial you're really trying to answer all of the questions all at once. Is—what's the efficacy? Is this drug safe? Is it effective? And is it helping?

So, you know, in the case of something like coronavirus vaccine, you know, making sure that it's hitting all of these markers in an even larger patient population. So, in a phase III trial you're going to get over 1,000 patients, anywhere up to maybe 5 or 6,000 patients, depending on

what the researchers feel would be an appropriate number of patients to go through a phase III trial like this.

Dan Poppy: We make it through phase III, and then what happens?

And this is the point when the drug is now really—is available for anyone seeking treatment for the coronavirus or looking for the vaccine. This would be the phase at which that actually becomes a reality.

Dan Poppy: Patients are vital to clinical trials happening. Who are these people participating in trials?

Alicia Staley: In the early phase clinical trials it will be healthy volunteers. You know, as you go through later phases, in oncology you'll have patients that are looking for additional therapy options to help them if they're in a metastatic state.

But in general, you hope as many people as possible would participate in research or in a clinical trial, but unfortunately I think clinical trials are still not looked upon as part of someone's healthy journey. Clinical trials have always been thought of as a last resort kind of area for some treatment options.

So, there's so many other therapeutic conditions or disease states that need volunteers; for some reason we still aren't doing our best in letting patients and people know about clinical trial opportunities. And that's, I think, something that we really need to change.

Dan Poppy: Yeah—why aren't people participating in trials, and what do you think can be done about it?

Alicia Staley: I think in the U.S. in particular we've gotten away from building relationships with our healthcare providers, and I think that that has had a very long-term effect on how patients think about not only their health care, but clinical research.

Clinical research has always been this faraway kind of thought for most patients. And we really need to bring clinical research into the everyday conversations that patients and their primary care physicians are having.

Dan Poppy: And you've participated in clinical trials before, right?

Alicia Staley: Yes, I have. I've participated in a medical device clinical trial when I was diagnosed with breast cancer in 2004. And I've participated in a number of follow-up clinical trials over the last few years, and currently I'm actually on a clinical trial that's tracking COVID-19 every day—basically, your health every day to help you assess your risk for COVID-19.

Dan Poppy: Your professional life is spent thinking about clinical trials. So, also, your personal life is devoted to thinking about participating in clinical trials. What have you learned about the trial experience, as a participant yourself?

Alicia Staley: I think the clinical trial industry at large could really make significant progress by looking at how different industries approach building relationships with customers. I think that we don't do enough in the industry to be champions for patient experience and to really try to help patients have a seamless, or what I like to call frictionless, experience with clinical trials. So, we've made the process much harder than it needs to be for patients.

And I feel like that's unfortunate because in some ways that really affects how many people will enroll in a clinical trial. And I think we need to, as an industry, really begin to address that and come up with ways to build best in-class patient experiences for patients that are volunteering and taking time out of their life to participate in the clinical research process.

Dan Poppy: Is it getting better, do you think?

Alicia Staley: It's definitely getting better. Absolutely. There's no question about it. And I think we're making small, incremental change year over year, but I would really—it would be wonderful to see the industry really shine a light on this in a big way and really begin to work on delivering best in-class experiences for everyone that are involved in trials.

We need to make it easier. We need to reach greater population of potential research participants, and we just have to keep pushing hard to make sure that we're not leaving patients behind.

Dan Poppy: So, I'm recording this from my living room. You, I think, are doing something close to the same. We're clearly in a different world right now—

Alicia Staley: Absolutely.

Dan Poppy: —thanks to COVID-19. What is happening to patients in trials right now?

Alicia Staley: It's really a varied experience out there right now. As a breast cancer survivor, I've really gotten involved in a lot of the breast cancer communities, so, we've had some patients share some exceptional stories. They're on—they're late-stage breast cancer patients that have—their trials are continuing. They're working with trial teams that have been very communicative with them, reaching out, letting them know about either changes in the sites where they need to go for infusions.

In some cases, unfortunately, I have heard from patients that have showed up at sites for infusions, only to find the doors locked, that the site has been temporarily closed or the site's been repurposed as a COVID intake facility. But, unfortunately, those patients that were on those clinical trials were not informed of the change before they made their way there for one of their site visits.

So we're seeing sort of the best and the worst right now, and that's, to be expected at this time. We're truly in uncharted territory. There is no roadmap. There is no playbook for a pandemic like this. And I think the industry is really learning a lot of lessons about what we should be doing and what we can be doing to better care for our patients and our healthcare teams as this unfolds.

Dan Poppy: What advice do you have for patients and researchers and healthcare providers as we go forward?

Alicia Staley: Ask as many questions as you need. I think to the patients, just if you are considering a clinical trial and aren't sure about something, ask. Don't be afraid to ask the tough questions. This is—it's your life. It's your health.

And I encourage everybody that wants to participate in clinical research to do so, but the caveat is understand what you're signing up for.

And I think to the sites and sponsors that might be listening to this, just make sure that you're constantly communicating with your patients and the people that are involved in your clinical trial, and make sure that everybody's always on the same page. That pandemic notwithstanding, I think that's good advice for any trial at any time.And that truly goes a long way for building or creating a better patient experience overall.

Dan Poppy: Alicia Staley, thanks so much for joining us. You've been listening to Clinical Minds. Make sure to sign up where to get your podcasts. Let us know what you think of the show, and we'll see you next time. Bye.