**MedTech Chat Podcast**

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**Respondent: Adam Samson**

**Welcome to MedTech Chat where we discover the latest healthcare tools, device technology, as well as research approaches. We’ll be talking to designers, insight professionals, and other executives to better understand how MedTech is helping patients and those caring for them now and in the future.**

**Today I’m very excited to be talking to Adam Samson. For over a decade, Adam has conducted clinical trials across multiple therapeutic areas as a clinical research coordinator, clinical research associate, project manager, and director within academia, research sites, CROs, pharma, and tech. He currently serves as Senior Director of Clinical Operations at Curebase, a software and services purpose built for decentralized and virtual clinical trials. Adam also serves as adjunct faculty at George Washington University in the Master’s in Clinical Research Administration program. He is an active member of working groups within the Clinical Trials Transformation Initiative, Decentralized Trials and Research Alliance, Digital Therapeutics Alliance, and HealthXL, focused on areas such as decentralized trials, participant engagement, clinical trial design, and clinical evidence generation. His main goal is to improve clinical trial experience for patients by leveraging digital technologies. Thanks for joining me today, Adam.**

Thanks so much, Tom, and yes, thanks to the listeners. I’m looking forward to this.

**If you could tell us all about the kind of work you’re doing in clinical trials.**

Sure, I’d be glad to. My background in clinical trials, as you mentioned there, started in a very traditional sense where we would run trials in person. Everything that we did with clinical research participants meant that they had to travel to a physical location, a research site, whether that’s a hospital or a private clinic where they would see the doctor and the research staff and they would complete assessments to see if they qualify for the study; give them the study therapy, whatever that might be; and then have follow-up visits to check-in on status, take blood, things of that nature. As you might expect, those can be quite labor-intensive, quite time-intensive, for the research participants. They are compensated for time and travel, but still, it makes the opportunities for participating in clinical trials prohibitive for many people: those who are in rural areas, it might be hours away from the closest research site; those who work two or three jobs, you’ve got kids, it can be hard to take a couple hours out of your day once every few weeks or once every couple months. Increasingly, I’ve recognized throughout my career that we’re not using technology in a way that is equivalent to many other industries, even highly regulated industries like banking, and there was kind of a resistance towards doing more with patients remotely, collecting data remotely, and because of that, it kind of limited the capabilities around being able to offer options like that to research participants. Then, of course, the pandemic hit, and things shifted quite quickly: that’s actually when I left pharma, I was at a large pharma company running large, late-phase trials, and recognized that—this was in April of 2020—recognizing that we were really going to have to lean-in to technology all at once to be able to continue running our studies because we really couldn’t be bringing patients into the clinic just for reasons of clinical research if it was going to put them at risk. We started implementing things like televisits and letting patients answer questionnaires and things on their own devices. I got really excited about the space and I joined Curebase. We, at the time, and even now, we’re a start-up, we’re a growing company founded in late 2017 and we have software that helps doctors, patients, sponsors of these products to basically have everything they need to conduct clinical trials virtually, so consenting participants virtually; allowing participants to enter data; allowing investigators and site staff to enter data remotely; and giving a platform so that if we need to collect blood for a participant, rather than making them come all the way into a site, we send a phlebotomist out to their home, as an example. It’s an exciting time in clinical research. Curebase has continued to grow significantly over the past year and a half since I’ve been here and we, in addition to having the software, have really expanded our capabilities. That’s kind of where my team sits, around services, so we do project management and we manage the data. We have staff that interact directly with participants to really give a comprehensive and end solution for decentralized clinical trials.

**That’s very exciting. It’s interesting that there obviously was a need before the pandemic, and I could see that your company had been moving in that direction, but the pandemic really seemed to accelerate and have the need to force us to kind of go in that direction. But I’m curious—I know you’ve told us a little bit—but how significant of an impact has the pandemic been on the adoption of digital technology in the clinical development landscape?**

Really huge, Tom, it’s hard to overstate. When we look at things like the adoption of televisits within clinical trials, I don’t have the exact statistics off the top of my head, but it’s incredible, the adoption, when we’re talking about in the single digits now into more than half of studies that had to adapt to some level of interacting remotely with participants, at least during the pandemic. I think what it’s shown is we all kind of knew it was moving in this direction, but there were concerns about being the first one to do this. As you know, as your listeners probably know, clinical trials are heavily regulated, you have to collect data in a very structured way and submit it to the FDA, and that data that you collect is the evidence that you’re using to say, “My treatment is safe and efficacious,” and if there’s anything that gives regulators pause, then that data might be called into question and you might have spent 20 million dollars on a failed study because of that. So there’s, I think, a lot of perceived risk, but what the pandemic did is it kind of forced everybody to say either we pause our trials, cancel our trials, delay our trials—which is also costly—or we take some of these technology solutions that are being used in other industries, apply them to clinical trials to keep things going, and what our industry is learning, now that the dust is settling a little bit on many of those, is that it worked quite well in many cases. It’s not always a fit for every study, but many times we can be applying technology and decreasing the burden for the participants in the study, making it easy for the research site staff to do their job, and all in all, can have an impact on overall the cost of the study, which can eventually drive down the cost of drugs. So, lots of adoption due to the pandemic, and I’m very, very much excited to see as we move out of the pandemic to try and advocate for many of these things to stay on board.

**I’m curious as you’re talking, you’ve given us some examples of what kind of digital aspects have come along through the clinical trial, but I’m curious—so I’ve heard blood draws where they come home to the person, I’ve heard telemedicine where you’re connecting with the physician—can you tell us more about any other ways that the patients are being digitally connected with the staff and the people running the trials? Are there other things they have to get information on or receive information about?**

Certainly. The most advantageous thing of having the technology platform—when I first started as a clinical research coordinator, we did everything in paper and we brought everybody to the site to do everything, and there are often long stretches between these visits for clinical trials—sometimes it can be three months, six months—so in order to continue engaging with those participants, we would pick up the phone and call them, we would send them something in the mail. Now we have platform solutions like Curebase where the participants can receive everything they need through a single web application; at any time, they can go in and they can see what’s coming up for their next visit, they can communicate with the research staff through the portal to let them know about any changes in their health status or if they moved or anything like that, they can also receive reminders if that’s something they’re interested in using the method of their choice. I always joke try and call a millennial on the phone and leave them a voicemail, right? It’s not going to work. We have to know our audience and use text messages for those folks. I think that’s the biggest area, for me, that I’m excited about is the participant engagement piece that we can do by using technology, by giving a single place, a single platform solution, that the research staff and the participants can interact with each other and enter data. The participants will often—for a clinical research study, we’ll try and collect some of what they call patient reported outcomes: in addition to testing their blood to see if the therapy is doing what we would hope or some other measure, some other objective measure, it’s often good to hear from the participants, what is your subjective experience about this? Is it impacting your quality of life in some way? And, again, we used to either bring them all the way into the clinic to have them fill out a paper questionnaire or we might send them home with a paper questionnaire. Either way, one is very burdensome to the participant to come in; the other one, you don’t really know when they’ve filled it out or if they’ve forgotten to fill it out, where if you have digital technology, you can see in real time when someone is due, you can send them a reminder, and you can even have that personal touch and we have coordinator staff that might reach out if it’s been a day or so since they were supposed to complete a questionnaire to make sure everything’s OK and see if there’s anything we can do to help get them to complete the questionnaire.

**This is very exciting that this is sort of the beginning of what could be a definite change in the way we do clinical trials, and I see you’ve how set up this platform and you’re communicating with the patients, and I can’t wait to see what could be the future of what other ways you might need to get their data, whether it be wearables or other things that might help you in understanding how the patients are doing. But I’m curious if you see—what you think the key innovations might be in healthcare in the next five years, from your point of view.**

You hit on one right there, Tom: one of the biggest ones is wearables from my perspective and we’re already starting to see some of that in our clinical trials where we will integrate our data collection platform with—I don’t want to give a name brand or anything—but a popular device for collecting things like information about sleep and how many steps someone’s taken and things like that. We can integrate those things into our clinical trials and, depending on the nature of the study, of the therapeutic area of the treatment, it can make a real impact to be able to see—rather than it used to be, we would take blood pressure when they would come to the site once a month or so—now, with patients’ permission, and if it’s really advantageous to the treatment, we can be getting real-time information about their heart rate or blood pressure over the course of everyday, over the course of however long that’s needed to really assess clinical efficacy or safety. It really is—the future is kind of already here for many of those things. I would say the biggest innovation that I think we need to achieve over the next five years is inter-operability between systems and availability. Right now, we have electronic health records, electronic medical records, that are kind of their own standalone system that is really hard to integrate with other platforms. There are a lot of companies that are working on solving this, but it really is a tough nut to crack because even among the EHRs, there are many different systems that all don’t speak the same language, so then you have to create kind of some sort of bridge between that. I’m definitely not as tech savvy as our software guys, but this is a huge opportunity for us to be able to, say, enroll a participant in a clinical trial and that participant, or every patient, every person, in my view, should really have access to their data in such a way where they can say, “OK, you can have access to my medical record data for the next ‘x’ period of time while I participate in this clinical trial,” that way we’re not doing what most of us are doing right now in clinical trials which is either asking patients about their medical conditions/medical history or obtaining medical records that are extracted from an EHR but potentially in a paper format and being transcribed into another electronic system; just a very inefficient way of using multiple electronic systems. We’re on our way but I think in the next five years, that’s a big innovation that we will see. So, that combination of real time data coming into our systems automatically from wearable devices as well as date coming in authorized directly by participants and patient: all of that can be integration as part of the clinical trial program.

**This is great. I was wondering, when developing a new therapy, regardless if it’s a drug, device, digital therapeutic or what have you, what would you say the primary consideration is that developers should take into account when designing their clinical research and evidence generation plan?**

One thing that we’ve learned increasingly over the years is that putting patients at the center of drug development, front of mind when you’re developing your therapy, when you’re developing your clinical trial program, in the end it’s the right thing to do because it’s all about bringing new treatments to patients, but it also turns out to be the thing that gives you the best chance of success to bring a new drug, device, or other therapeutic to market. Over the past 15, 20 years, there’s been this big push towards what’s termed in the clinical research industry patient centricity, and it was quite a bit of a buzz term for a long time but now we’re really seeing how, whether it’s a pharma company or a digital health company that is at the very beginning part of they’ve identified a new molecule, a new digital health product/device/whatever it is, identified a patient population, really get to know through advocacy groups or others what are the outcomes that matter to them, and then when they do develop a clinical research program, oftentimes they will come to a company like Curebase or other companies and will basically say we’ve identified what we need to gather in terms of clinical evidence so that we can submit this drug or device or therapeutic to regulators for approval. Curebase, a partner on the CRO side can say let’s operationalize this, see how we can get you the data that you need in order to submit. As part of that, what we’re learning is that, in the same way that early on, drug developers or device/therapeutic developers are gaining information from patients, it’s in our best interest, too, to go to patient populations and say we’re going to conduct this clinical study, if we were going to do this, what are the things—if we’re going to do the study this way, is it reasonable for you? Oftentimes we get a lot of great feedback from participants, and this is across the industry when we do these things, when we take the time to ask them, we end up finding out that well, in actuality, this outcome that you’re measuring, it doesn’t really matter to me. We might use a six-minute walk test and ultimately the patient says I don’t really care about that, I just care that when I get up in the morning, I don’t have so much pain; so it’s important early on that we identify the things that really matter to determining whether or not this drug really meets the need. The biggest thing I would say is regardless of what kind of therapy you’re developing, put the patient at the front, include all stakeholders—you want input from doctors in the space, when you’re developing your protocol, you want information from experienced clinical research professionals, but be sure to include the patients early and often and try and fit them into your program as key stakeholders in the process. We’ve shifted from calling them research subjects to research participants, I think exactly for that reason: now we see them as our partners in bringing these devices/drugs/therapeutics to market; we truly can’t do it without them.

**I’m glad you brought that up because that’s the same thing that we think at our company: we always put the patient first. Obviously, we’re helping our clients, but helping the patients, and what might seem obvious is that the patient is the eventual final end user, sometimes that gets lost in the shuffle when you’re busy doing everything else. I’m glad you brought that up. But that brings me to one other thought—I’m not sure if you can help me here or not—but I’m wondering if as you’re going to these digital approaches in doing clinical trials, do you think we’re able to make it more available, more equitable, have more diversity in clinical trials? Or do you think it will become harder to go in that direction?**

It’s a really great thing that we’re opening up access to right now, actually, by leveraging some of these digital technologies. This is an area where we got recent guidance from the FDA, I guess it was last year already, but there’s a lot right now happening in clinical trials. Even in the Covid trial that came out, there were companies that were really slowing their programs down so that they could get the right kind of diverse populations to really understand and make sure that these therapies, these vaccines, are working across many different people. I think that the fact now that, kind of going back to the traditional model where we had to have participants go into the clinical trial site and a physical site, it really limits—you can only open so many sites. Opening sites is a very labor-intensive and costly thing: certainly we need to open a number of sites so that we can have plenty of research staff, but if we can limit that to a certain degree by having a remote site or having a physical site that can have a wider range and limit the amount of time that participants have to spend going in, then we can tap into communities that otherwise would likely not participate, again, whether that’s because of time restrictions or the fact that they just don’t have the capability to travel such a long distance, bringing these trials to participants’ homes or a place of their choosing. I think the other thing, now that there’s this kind of shift toward really wanting to increase diversity in our clinical trials, we have to look at the other side, which is sometimes there’s just a mistrust, and often for good reasons, within certain communities of clinical trials or the medical establishment in general, so it’s looking beyond just the individual trials and trying to say, as a provider of these type of services, what can we do to engage with the community through organizations such as SysSCRIPT, the center for information and study on research par to the patient, a phenomenal nonprofit group that we work with on a number of initiatives that really tries to go into communities, educate people about clinical trials, why they’re important, why they’re a good option for some folks. It’s looking at both things: it’s leveraging that technology so that we can give more options and flexibility to our research participants so that everyone feels like they have ready access to them, and it’s also doing what we can to try and educate communities about the importance of clinical trials and how they can be a safe and effective option for many people.

**This is a very exciting time to be in, I think, now that you’re really getting into this using digital technology in clinical trials and possibly making it more available in a more diverse patient base, so this is very exciting. I’m curious as we’re sort of winding down here, I like to find out a little bit about what motivates people. What would you say is a historical figure or fictional character that you relate to or are inspired by?**

One person that always comes to mind when asked this type of question is Charles Darwin. He, to me, looking at his story in life beyond just obviously the fact that he was brilliant and insightful, he was someone who took his big chance in his life getting on a ship that went to South America; he took this amazing trip and in doing so, he saw things and made connections that others hadn’t yet before, and the reason he was able to do that was he was very meticulous and he was someone who knew how to both dig down into the details but then to take a broader view. Beyond that, I think part of what made him a great scientist is that he, when he published *On the Origin of Species*, there was no mention of how evolution might impact humans because he realized that that was just too explosive an idea at the time; it wasn’t until more than 10 years later when he published *The Descent of Man* where that came up. I think that he had that right level of deep understanding of science, dedication to his work, but also a connection to humanity to be able to know when things are the right time. That’s something that I really try and—I mean, I carry some of those values with me too so that in the end, what I’m doing to try and help contribute to drug development and to development of therapies and advancement of clinical trials is both sound from a scientific perspective, but also from an ethical and just overall humanitarian perspective as well.

**That’s great. Sounds like, like him, you took a chance and are on this amazing journey and are doing some great scientific work, so I appreciate that.**

That’s nice.

**I’m wondering if people wanted to follow-up with you, see any articles, websites, etc., what’s the best way for them to be in touch?**

Any of your listeners can feel free to reach out directly via email if they’d like: Adam, A-D-A-M at Curebase, C-U-R-E-B-A-S-E, adam@curebase.com. They can certainly find me on LinkedIn, Adam Samson, that’s S-A-M-S-O-N. I’d be glad to chat with anybody, this is a space I’m really passionate about. They can feel free to check us out at curebase.com as well to learn about what we do. Glad to be available.

**Excellent, I’ll be sure to post all those on the website. Really appreciate your talk today, and I also saw you at a recent conference, and I hope to see more from you in the future.**

Absolutely, same here, Tom. Thanks again for the time and thanks to everyone for listening.

**Great, thank you. Thanks for joining us. Please check out MedTechChat.com for more podcasts and blogs. See you there.**