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In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE Magazine, meets with Barbara Enger, Associate VP, Clinical Science, Signant Health.

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

Barbara: Thank you, Taren. It's a pleasure to be here.

Taren: Our pleasure to have you. We are so looking forward to getting to know you a little bit better. I understand you have an advanced background in nursing. Tell us about how this expertise has influenced your career to your current position.

Barbara: Well, this is my favorite question. My nursing education and experience has been foundational in my life, and I mean that both in my jobs and outside of my jobs. Beginning in 1979, when I graduated with a BSN, I started working in a burn center intensive care unit and then I moved on to inpatient psychiatry. I got my Master's in nursing, taught psychiatric nursing, became a family therapist, and finally landed in clinical trial research.

I became a nurse not because I had a passion to be a nurse especially. I put myself through college and I was really looking for a reliable way to support myself, and it turned to be so, so much more for me. So being a nurse, it gave me a ton of life experience that I would not have had otherwise. I would say, it has informed every aspect of my life. Most importantly, I found out that no matter what job you take as a nurse, in order to be successful you really have to do two things – you have to think critically and you have to act systemically. I feel like that's the core of nursing and it's what I've taken into every single job.

So no matter how far off the path I think I might have gotten, nursing always seems to come back around and find me again. And just yesterday, I was in a meeting where we were talking about how Signant can better support home visiting nurses doing clinical trial research visits. So, here it is again and that just seems to be the pattern.

Taren: Wow. Talking about coming full circle, right, as we look at this current new virtual reality, as I like to call it, while living during the COVID pandemic, that we're looking at different ways in which to engage patients in clinical research. So that component of bringing in home nurses to the patient rather than the patient going to the clinic is so critical right now. So what were some of the learnings from that conversation? Can you share with us?

Barbara: Sure. We have a huge infrastructure, not just in this country but really throughout the world, where you can get home healthcare into someone's home without too much trouble. There are a lot of visiting nurse agencies and agencies that work out of hospitals, so the healthcare part in the home is really pretty well established. But of course what we have not established is clinical trial research in the home. I think from my perspective, you would use the same infrastructure and offer training programs in clinical trial research, maybe a basic program that would include GCPs and the phases of research, and then move on to more of the specifics of what you might be asking the nurse to do in that particular trial.

Taren: Do we think that this can really become something that's sustainable as we go forward; is bringing that nursing aspect to the clinical trial field?

Barbara: Absolutely. Yeah. When I look at the trials that I've been involved with over the years and you think about if you were to decentralize this, could you still do it? The answer is really always yes. You can piece this together in different ways that would be very reliable and would be successful.

Taren: I think that's an interesting thing to think about as we move forward as I said, and what we look at post pandemic and what becomes that next phase of what is… whatever we want to call it – the new normal or the new extraordinary. So really an opportunity for the industry. Thank you for bringing that to our attention. Barbara, you have an interesting title. I don't know that I've ever heard of clinical science as part of a title. What does that mean?

Barbara: To me, I would say clinical science refers to the application of research principles and scientific evidence in the practice of clinical research trials. So, taking basic research principles, basic research methodology, what we know from scientific evidence, the studies that have been done – taking all of that and then translating it into clinical practice within the context of a clinical trial. We have clinicians at Signant and this is specifically what they do. They may do this in the context of eCOA design or they may do this in the context of training investigators or training study subjects. They might do this in the context of doing quality reviews of endpoint interviews and exams.

I can give you an example. Let's say we see data from video recordings that we're reviewing and it shows a high error rate on the administration of a certain item on a certain endpoint scale or exam. What we can do is add a design feature to the eCOA screen with a message reminding the investigator of the correct administration. The goal is to increase data reliability and this is the way you can do it, by using what we would call clinical science and practice.

At the top of the mind for all of us is really the importance of blending the clinical science with the need to support the study investigators and the patients in their research alliance because that is truly the source of scientifically sound and reliable data.

So simply put, we're standardizing the administration and the scoring of the endpoint instruments, and I would say that Signant clinical scientists, they are really the stewards of research science practice.

Taren: I love that. I love how you call it a research alliance because it is that partnership that is critical in terms of that research paradigm. I love that, the way you couched it. You are managing Signant's internal team of clinical scientists, clinical consultants, central raters, central scorers, central reviewers – all of them have to bring a different skill set to the table I would assume. How do manage such a diverse group of individuals?

Barbara: If you look at who they are, we've got 35 full-time clinical scientists across five international offices and we have over 200 external clinical experts around the globe who are active right now. Over the past 15 years, we've really worked to build a significant global bench strength of clinical experts most particularly in the area of psychiatry and neurology.

I mentioned earlier that one of the things we focus on or *the* thing we focus on in clinical science is the training and calibration of site raters on the administration and scoring of endpoint measures. So, really it's not so different what we do for our clinical scientists and our network of clinical experts. We're doing basically the same things on both levels. Internally, we also have to be calibrated in order to consistently train and reinforce the same with site raters. On both of these levels, it's really quite a challenge because neuro-clinical trials endpoints are often subjective in nature – subjective in terms of, you have to measure the level of depression, you have to measure the severity of psychosis, you have to measure the degree of joint rigidity or maybe of tremor. You've got to calibrate all of your external, internal, your raters, everybody who's going

to be involved in that trial must be calibrated with one another, whether your role is to directly administer the instrument or your role is to review the administration of that instrument – you all have to be on the same page there. And I think you do what you do, you select carefully, you train thoroughly; you include both didactic challenges and performance challenges, and we often will use standardize study subjects both with our investigators and with our internal staff in order to achieve that calibration.

Taren: I know that Signant brings a lot of new products and technologies to the market. I also understand that you have a very strong feeling the it's very important that the culmination as well as the patient and site experience is considered when those products are being developed. Tell me why you think that's of critical importance.

Barbara: I have always thought it was of critical importance. I feel like I have to say something about patient centricity before I go to the rest of the question. In my career, it's relatively recent that pharma and pharma vendors are talking about and, indeed, even competing in the area of patient centricity, even though it's been around for a long time. It is not a new concept. And sometimes I feel a little bit defensive with this because I feel like at the Signant Clinical Science Center of Excellence, patient centricity was always something we were thinking about without calling it out specifically.

We have been practicing it all along, and I think some of that is certainly related to my background in nursing and the fact that all of our internal clinical scientists have a clinical as well as a clinical trial background before they come to us. We really want to integrate both the patient perspective and the investigator perspective, and how we design eCOA, how we train, how we do our data analytics – all of these is really critical to the collection of reliable data because if you think about it, it's not us at Signant who meets with the patient, it's our investigators. So we want to support the investigator in the site in every way we can in order for them to be able to form a trusting and secure research alliance with their study subjects. And in my opinion, this does as much to improve adherence and retention as the best wearable, the best handheld device, the most streamlined eCOA – all of those things are of course part of what we provide in order to make the date more reliable. But when you think about it, patients aren't returning for study visits because they want to be a reliable partner to Signant Health; they're returning because they want to act as a reliable partner to the investigator. Supporting those frontline clinicians and study site staff is really where we want to focus. We definitely want direct from patient feedback but we also want investigator and site feedback.

Taren: Excellent. I didn't mean to over skip the importance of that patient centricity, and you're right, it's become a buzz term as of late…

Barbara: It definitely.

Taren: … to all of what you have been doing has been focused on that all along. I completely understand that and thank you for that clarification.

Your experience in the clinical research field going on 20 years or so, you have, I would imagine, a pretty good finger on the pulse of what's happening. What are some of the biggest trends you're seeing right now?

Barbara: When I think about my introduction to clinical trials about 20 years ago and then coming to Signant around 15 years ago, I would say there's a couple of things that really stand out to me. One is that when I first got into the vendor field in clinical trials, we use to lead with science. So technology was important, but what was really most important was to go out and compete with the other vendors in the area of who could offer the best science to support the study.

Now, we really lead with technology, so that's been a huge change. And it's not that science isn't still there, it is, and I would say it's as strong as ever, but that's not what we lead with. If you open our website, the first thing you're going to see is technology. That's one big change.

I think the other one is marketing. When I first started out, we had virtually no marketing department at all, and now it's a big part of Signant Health, and that's also been something that I've watched with a lot of interest in. I certainly see a lot of benefit to expanding your marketing because you're selling technology now so you need more marketing around all of the technology. So that's been another thing that is very different.

I would say though, if you kind of take a step out and look at the broad view, the nature of clinical trials hasn't change very much, in my opinion, because research principles are basically the same as they've always been. However, we're just including a lot more technology now. eCOA is still relatively new, maybe 12 years or so, at least, in my experience. Now, we are moving more to decentralized trial remote assessments needing all of the technology platforms that you need in order to accomplish that reliably. I mean, no one ever thought 15 years ago that we would be video recording psychiatric interviews between study subjects and investigators, and doing an independent review of those, but we do, and we think that that has contributed to data reliabilities.

Things that I've certainly wouldn't have predicted, I now find that I accept very easily. I think if there's any place for improvement right now, and this is definitely skewed by my clinical science thinking, it's really that line between science and marketing. The other thing is that science has become politicized as we know and we might think of that in terms of climate change or now what we hear about COVID science, but we've got to be careful because that will happen in pharma as well. I think for young people getting into the field now, maybe they need to be prepared for a bit of a fight to maintain the appropriate focus on science.

Taren: Great point. Certainly relevant as we are in this COVID state. Again, you've had a lot of success in your career. What is your secret sauce to effectively leading and managing teams in the clinical space? I mean, it's fraught with a lot of disappointments, and trials don't go well, they don't succeed, an endpoint isn't met. So how do you keep your teams inspired?

Barbara: Well, I don't know that I have a secret sauce, I mean, I read what other people who know a lot more about it than I do and I try and do what they say. One thing I'm really clear about is I work for my team; they don't work for me. I am really fortunate. We have a lot of amazing clinical experts, both as clinical scientists within Signant and our entire network of global experts. I listen to what they say. I listen to what they say they need. I listen to their opinions, and the more I listen, the more clear it is to me that I should act only occasionally in order to sort of maintain certain boundaries or frameworks or levels of expertise. There has to be some structure around it but I really should just go ahead and trust that these people are experts. We all kind of function the same. People want to work to their potential. Sometimes I just need to stay out of their way and let them do their excellent work and then we all benefit.

I think people come to work because they want three things and maybe not in this order, but I think for most people if they have camaraderie, if they have compensation, and if they have challenge, they'll be satisfied with their job. And again, maybe different order for different people but those are the three things I think that really keep people engaged.

Taren: I think those are the big three C. I think that's excellent. I love that. When you're building your teams and you're looking at that next generation of leaders, what are some of those qualities you look for?

Barbara: I'm going to look for people who are great communicators. One of the things that I explain to people when they come in to become a clinical scientist is it's your job to deliver scientifically sound, deliverable in a business environment. That means

you've got to get along really well in a group because for every single project you're going to be working in an interdisciplinary group and you may be the only clinical person who understands the clinical intent of what we're trying to do, and you need to be able to communicate that in a way that makes the team want to work on it and in a way that makes sure that whatever the delivery system is for this clinical deliverable that it maintains its integrity throughout the adaptation.

I want people who are really, really good communicators, who really know how to get along in a group. I think everyone is a superstar in some areas and when it comes to creating a specific team or in my department, for example, we have three large teams and when I look at each of those teams, I think okay everybody on each of those teams has some superstar strengths and we want to make sure that we balanced it so that every team has some strengths in each of the areas of being scientifically sophisticated or being especially productive or especially creative, or an especially good communicator or someone who presents especially well in front of sponsors. We want to be able to mix it so that each team can observe one another functioning in the context of the team. I think it kind of brings the whole team along – so, you know, that saying that the sum is more than the parts – it's that thing. When a team starts really clicking and working together, everybody gets better.

Taren: That's awesome. That's great advice. Thank you so much for sharing that. As we wind down, I'd like to know is there something you know now that you wish you had known as you were moving up the ranks in terms of crafting your career?

Barbara: I like to be in charge and I've always been like that. I think when I look back on it, I probably did some micromanaging that was completely unnecessary and maybe even obstructed people doing their best work. So talk less, listen more. I think observe a lot, listen to what your experts tell you. When you intervene, do it on a systemic level. Trust that other professionals have the same intention that I have, which is to do the best job you can. I think you just keep some boundaries. It's probably harder to step back than to step in sometimes, but sometimes the stepping back is the thing that you really need to do.

Taren: Having achieved this level of success in your career, you're viewed as a role model to many; how does that mantel of responsibility sit with you?

Barbara: Oh geez, I don't know. I would be super flattered if that was true. I try to be honest and forthright and sometimes I go overboard. I have to be able to admit when I made mistakes. I have to apologize to people if I've kind of hurt them in any way. That happens at work sometimes when you're managing people; you don't understand the

whole story and maybe you made an assumption that wasn't correct. So I just try and keep the communication as open as possible so that people will say exactly what they think and that I have a chance to respond to that, and keep my relationship with every single person in my group healthy and help them keep healthy relationships with one another.

Really, everyone who comes in has already had a professional life so they are already pretty good at professional development, at work habits. They already know these things, so it's really more of that soft part of it that I think you end up doing your best leadership in. Because I'm not the expert that they are, I'm just not. So what I'm really trying to do is create a group and make that group as powerful as possible in the setting for the greater good.

Taren: Excellent. Finally, tell me about an accomplishment or a wow moment that either has influenced your career or maybe has left a lasting impression on you.

Barbara: When I think about my career at Signant, I often think of an investigators meeting that I went to in Athens. This was many years ago, but being someone who loves to travel I was just tickled that I was going to go to Athens for an investigators meeting where I was going to do some of the training. Not only that, but when we got there the room where we're doing the training has a wall of windows that looks out onto the acropolis. I was just completely wowed by this.

It was a meeting for a study that was treating bipolar disorder and we probably had seven or eight western middle and Eastern European countries there. We had simultaneous translations, so it was sort of like the United Nations across the back of the room and everything about this impressed me so much. And being able to sit and listen to the conversation about how bipolar disorders presents differently in different cultures and how the scoring of this instrument was also going to be different in different cultures, and how are we going to make that work so that there was calibration and that everyone would be able to detect signal when it happened in their culture using the same scale.

I just remember sitting there and being really struck by a full understanding of what this job would be about and how important it would be to recognize the challenges, and getting a group of investigators around the world across many languages and cultures to all be working in the same study and end up with data that is reliable and drives a study towards success.

Taren: That's a fascinating story. I can't even imagine like sitting there and listening to all these different points of view and trying to knit it together. Really an important work in a category that needs significant improvement, so, that is a wow. Thank you so much for sharing that personal story, I appreciate it.

Barbara: Wow, thanks for reminding me of it.

Taren: My pleasure. And thank you so much for bringing such clarity to what you do at Signant, as well as how important it is for clinical science in this day and age, and the good work that you're doing. So thank you so much for sharing your journey with us.

Barbara: Well, Taren, thanks for inviting me. I was super flattered and I really enjoyed doing it.

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