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ALEX MERSEBURGER: There's been an explosion of new data sources in life sciences. How are pharma companies using these insights and all that data to get new drugs to market safely and effectively? We'll answer that question today.
I'm Alex Merseburger, host of the SAS Health Pulse Podcast, and today we're joined by not one but two wonderful guests-- Krishna Tangirala, Head of Data Analytics and Director of Field Outcomes Research at Organon pharmaceuticals, and Sherrine Eid, Global Lead Real-World Evidence and Epidemiologist at SAS. We'll start with Krishna. Welcome.
KRISHNA TANGIRALA: Thank you so much, Alex. I'm so glad to be here.
ALEX MERSEBURGER: As a trained physician and epidemiologist, there's many directions that you could take your career. What led you to pharmaceuticals, and what has kept you engaged in the industry?
KRISHNA TANGIRALA: Alex, so I have my medicine degree from India. I did my master's of public health from Indiana University, IU Bloomington, and then I started working as an epidemiologist at Indiana state Department of Health.
So I used to do the needs assessment for various state and federal-funded programs. So what I noticed was not all the programs work the same for all the population. There are different confounding factors. For example, there is a financial access to the health care, or there could be financial status. So then I realized there is a lot to learn than, actually, the programs we implement or the drug that comes into the market than we actually do in the clinical trials. So that led me the interest in the population health.
So obviously, pharmaceuticals is a $400 billion industry. The pharmaceuticals spend a lot of money on research and innovation compared to any other industry in the world. So if you are in the pharmaceuticals, you will be in the forefront when we create the medications, medicines. So you will be in the forefront when we are talking with the government on the reimbursement policies.
You will have the cutting-edge, latest technology for the research tools that we can have and also the access to a lot of data sources that is not available normally if you are working for any other industry. And if you want a lucrative, stable job, so pharmaceutical is the way to go. So yeah.
ALEX MERSEBURGER: You talk about being at the forefront. Being at the forefront of creating the next medicine sounds so exciting. Part of bringing a new drug to market is health economics and outcomes research-- in your title-- studying the data to make sure products are safe and effective. Is there something you wish people knew more about health economics and outcomes research or the behind the scenes of what goes into that process?
KRISHNA TANGIRALA: A great question. The health economics and outcomes research is used with a pharmaceutical company to understand the physician prescribing patterns. Even though the drug, we have the guidelines, each physician will look into the patients, and then the prescribing patterns are different. So we look into it.

We also look into how the drug perform when it comes to the real world. So the health outcome economics and outcomes research is used in various organizations, not just in pharmaceuticals. The company who sells the drugs, they're going to use the health economics and outcomes research. The company who buys the drug, even the federal and state, they are going to use the health outcome economics and outcomes research.

So in the clinical trial, it's very regulated. We are going to look at the safety, the risk of the drug within the limited population. But when it comes to the real world, we look into the value and impact of the product. So we're going to look into more of the financial status of the patients, and also we look into socioeconomic status of the patient.

So the real world-- the drug, when it comes to the real world, it acts differently than what is in the clinical trial. So health economics and outcomes research we use in the preclinical and also the clinical phases, where we look into the outcomes within the clinical phase of the drug. We use in the prelaunch, and also during the launch we look into the budget impact model, for example. We look into health economic models.

Once the drug is launched, then we carefully follow the drug into the real world. We look into the label extensions, for example. What is the off-label use of the product? We look into health care reimbursement and policy, how it changes over the period of time. So basically, follow the life cycle of a product when it is in the post launch. So it's a very broad department in our industry that is widely used across the organizations.

ALEX MERSEBURGER: It's certainly something I wish I knew-- or now I know-- that you brought up that broad department and how diverse the backgrounds are that all come together. A similar experience is happening not with the people but with the data. How varied are the sources of data now? Is it just a wide range of different sources and different areas of everyday life at this point?

KRISHNA TANGIRALA: Well, yeah. So we'll be pulling data from health care claims that we have across the US. We'll be pulling data from electronic medical records. We'll also be pulling data from registries, patient-reported outcomes. So we'll be pulling data from the social media.

So data is everywhere. So we'll be pulling data from different resources that we have. And that's one of the challenges that we need-- we have internally, how to synthesize, how to get all the data and synthesize it. So yeah.

ALEX MERSEBURGER: Within that explosion of new data sources, there's remote patient monitoring, internet of medical things, all the connected devices. How does that change your work? What value do you expect all of these new areas to bring in the future?

KRISHNA TANGIRALA: Well, I remember when I joined in early 2000s, we used to have a lot of clinical trials where the patient needs to come to the hospital and record the vital signs. So having the remote monitoring-- patients can now have an iPhone. Patients can have iWatch and record the vital signs within every day. A patient can monitor any changes in the health care status for the patient. So it helped tremendously how we do the research within the pharmaceutical industry.

Now, the patient can also be proactive. If he sees something changes in the vital signs, he is going to reach out to the physician. Physician can do the Teladoc. The patient doesn't have to come into the office. He can remotely log in and provide the medication or diagnosis for the patient.

So this data is captured very widely, and all the data is securely placed on the server, and it is readily available for access for any of the researchers. We look into that data as well. There is a lot of data on

social media. So the internet of things, what are you saying, changed the way we look into the research and how we do the research. So we are advancing into the AI, Artificial Intelligence.
So I would say that it changed the perception of how we look into the patients and how we treat the patients. Now it's a patient-centered research. It's not any more like doctors is going to collect all these vital signs and going to do the research, but it's how actually patient is involved within the research and how patient is providing his input into the development of these drugs.
ALEX MERSEBURGER: Synthetic control arms or extended control arms have been really talked about as a way to make sure that patients with a rare or life-threatening condition are provided the opportunity for life-changing therapies versus randomly receiving the placebo. Are you optimistic that this is going to receive more widespread adoption? Are synthetic control arms the future?
KRISHNA TANGIRALA: Yes, definitely. When we have the patients, for example, in the life-threatening events, it's unethical for the patient to put it on the control arm, on the placebo arm, and say that, oh, you're not going to get the drug for this clinical trial. It could be for oncology reasons, or it could be cardiovascular. So we cannot delay the treatment for these patients. It's very unethical to put them in the control arm.
Having synthetic or the extended arm will take off this problem. Now we have the synthetic arm for the cases. And we get this data on the synthetic arm using various data sources that we are available. We have claims, health insurance claims. We have data from electronic medical records, registries. We have patient-reported outcomes. Using all these data and having that accurate methods of analyzing the data, we are able to closely match the synthetic trial control arm to the cases.
And there are many advantages. For example, the patient's recollection is limited. So if you are going back to maybe one year or two years and trying to collect all the information from these patients, if you ask the patient, hey, how did you do last two years, did you take any medications, he might miss telling that information to us. But having that reliable data sources, we track the patient more reliably, more accurately, going back even a couple of years. That information is very valuable.
And we can also retain the patients. For example, if you have the control arm with the real patients, the patient might drop from the trial. But having the data from the data sources, we don't have to worry about it. So there are a lot of advantages of having synthetic arm compared to having the control arm for the patients, but still there are some regulatory, ethical reasons. We are not there yet, but we are getting closer based on the latest technology that we have now.
ALEX MERSEBURGER: How close are we to digital twins? Are we close to a digital twin for clinical research purposes?
KRISHNA TANGIRALA: Great question, Alex. Digital twin is a virtual replica of a person. It is more than the synthetic or extended arm that we are talking about the clinical trial. For a digital twin, we need to have the deep data science, and also we need to have the clinical experience to create the digital twin. Well, a digital twin, actually, we use digital twin to have an outcome that is not a primary. For example, if you are looking at the diabetes, we are following the diabetes, but we wanted to see if the patient got hurt, how much time it takes to cure the patient. So having the digital twin is cost effective. We don't have to run a separate trial for a digital twin. So there are many advantages of having digital twin.
For digital twin, the data we need to look into is very deep. We need to look into the genomics. We need to look into the patient's labs. We need to look into the patient's insurance claims or the electronic health records to go back five, six years and completely understand the patient to develop their digital twin.

So having the latest technology that what we have, such as AI, and then we are getting closer to the digital twin. We are not there yet, but we need to keep working on this, the science that we have.
Well, a lot of people say, hey, it's not possible. Why even we do this? So what I would say is either come along with the advanced technology that we have now and work with the researchers to get to the goal of this closely digital twin rather than saying we cannot do this and just going with the normal clinical trial.
So as I said, it's very cost effective. We are going to-- we can look into the different outcomes than the primary outcome if we have the digital twin versus having the other person, actual persons, to use as a control arm.
There is a lot of looking into the retention of the patients, for example, as I said before. It's very tough to retain-- have a patient to follow the clinical trials within two or three years. Having the digital twin, we don't have to worry about the patient's retention. So I would say we are not there yet, but we should move towards the technology and understand-- having the research rather than saying that we cannot do it. So yeah.
ALEX MERSEBURGER: So you talked about extended control arms and digital twins. There's a lot of opportunity. It sounds like we're getting fairly close to solving some of the most pressing challenges and getting more widespread adoption in the clinical trial space. If there was one challenge that technology could solve for you or for the field of outcomes research, what would it be?
KRISHNA TANGIRALA: Well, data is key for health and economics and outcomes research. So data comes from various sources. It comes from health insurance claims. It comes from electronic medical records, patient-reported outcomes, registries, social media, such as even Facebook. So data is everywhere.
So one of the challenges that technology can solve is to get the data from various sources and then deduplicate it because the patient-- there's a lot of duplication, and there's a lot of fake data. So technology can get all the data into one place, and then clean the data, and then use it for the research and create the dashboards that we can directly give it to payers.
The other one technology can do is a low code or no code. My team spends a lot of time in writing the SAS programs. There's a lot of technology, even the tools that we have to use. But there could be an advancement within the tools that we are currently using, such as SAS Viya. We are getting into SAS Visual Analytics. We are going to SAS Visual Statistics. So we have to use the latest technology that we have and get the valuable information out from the data quickly, as soon as possible. So saving time is something that technology can do. So yeah.
ALEX MERSEBURGER: Krishna, we've learned a lot about Organon and about you and your role. Thank you so much for sharing your expertise with us as well as your personal career journey.
KRISHNA TANGIRALA: Oh, thank you for having me. It's a great pleasure to be here. Yes.
ALEX MERSEBURGER: I appreciate how we've learned from how Organon is using the explosion of data to bring new therapeutics to market faster, safer, and better than ever. We'll now jump over to Sherrine Eid, Global Lead for Real-World Evidence and Epidemiology at SAS, for her take on the endless opportunities data provides. Welcome, Sherrine.
SHERRINE EID: Oh, thank you so much for having me.
ALEX MERSEBURGER: So you're an epidemiologist. We've talked to a few epi leaders in local and federal government alongside inside insurers. This is an area that's had a lot of interest, especially these

last few years. We had one of our guests joke that kids are dreaming of becoming epidemiologists now instead of astronauts.
SHERRINE EID: Yes.
ALEX MERSEBURGER: So you can choose what to do and where to go. Why choose SAS?
SHERRINE EID: Oh, SAS is beyond the leader. It's always been the gold standard. Even in my epi training, we were told it's the gold standard. But it's the best-in-class software.
And I believe that my purpose in this life is to find ways to impact people's lives for the better. That includes giving them better health, saving their lives. And the best way that I know how to do that is to mathematically model disease patterns and find ways that we can intervene. And SAS is the best platform and best software to do that. I believe that this is part of my acts of service, if you will. And doing the best work that I can do with the best tools that I have is one of the ways that I do the best service that I can.
ALEX MERSEBURGER: What do you see as the biggest opportunities for the application of real-world data? You mentioned sensors, and wearables, and new technology. Where are you seeing the biggest opportunities for the application of real-world data in life sciences, and have we reached that tipping point yet, where the use cases are accepted into mainstream clinical research?
SHERRINE EID: Well, we're not at the tipping point yet, but it's increasingly being incorporated. I was just speaking with some life sciences organizations this and last week, where they specifically asked us, well, can we do sensor data? This is our plan to incorporate it.
I, myself, am a diabetic, and my mother was a diabetic. I wear a sensor. I'm very excited to see when my blood sugar goes too high because of stress or because of something I ate. So personalized medicine is really at the forefront. And how you personalize the medicine is something that we're exploring as an industry, knowing that what works for me might not work for my mom, for example.
I mean, our lifestyles are very different. Even though she was a veterinarian, she was a stay-at-home mom. She didn't have the financial burdens that I carry, and her stressors in life were slightly different than mine. And so maybe what was contributing to her underlying condition will possibly be different than mine.
Maybe her triggers, and the food, and the diet that she followed is slightly different. Even the composition of our diets and our lifestyles, whether it's sedentary or otherwise. I remember watching her do exercise videos on a VHS tape. I don't have the VHS tape. Instead, I might go to the gym, and that burden might be a little different for me.
And that kind of personalization because our circumstances are different is, I believe, really critical. And we have the data and the computational power to do that, knowing full well that we all have digital exhaust.
Is there anybody today that doesn't have a smart device? We have smart homes. We have smart watches. We have the smart phones. And that digital exhaust that we leave behind is critical because it's our digital fingerprint, if you will. And every person is unique.
Even if we're deliberately trying to limit our screen time or modify our behaviors as we interact with these smart devices, we're still interacting. And as long as there's an interaction, I'm leaving a mark behind. And when I leave that mark behind, that's a piece of me.
Personalized medicine really is intended to get to the whole person, whether I have behavioral stressors, if I have emotional stressors, if I have psychological stressors, or physical, or genetic, as well as just other

economic stressors. Whatever those stressors might be that put me in a situation that I might manifest a particular condition or overcome that condition.
Mind over matter. These sayings that we've had-- and these are age-old sayings-- are not for nothing. And so how can I support the whole person so that they could have the best health outcome? Because when I'm at my best health, I can be at my best self.
ALEX MERSEBURGER: You have the unique perspective living with a chronic disease while impacting others with chronic diseases. Can you share a little bit more-- I think you started to. Can you share a little bit more about how you mesh those two worlds?
SHERRINE EID: Oh, I'm so grateful knowing that I have the sensor on my arm, that I have the computational power in a platform, that I have the data to make really critical lifestyle changes. So for example, there's a family wedding coming up in just a couple of days. Am I going to have a piece of that cake or not? Have I maintained a healthy enough lifestyle and made positive enough choices that I could maybe indulge in a smaller piece of cake instead of not?
So because of that, I can see I get immediate feedback on my choices and my behavior, which modifies, then, my tomorrow. And so knowing that I have access to, and I have a direct role, a very tangible role, in my care, and I get immediate feedback, especially in an era where we have immediate gratification all around us, this is really critical for me to manage my health better and gain wellness in a way that makes me present for my children, makes me present for my job and the work that I do.
I'm excited to be that living example of a potential. This is why we do what we do, folks. And I know that the things that we have discovered today and that I have at my fingertips I know would have impacted my mom's life if she had access to it.
ALEX MERSEBURGER: You mentioned common phrases or different words that you hear consistently at life sciences events. So if you're listening to a mainstage panel, or in the hallways, or just in the advertising for a life science event, you see ethics. You see DEI. You see a lot of buzzwords that have commonality. When you hear these, what do you think?
SHERRINE EID: I think, oh, wow. So epis have been talking about disparities in health for decades. We have noticed in patterns because that's our job is to assess the pattern of a particular disease at a populational level. We've been able to assess that, hey, there are differences between different people, whether it's a geographical difference between them, like urban, rural, whether it's an economic difference, whether it's an income difference, educational differences, in addition to our traditional demographic differences, so race, ethnicity, language. All of these contribute to differences.
And I'm very grateful for my profession. I'm very proud of the work that we've done to highlight that there are differences between people for a variety of reasons. And it contributes to health outcomes. And how can we intervene in a way that is contributing to that?
I'm impressed with how much more mainstream these conversations have become, and I'm impressed with the policies that are supporting the activity to make it worthwhile to accompany a multibillion dollar company to invest in it. But what I'm most proud of is that SAS is at the forefront, talking about ethics and responsible AI and identifying that diversity doesn't just mean a language that you speak or don't speak.
ALEX MERSEBURGER: Yeah. You talked about the unique challenges and the so much that we've overcome. You talked about how epidemiologists have been looking at diversity data for decades. And so we've obviously come a long way, and we still have a ways to go. What's something that keeps you optimistic about epidemiology, about technology, about the future of life sciences?

SHERRINE EID: I'm so excited that we're objectively investing in better care and better ways of working and collaborating, quite frankly. I see a convergence. We talked about the convergence for a while and knowing that there's an opportunity for like-minded people who are passionate about getting people healthier and saving their lives, knowing that there's so much more that we can do because we have the technology. We have the best-in-class analytics. And we have the data.

They talk about data being the new oil. And how you refine the data is the product that you get out of it. Well, that for us is insights. And I can tell you, in some of my publications just last year, the risk of a metastatic cancer, for example, in a cancer patient is heavily driven by their liver health. Well, when you look at it, you're like, oh, that makes sense. But we'd never had it quantified before. And we were able to do that with SAS software, on SAS Viya.

So that makes me optimistic, that when you bring this kind of quantitative modeling to a scientist who really understands the science of that disease, or of that organ system, or of the body, and they're in the business of caring for people because it's a labor of love and passion. And I can say, look, my numbers are telling me this. I'm like, aha. Of course.

And they didn't even realize that subconsciously. That's part of their prognosis. They look at their liver health, their patient's liver health. And it was an unknown or an unnamed factor, even though subconsciously they've done it. So we were able to uncover that.

So things like that make me optimistic, things like, hey, we're all in this together. And the dialogue and the discourse at a global level is so inspiring and motivating to know that we are all collectively as a human race trying to do better for ourselves with better tools. And we're having healthy dialogues, especially because I don't know everything. The next scientist doesn't know everything. And the meeting of the minds allows us to have a very healthy discourse around, what can we do that's better for our patients?

ALEX MERSEBURGER: Well, we are so fortunate to have you at SAS. And societally, we are so fortunate to have people like you and Krishna as trained physicians and epidemiologists living out your purpose and your passion, and the expertise that you provide, being able to go out and use technology for good, and, like you said, turn those data into insights that really have an impact on individual lives and can change the outcomes of family histories. And so this was so wonderful. Thank you so much for being a guest today.

SHERRINE EID: Oh, it was absolutely my pleasure. I cannot tell you how grateful I am to have a platform like SAS be invested in saving people's lives. SAS does save lives. And partnering with people like Krishna makes me hopeful that this is just the beginning.

ALEX MERSEBURGER: Well, two great guests. 2,000 learnings, I think. This has been such a wonderful experience. Let us know your thoughts. Send us an email with your industry learnings, the insights that you're gathering from the data that you have or the industry trends that you see.

Thehealthpulsepodcast@sas.com. We're rooting for you always.

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