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In this episode, Taren Grom, Editor of PharmaVOICE magazine, meets with Rauha Tulkki-Wilke, Senior VP, Product Management at Signant Health.

Taren: Rauha, welcome to the PharmaVOICE WoW podcast program.

Rauha: Thank you, Taren. It's really lovely to be here this morning. Thank you for asking me to join.

Taren: Well, we're thrilled to have you. I know you're an expert in eCOA. And for those in our audience who are unfamiliar with this term, it means electronic Clinical Outcome Assessment. Can you please talk about why eCOA is so important in clinical development as well as to patients?

Rauha: Fundamentally, COA without the 'e' is a way to ensure effectiveness of new medications and that they are measured in terms that are truly meaningful to patients. And eCOA, which is an electronic Clinical Outcome Assessment, is a way to capture these outcome assessments accurately and securely using electronic means.

And how this may be different to what was done years ago is that for example, when we are developing new drugs, let's say for example, Parkinson's disease, that before we start measuring how these drugs are working, we actually establish an understanding of what's meaningful to Parkinson's patients and what would they consider to be an improvement in their condition. And then after we've established that eCOAs in a way for us to measure that accurately, so for example, patients might be using a diary at home on their smartphone that captures data exactly at the right time and presents questions to patients exactly at the right time, and then no one else than the patient can actually answer these questions. So it's really been significant in ensuring that we are able to conduct these clinical research studies much more accurately than we were before.

Taren: Excellent. And by increasing the accuracy, that also hopefully increases the efficacy of the drug once it's approved, correct?

Rauha: That's correct. Yep.

Taren: Fantastic. So let's talk about what some of the biggest opportunities there are during designing and developing eCOA solutions for clients, and then we'll talk about the challenges as well. So what are some of the biggest opportunities for these kinds of technologies?

Rauha: One of the biggest opportunities for these sort of technologies that by designing a good solution for patients, sponsors can actually collect much more data from those patients in relation to their everyday life in home setting. So in addition to asking them questions about their symptoms or their wellbeing, we can also utilize for example, sensors and wearables to collect additional data and get a more kind of well-rounded or much more comprehensive understanding of how the drug is actually impacting patients. And that's what we are doing in clinical studies today much more than what we used to do.

Taren: So it's an active ability to measure those outcomes rather than asking patients to sit down and fill out a paper diary, for example.

Rauha: Exactly. So it's the end of the day, it's easier for patients because they just simply do not need to spend as much time reporting data as they perhaps used to before.

Taren: And it's not subjective either because it's not dependent upon a patient's memory of what happened three days ago, because we know patients aren't always so good at filling out their patient diaries.

Rauha: Exactly. Yeah.

Taren: Excellent. So those are great opportunities, but what are some of the challenges involved with some of these solutions?

Rauha: One of the challenges is they really focus on the need to make eCOA solutions work for patients so that they can easily use them as part of their daily lives. And what makes this challenging is we kind of need to understand the needs of different patient populations, so it's not the same to for example, a parent whose children are receiving a vaccination or if you are a patient with a terminal illness or if you are diabetic. There are variety of conditions that impact patients in different ways. And then of course, they can be young or they can be old. They can be highly educated or they might be barely able to read. So eventually we kind of need to design these solutions for patients who can be like almost anyone, and they can have very different skills and abilities to use diaries. It requires sophistication to be able to design solutions that work for everyone as well as for, of course, the indications.

And then we have sponsors who eventually want to collect relatively extensive amounts of information. Not in every study, but there are a lot of studies where sponsors really want to maximize the information that they are capturing from patients because it's so important. This is an optimization task in the end of the day, so how can we capture as much information as

possible with as little burden as possible. And it's something that we work on for every single study, as studies are unique, as we all know.

And, of course, there are the sites, so it's not only about designing solutions for patients, but we also need to make these solutions work for sites. And sometimes it's even harder than making them work for patients. I think that we actually as an industry, we do a pretty good job making these solutions work for patients, but may not be as clever and as smart in making them easy to use for sites. So that may be something that we still need to work on. And as a wider industry, of course, something that we are working on.

Taren: I think that's an excellent point. I think sites are so often overlooked, yet they are the first gateway to patients once they've been recruited into a clinical trial.

Rauha: Exactly. And it's so easy to think about, like let's add this one more solution or let's add this technology. And every single technology that you add is an additional burden on sites, so you really need to think about how you are going to do that so you'd minimize any disruption to them.

Taren: Absolutely, yet at the same time, given the tools to conduct the study in the best way possible, but there are so many sponsors and so many different companies coming to them that they must have to juggle a jillion different types of technologies. It must be very difficult for them.

Rauha: That's right.

Taren: Excellent. Now in terms of the technologies you're using and the categories you're looking at, are there any therapeutic areas that are better suited for an eCOA technology?

Rauha: To be honest, not really. Essentially, all therapeutic areas that collect outcome assessments are suitable for eCOA. It depends on having a solution that works for that particular indication. And that's something to ask from eCOA vendors obviously is that do they have experience in that particular indication or therapeutic area and how do they recommend building a solution that works for studies in that particular area. And you can then evaluate whether a particular eCOA vendor, for example, is a good match for that study. But in the end of the day, the technology can work for all areas.

Taren: Wonderful. You have a real interest in digital health. When did this start for you?

Rauha: So I studied biophysics and biomedical engineering, and one of the reasons why I started studying that particular area was that I went to uni and I started studying physics and math. But then I kind of decided very early on that I'm not going to be a scientist. And I was thinking in this biomedical-biophysics field I'm sure I can figure out something, something to do, something interesting. And I can remember this first research that I did with functional MRI,

where the subjects of the study were my fellow students and we were researching how our brains functioned in different kind of settings. And I really thoroughly enjoyed it and I've been excited about digital health ever since. That was really the start of it for me.

Taren: So during that experiment with your other colleagues, did you find anything interesting, like did somebody's brain like pop out as being completely different? But what prompted that?

Rauha: Well, it was just that we were able to do such experiments and find out such interesting things about how our thinking worked. And actually it was super interesting that very similar experiments yielded very similar results across the whole kind of student population. So we weren't as different as we might have been thinking that we are. Our brain seemed to work in a very similar manner in these experiments.

Taren: Cool. So when you think about what's happening in digital health today, what are some of the biggest trends that you're tracking?

Rauha: From my point of view, I think the biggest – or one of the biggest challenges is related to the aging population, especially if we consider the Western countries. And we can use digitalization to make sure healthcare is accessible to everyone, even if eventually the population that's providing it to many others is getting smaller. So it's a really big challenge in many countries to maintain healthcare costs at a level that are affordable and still be able to keep access to healthcare at a good level. Digital health could really help managing this and ensuring that kind of uniform access to healthcare is maintained. But even if that's perhaps a view that's more focused on the western world, if you just look at developing world and then developing and emerging economies, digital health is also a way for these societies to provide better access to healthcare simply because it's more effective and also, to a certain extent, may be easier to establish than the kind of the older and more traditional methods. Just look at, for example, mobile banking has established new ways for people to do commerce in many developing countries, then digital health can be a similar big change driver for them.

Taren: Interesting that there's ways for a clinical researcher in our industry to take cues from other industries that are also highly regulated.

Rauha: That's right. Yeah. And it's actually something that I think that we should be doing more regularly and more often because there's a lot to learn from kind of other areas of life.

Taren: Fantastic. And when you think about the future, where do you see digital health heading? Do you think that digital health is going to be the future of medicine as we go forward?

Rauha: Definitely. We'll be more reliant on digital health to deliver good healthcare to people. And of course, I mean, there's the aspect of digital health also being a way for people to take

responsibility for their own wellbeing as well, so making sure they have better methods available to manage their own wellbeing, especially chronic diseases. That's important as well.

Taren: So it's almost like a reward system, where that, say, you have high cholesterol and you go to eat something that you shouldn't be eating, is there a way to kind of monitor that in real time and alert a patient that this may not be so good for them?

Rauha: That's right. So for patients who are motivated, digital health can be a huge tool in making sure they are making the right choices and they are going to be developing and improving the ways they take care of themselves. It's obviously also for people who may not be so motivated. Digital health offers ways for them to be better connected with their healthcare providers, who can then perhaps reach out and make sure that things are going as they should.

Taren: Wonderful. Before entering the clinical space, you developed solutions for anesthesia management and neonatal intensive care. Talk to me about this experience and how it informs your current role, perhaps.

Rauha: I think one of the most fundamental things I learned in that space was that we were developing technology that was essentially responsible for keeping patients alive. So the focus on the quality of that was super critical. It was a huge factor in the way how we developed software in that kind of an environment. So it keeps you honest about the true quality of what you are delivering when you know that the solutions that you build are actually responsible for keeping your kind of like fellow people on the planet alive. And I think it's something that even though in the clinical research space, if you think about eCOA solutions. eCOA solutions, they don't need to keep patients alive at that very minute. But on the other hand, they contribute to collecting information about new drugs invariably like doing it in the most reliable ways. And in that way, they contribute to patient safety in the end of the day. So I think it was a good experience because it highlighted at a very early time in my career how important quality really is.

Taren: Fantastic. You are based in Finland, correct?

Rauha: That's right.

Taren: And where's most of your team located? They're located with you in Finland as well or they're located around the globe?

Rauha: Some of them are with me here in Finland. Some of them are in California. I have a team in the Philadelphia area, in London, and also elsewhere in Europe. It's a highly dispersed virtual team.

Taren: Tell me how do you lead a global virtual team? What are some best practices that you can share with some of the folks who might be listening in?

Rauha: Well, what's really fundamental is to get to know people. So even if you are in remote locations, and you might not be able to meet face to face that often, but it's important to keep connected on whatever digital methods are being used in various companies. We, for example, use Teams and Slack, a lot of video calling, a lot of calling, so we just keep in touch all the time.

As a leader of the team, I try to Slack everyone every once in a while, ask how they are doing, help them with things that go on in their kind of daily work because in a virtual environment, what usually happens is that people can kind of contact one another about like really big things, like big challenges or some great milestones, but they aren't connected about the everyday little things. But the everyday little things are the ones that actually matter to people a lot, so it's really important in order to have a good relationship to keep talking about the smaller things and just keep that connection going.

Taren: And how would you describe your leadership style?

Rauha: I like to listen. And I like to learn from everyone. It's partly because I've been in the same organization or the organization has actually changed so much; it's not the same organization, but I joined the company about 20 years ago. And for me, it's really fundamental that I keep learning from everyone around me. So whether it's my team or whether it's colleagues around me or people that I report into, I like to listen and learn because that's the way how I can develop and how I can help develop my team. That's really fundamental in my leadership style, and I also believe in this everyday trusting collaboration as a team. I think it can move mountains and the things that we do are usually not particularly easy. We deal with global clinical trials and being able to provide really reliable solutions, it's a challenge most of the time to build this technology. So if we just keep on working as a kind of a global trusting team, we can really make a difference and that's what I focused on is to make that happens essentially.

Taren: Wonderful. A minute ago, you talked about celebrating those big milestones and how important it is to also keep in mind those everyday steps that are successful. So how do you measure success to yourself and your team?

Rauha: I work in the product area, and so does my team. What we do is that we analyze what sponsors are requesting from us, where the whole clinical research space is going and make plans based on what we hear and what we know is needed. And essentially we just track how we are doing against those plans.

The rewarding moments are also related to that. So a lot of the time in our everyday life what we do is that we develop a product or we develop a functionality and we just simply hope that we've done it in a way that we've been able to capture the essence of what sponsors need from us and also what sites and patients need from us. And when we then see that the functionality being used by our clients and by those end users and they are able to use it successfully, I mean,

those are the moments that are really rewarding to us. So those are the moments that we see essentially that we live for in our professional lives.

Taren: Right. And I can imagine how gratifying it is to see a product that you've developed come out that actually gets implemented in a site in a clinical trial to help patients.

Rauha: That's right.

Taren: That's fabulous.

Rauha: It's fundamentally important, yes.

Taren: Yes, yes, yes. What's one piece of advice you would give to your younger self. If you could go back in the way back machine and say I wish I knew or I wish I could have done that differently or maybe that's something that I would have thought about differently for today. What's one piece of advice you would give to your younger self?

Rauha: I would really say, be patient, be resilient, because I think I was perhaps a little impatient. I went to a museum once in New York. It was probably the Natural History Museum if I remember right, and there was this quote on there, and it says, "Keep your eyes on the stars, but your feet on the ground." And I think that's super important, especially it would have been important to my younger self because the whole idea is that if you patiently work towards your vision, you'll get there, but you have to take those steps every day and be meaningful for the short term while you are striving for that longer-term vision.

Taren: That's great advice. And finally, please describe a wow moment in your career, something that stands out to you as either changing the trajectory of your career or highlighting a specific moment. What's your wow moment?

Rauha: So one of the wow moments and this goes years, years back. This was in the days of when we were first starting with electronic patient diaries and we were working on our first global study. And it wasn't typical back in the day to use electronic diaries in any studies and definitely not in global studies. This study went live in something like 23 countries, and when it went live outside of the US… US was kind of like… we had done solutions or deployed solutions in the US before, but it went live in Colombia as one of the first countries outside of the US. And we had delivered diaries to Colombia. They were palm pilots. This was back in the early 2000 something, maybe 2003 or 2004. And they were sending data for these like analog modems, the kind of old modems that were beeping and had cables and so on. And then there was this one day when our production team, they sent me a message, we've actually received the first day diary from Colombia 5 a.m. this morning. And it was very early in the morning because we were in Finland and there's a time difference. But that's a great moment because it actually worked and I got to send a message to everyone who had worked on that study that we had received that first diary from Colombia.

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Those kind of moments, I mean, I've had them obviously… We've all had them so many times after that, but that was one of the first ones, and it was just so great to see that with hard work, you can really make technology work even in the most difficult of circumstances. I just wonder at times, obviously we are a solution provider, so we try to make this look easy for sponsors and end users and so on. But when you start from scratch and you build a technology and it's supposed to work reliably, it's clinical research and so much hard work and sweat and tears goes into it, and when it finally works, it's just awesome. It's hard to describe those moments.

Taren: Yeah, that's very cool. That had to be like receiving a signal from the dark side of the moon almost.

Rauha: That's right.

Taren: Well, congratulations. And congratulations on all your continued success through the years. It's vitally important, not only to your sponsors, but to the patients who are waiting for these medicines. So, thank you so much for all that you do.

Rauha: Thank you. And it's a pleasure to keep innovating for the industry and for our patients.

Taren: Fantastic. And thank you for being part of our WoW podcast program.

Rauha: Thank you.

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