accenture

REVOLUTIONIZING CLINICAL TRIAL DESIGN

VIDEO TRANSCRIPT

Marc: Hello everyone. My name is Mark Phillip. I'm a partner and managing director with Accenture strategy and I'm joined by Marcy Kravet here in Barcelona.

Marcy: Thank you Marc.

Marc: So, if you look at the industry right now, we're pivoting to a world where personalized medicine, smaller patient cohorts and a much more rigorous execution of clinical trials is required to really make sure that pharma companies need the pressure on productivity in R&D. From your perspective, what are some of the solutions you see to fix the drug development model and sustaining in the future?

Marcy: So I think it's a great question Marc. I think that the industry, in terms of the competition, the number of companies vying for similar patient populations going after more niche populations makes the efficiency of clinical trials a much higher priority. And so personally I think that using data and analytics to design and execute clinical trials in a more efficient manner is really key to where we need to go. I also think that decision making needs to be accelerated. I think using data to make decisions in a more expedient way is one way forward to bring new medicines to patients faster.

Marc: If you look at Merck from an enterprise perspective across the divisions of healthcare, life sciences and performance materials, Merck has put out his vision of being a science and technology driven company across all of those divisions. What is your thought on global clinical operations and how clinical operations and clinical drug development contributes to that vision?

Marcy: I definitely think that patients are at the center of everything that we do within healthcare. They have to be the reason that we come to work each day. And in terms of a science and technology company, we have to bring our science and technology to bear to bring new solutions and new medications to patients. I think the beauty of what we have here at Merck EMD Serono is this collaboration across the three business units and that leveraging some of the data science technology, some of the analytics use cases are really going to help us propel forward in global clinical operations in terms of bringing some of these solutions in the clinical trial space.

Marc: The reason you're sitting here, and we have invited you to talk about your experience is that we partnered up in the what we call operations design centers space. So creating a new entity within global clinical operations, you're now leading which is about improving the way trials are designed and then also executed. Can you describe a little bit of the learnings you've gathered over the last months since starting in this position? How you ramp up that capability in that rapid time frame?

Marcy: I think Accenture was really pivotal to our success in terms of an accelerated startup. I came into the organization and Accenture had already been working within the cross functional team to understand sort of the needs and the initial use cases as well as helping us to develop a roadmap. So within that framework,

the operational design center was really able to hit the ground running the beginning of 2019 and start implementing technologies, data sources, using vendors and strategic partners to bring some of the solutions to the clinical trial teams. Initially our focus was on the operational part of the operational design center. Really thinking about how we validate our CRO partners recommendations on country and site selection, enrollment projections. We're now moving into the design part of the operational design center and really working with study teams early on to define patient populations in a more broad perspective without compromising the scientific rigor of a particular study. Really thinking broadly about how we bring more patients into our clinical trials that will allow us to meet the endpoint of this study. So I think that having that initial ramp up helped us get to where we are currently. I think the other piece of it was within Merck KGaA we have within the healthcare spectrum, our R&D organization has committed to a vision of what we want to look like in 2023 we want to be a specialty innovator of medicines. And so this use of science and technology to design and execute clinical trials is a big part of that. So I think that having that overarching strategic framework in which the operational design center is operating also helped accelerate. And then finally, I think really being able to get out to all our key stakeholders within the global development organization and share what the vision was for the ODC, our initial use cases as well as where we're going in the future. And that frequent conversation with key stakeholders helped us drive from the ground up support of the model we were building.

Marc: So let me ask you, if you would step out a bit from the daily routine and look at this from a more long-term perspective, maybe within the next three to five years, what do you think the ODC can achieve from an impact perspective and where do you want to take it?

Marcy: So I definitely think overarching is this vision of more efficient clinical trials. How do we bring innovative medicines to patients faster? And I think a lot of that is around our study designs. We are dipping our toe in the water in terms of some virtual clinical trials, synthetic arms trials at home. I think moving forward we have to go boldly into more of these innovative study designs. I think the other piece of it is around sort of the data perspective. And we're currently embarking on a very bold data science project. So we are trying to understand what are the causal drivers and the strength of those networks around clinical trials. And so we're looking at this as a big data project to assess what leavers we can move within a clinical trial to make the trial more efficient, include broader patient populations and bring the study and drive the science faster.

Marc: So Marcy it's great that you mentioned the importance of data and what you are trying to do with data over the next years. So from your perspective and from a more clinical perspective, do you think this whole idea about using data as a fuel for driving some of the analytics cases, is that an overrated statement and is the importance overrated or is it even under estimated?

Marcy: I definitely don't think it's over overstated. I definitely think that data is going to be sort of an asset that we have to leverage. I think the challenge and the opportunity really comes with the data sources. As data sources evolve, as we get access to more data, understanding how we use that to design and implement more efficient clinical trials will be key to our success. I don't want to downplay however the importance of people in the equation. So as much as data is really important, the people that are working with the data that understand the data, that can drive the change management within the organization to accept data to help make better decisions, I think we can't overstate that enough as well too.

Marc: Marcy, we thank you for your time and for sharing your perspective. We wish you all the best for the way ahead to help improve and transform patient's lives.