Trends, Challenges, and Opportunities in Clinical Trials

Welcome to the PharmaVOICE Webcast Network.

In this episode, I meet with Sheila Rocchio, Chief Marketing Officer at eClinical Solutions. We speak about trends, challenges and opportunities in clinical trials today and we touched on some of the findings in the recent white paper on decentralized and digital trials.

I'm Dan Limbach, your host and producer of the PharmaVOICE Webcast Network.

Dan: Welcome to the podcast program, Sheila.

Sheila: Thanks, Dan. I'm so happy to be here.

Dan: Well, we certainly live in interesting times, that's for sure. What are some of the trends you are seeing in clinical research today?

Sheila: Absolutely. And yeah, it's been an amazing year and it's been well publicized and it's nice to be a little bit on the other side of things and having it seem to get approaching to normal. So I'm really grateful for that and have the opportunity to vaccinate my 13 year old today. So very, very grateful.

One of the things I think that has been the most prominent change or the biggest catalyst that we've seen from the last year is the ability, understanding the lessons learned from the rapid development of the vaccine and how we can apply them to other therapies. And having spent nearly 20 years working in clinical trial technology, it's definitely been an industry that has not adopted new capabilities or new technologies quickly. And in the past year there's been numerous components of digital acceleration, and I think that's a huge trend.

And just the increases in data sources, the adoption of decentralized trial models, which have been around for many years, but really needing to pivot to those models and enable participants to continue in the important research that they were already involved in and sustaining that has been really amazing to see. And I'd say the collaboration across the board in the industry with different types of groups coming together, the support of regulators for taking more risk-based approach and thinking digitally from the start for all trials and how to really embrace the capabilities that exist today to make research more accessible and faster has been really exciting.

I wouldn't say there's so many good things that have come out of this, but that is definitely one, and we are hearing a lot from our clients about how we can help them sustain those new strategies and new capabilities and working across the industry to try and support that goal.

Dan: Excellent. Those are some promising trends. Sheila, eClinical Solutions recently published a white paper on some of these issues. Tell me more about that paper.

Sheila: Absolutely. So right before the pandemic we published a study with the Tufts Center for the Study of Drug Development called the Tufts-eClinical Data Strategies & Transformation Study. And so we embarked on that survey with Tufts because of the trends we had been seeing over the past eight years with different clients in terms of the incredible acceleration of diversity of data, so different systems and different sources and different data types and clients needing to access that data and have more visibility to it and more data flowing outside of traditional EDC systems. And interestingly, the pandemic certainly accelerated that trend dramatically in terms of as mentioned some of these decentralized trial platforms and pivoting to having more data collected remotely due to not having the ability to collect data outside. So more types of sensors and e-sourced data from devices now being part of more trials.

So all of the trends that we saw in that study have really been accelerated and increased dramatically by what we've seen in the past year. And so with that study, as well and what we highlight in the white paper is not only the diversity of data, but the challenges that that poses for some of the downstream functions.

So there's a lot of excitement around new ways to capture data, but less focus on how that data is integrated and accessed and viewed by data managers and medical reviewers and data sciences. And so the tools for managing all of those new electronic data streams have really not kept pace with the way that those data sources have changed and is still primarily Excel-based or SaaS based, and it seems counterintuitive that if all of this new data is coming in there must be really sophisticated algorithms to sort through it and identify risk and identify trends and have a much faster time to insight, but that has not been the case.

The white paper really highlights what some of those challenges are and then ways to think about new ways to leverage modern technology to address those challenges and provide faster access and visibility and a more continuous review cycle to impact cycle times, which could be a rate-limiting step if we don't make some changes to that part of the overall clinical trial data lifecycle.

Dan: Well, it sounds like a great resource. So we all know adoption of decentralized trials and digital trial models are accelerating, but there's a lot more work to do to make this an industry standard. What should companies who want to move in this direction be considering regarding these approaches?

Sheila: So there's a number of different class industry collaborations and organizations that are addressing this. I'd say we're almost at the top of a hype cycle with decentralized trials or digital trials. There's different names out there, but for sure decentralized trial systems. There's companies going public and a lot of investment flowing into this sector. And so many companies running trials are looking at ways to incorporate these platforms both for existing trials, so pivoting some of the existing trials to enable more remote visits, or adding things like informed consent that can be done using electronic mechanisms versus papers. So adding things that embark on some of a more hybrid decentralized model as well as new trials that fully leverage this model and understanding and learning

from others, doing similar types of work I think sharing information, and I think there's a great deal of goodwill across the industry to share that in the Decentralized Trial Research Alliance.

DTRA is an organization eClinical is part of, and now I think it has about 114 members and a pretty ambitious agenda to try and share more best practices and insights across the board. However, thinking through the entire process and I'd say clinical teams get really excited about ways to collect data that are novel and interesting and hopefully make things easier for patients and exploratory endpoints. So thinking through the collection model, but also thinking through what that means on the backend and making sure that all of that data can be quickly assimilated and cleaned and reviewed and able for medical reviewers who are responsible for the overall safety of the trial to have rapid access to that data and bringing all of that information together.

So I think starting with the end in mind, thinking through the whole process and thinking through the patient experience, the site experience and still thinking through the sponsor side in terms of who does the work and not working harder, but working smarter all within the right regulatory framework to really benefit from this data that's being collected and have that rapid time to insight and having a solid analytics framework to really focus on the data that's most meaningful and requires most attention.

Dan: So Sheila, you've kind of painted a picture of the ideal world. However, change is rarely easy, so let's talk about challenges. What would you say is the biggest clinical data-related challenge the industry is facing today?

Sheila: So I have mentioned Dan, the volume of data is increasing dramatically, and the biggest challenge is really having the right infrastructure to handle it and benefit from it in the future. So all of this data that's available, including the new types of systems that can collect data from patients more easily, having more data available from electronic medical records systems, all of that can be assimilated for new insights and even existing data having some better control arms. There are so many opportunities to benefit from the data, but really having the right infrastructure to centralize that information and make it easy for the people that are responsible for reviewing it and cleaning it and connecting with the sites and asking questions and also monitoring it for safety and accuracy is extremely important.

And so bringing all of those stakeholders and the statisticians as well into the fold and coming together I think as a team to figure out how to benefit from all this data that's being collected and take the next step on automation instead of throwing kind of more manual work at it and taking a brute force approach, but really automating and rethinking what's important taking risk-based approaches and focusing in on what matters most to deliver the right outcome or the best outcome for the trial and for the patients participating.

Dan: Let's go a little bit deeper into that. So challenges often bring opportunities. What are the opportunities that life sciences companies currently have to address those data challenges?

Sheila: It is a very exciting time, and I was at a DTRA leadership meeting yesterday when someone said, "At this point in the industry we really have the chance to get things right and it's almost, it feels like a new day for clinical research." And so I think the opportunities are to think through the clinical trial product from many different perspectives, but from the patient perspective and from the site perspective and as someone working on the study team to work with the data and really building a new user experience for all of them that is the technology first model and a data driven model and doing things not the way they've always been done, but rather because it's the right way to do it and fully incorporates these new and automated ways of collecting and visualizing and sharing information about the data, creating new insights. And hopefully giving with participants and physicians and researchers a much more holistic view of how a treatment impacts them and the pros and cons of the approach and being able to make all of that happen faster.

So I think that's the opportunity for each of us to work really smart and not harder and think about what are the ways that we can do things differently, what needs to happen and always asking ourselves how we can do better for everyone that's waiting for these new important medicines.

Dan: I'll share something with you. Our editor-in-chief Taren Grom, who you know very well, anytime someone mentions that this is the new normal, she's like "Why do we use that term? Why don't we use what's happened here as an opportunity to be exceptional and not just trying to get back to some sort of adjusted normalcy?" And I think that's very interesting with that approach. She's very forward thinking. At times I think we think about how do we just get back to less stormy seas so we can go about our business again. So I like her approach to say let's take this as an opportunity to become exceptional as an industry.

Sheila: I love that. And I think that if we can all think about that everyday, then we can absolutely change, and not even think about the old way, but only think about how we can get better.

Dan: Absolutely. So as we talked about earlier, there is a lot of momentum lately around things like decentralized trials, digital solutions, collaboration, regulatory tailwinds and risk-taking. In a post pandemic world Sheila, can we maintain this momentum? Is it sustainable?

Sheila: So it is sustainable. But as we mentioned Dan, it does take a lot of hard work and I'd say a mind shift from the top. I was chatting with another colleague who said, the CEO of Pfizer mentioned being able to move at the speed of science, and science is changing rapidly, and we learned so many new things, but the roll out has taken too long. So I'd say collaboratively and across the board there's so much goodwill and excitement about delivering on and building upon everything that we have learned

in the last year and applying that to every new therapy that's out there and being able to truly sustain and reshape this industry, which I think will look very different and be a much more digital one.

So I think it is sustainable. I think it is never easy, but there's so much enthusiasm and momentum. I know, for example, my dad worked on the Apollo project and said, "There's nothing for your generation that has brought people together." And I feel like at least for life sciences this has absolutely been that Apollo moment. So the things we've learned and I think the way people work together and think about the overall drug development process will continue to change from this watershed moment, and my hope is that it will only get better.

Dan: I couldn't agree more. Sheila, this was a fascinating conversation. I really enjoyed it, and I thank you for sharing your thought leadership and expertise with us today. I wish you the best of luck, as well as eClinical Solutions.

Sheila: Thank you so much, Dan. This was a great pleasure.

That will do it for this episode. To download the white paper discussed in this podcast, visit pharmavoice.com/whitepapers or download it from this podcast page. And don't forget to check out our other podcasts, white papers, webinars, virtual panels, videos and more at pharmavoice.com.

Until next time, I'm Dan Limbach.