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DRIVING DIGITAL IN BIOPHARMA: VENKAT SETHURAMAN

AUDIO TRANSCRIPT

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CLIP: Data is the new currency, and many pharma companies are starting to embrace this; data being seen as another important asset for us. And so as much as I believe that the data is all generated within our own company, that is the old way of thinking about things. So today, data is being generated by patients every day, through wearables, through apps and other sources of ecosystem. There's also data being created by some of the data vendors that we know and are familiar with… So when you put it all together, the amount of insight you can generate from this data in terms of moving your drug development has become very, very exciting.

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VO: You're listening to Driving Digital in Biopharma, a podcast from Accenture. Your host is Tom Lehmann. Hello and welcome to Driving Digital in Biopharma, a podcast series from Accenture. My name is Tom Lehmann and I'm your host for today's discussion in this series.

01:03

TOM LEHMANN: I'm excited to continue this podcast in which we've been having real and insightful conversations with biopharma leaders on the topic of digital transformation in this industry.

I've had the opportunity to speak with guests from a variety of organizations and perspectives; most recently I chatted with Craig Lipset where we discussed the industry shift towards decentralized clinical research methods. If you haven't already, I encourage you to check out this conversation with Craig, in addition to our existing lineup of episodes on our Driving Digital in Biopharma website.

01:31

In today's episode, I'm excited to chat with Venkat Sethuraman, who leads Global Biometrics and Data Sciences at Bristol Myers Squibb. Prior to his current role at BMS, Venkat held a number of roles in the biometrics and R&D clinical services space, where he's been able to see firsthand the critical role that data and digital play in biopharma R&D. Venkat's statistical background has helped shape his unique perspective on how to maximize the value of data to create the best outcomes for patients and stakeholders, all which informs his "3 D's of R&D" strategy which we discuss in our episode today.

02:04

While we'll hear in the discussion that "Not all data is created equally" – a mantra which presents itself across all industries – Venkat highlights that there is a clear desire – from investigators to regulators – to embrace this evolving data ecosystem in the industry; the question is, though, how do you make complete sense of all this data? I'm excited to dive deep into this question and more with Venkat today,

and I hope you enjoy our conversation together.

Welcome, Venkat, to Driving Digital in Biopharma. I'm looking forward to our discussion today.

VENKAT SETHURAMAN: Thank you, Tom.

02:32

TOM: So in your career, you've had several different positions within the industry, and I presume in those positions seen firsthand the evolution of the volume and diversity of data across development. And I think we probably would agree at its core, biopharma R&D produces data. There's a lot of things that come out of it, but a huge portion of what is done across R&D results in data that needs to be analyzed and decisions made based on that data across the value chain.

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And we're seeing both at an internal level as well as an external, a huge volume of data and it's growing exponentially. And I think that's caused the ability to make complete sense of the data ever-challenging for people in positions, like the organization that you represent. So as we look to the future, I think we probably would agree it's going to get even more complex. And if you look at the role that digital and data can play, which is a topic for this podcast series, we're now seeing a number of different approaches underway and progress that's been made, but maybe not necessarily at the scale that the industry would like to get to.

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Sometimes it's because there's a misalignment of business and technology strategy. But often, what I think what we're seeing is where good progress has been made, you are starting to see a convergence of both business and technology strategy. And so along those lines, you've been working to help shape a broader transformation agenda at BMS. And I thought that would be a good place for us to start today's discussion.

So can you share your bigger picture of view and vision for the future of R&D?

04:03

VENKAT: Absolutely, Tom. I think this is a very exciting topic and exciting time, as you mentioned. First off, data is the new currency, and many pharma companies are starting to embrace this; data being seen as another important asset for us. And so as much as we believe that the data is all generated within our own company, that is the old way of thinking about things. So today, data is being generated by patients every day, through wearables, through apps and other sources of ecosystem. There's also data being created by some of the data vendors that we know and are familiar with… Flatiron, Concert AI. And several other data providers that we all know have been curating a lot of the EMR/EHR data that we have.

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On top of it, also data that was not very much accessible to the pharmaceuticals before are now being readily accessible. So the genomic data, the transcriptomic type data, as well as the images and radiomics data that is available to all the pharmaceutical company.

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So when you put it all together, the amount of insight you can generate from this data in terms of moving your drug development has become very, very exciting. So within BMS, what we are doing is, what I call is as 3D for R&D. The three Ds are data, design, and digital. When you think about data as what I just described to you: how do we maximize the value of the data that we have, internal external ecosystem?

05:31

The second is the design: how do you use this data in order to better design efficient studies so that we can accelerate our clinical programs? And the third piece is that digital, you know, the patients, as well as the investigators and others start to embrace more of these digital apps—and the data that comes through that and the experience that the patients get, could also be

mined for better experience. And so that's how we think about it within BMS. How do we bring this data, design and digital together to create value for our patients as well as our stakeholders?

06:06

TOM: And are you finding that all three of those are moving forward at a equal pace or is one or another moving forward faster and you've got to get some to catch up? How do those come together as you drive that forward?

VENKAT: Well, I would say that moving fast is very essential, but capturing the full value of any of these transformations certainly involves us scaling some of the best initiatives across the organization.

06:38

And so we are taking a slightly different approach. Rather than scaling almost everything at the same pace, we are thoughtful in terms seeing where the industry maturity is. So, for example, with the data space, the maturity's almost there. There we are trying to scale some of our capabilities. Whereas in the digital space, the industry maturity is very low, as well as it's very fragmented with all the startup ecosystem. This is the place where we are taking it a little bit more slow, trying to really understand how those experiences with our patients, how many different apps that do you have to use.

07:07

Are we truly generating a good experience for our patients? From a design perspective, it's somewhere in the sweet spot. The industry maturity somewhere in the middle. And we are also trying to pilot out many different initiatives within the design space.

TOM: So let me come back to data, if I can. You listed off a number of different data sources, and it goes back to my point at the beginning here around just the ever-increasing complexity that we have to deal with as far as the range of sources.

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Are you finding that it's naturally sifting itself out to the point where there are certain sources that you'll invest more time in because there's a perceived value or the realized value is greater as opposed to others, keep it as exploratory stage: “We're not quite sure what we're going to get out of this.” And other ones, “We've tried but we’re going to put it off the site because it's more noise than signal.”

How do you start to prioritize given that there is no shortage of data sources and choices to work through?

08:01

VENKAT: So I think the one of the most fundamental realizations we all have to come to is not all data is created equally. Right? And so as long as you understand the data that goes in—the level of quality and the level of curation that has gone in, the level of confidence, you have it this different data sources—the model that you build in that can accommodate for all of that.

08:34

So let me explain something in a simple way. Right. In a clinical study, there are a lot of inclusion/exclusion criteria. We very rigorously capture some of these information in a CRM. So I very well understand a patient characteristic. Whereas when you go into the EMR data, you might not see all of these fields which are very important to us being captured. But we can triangulate some of these information through some of the information presented in the notes, or other sources of data we see on similar type of patients that we can bring in that data to give a complete picture.

09:02

Now, when you put all of these data together, that's when the magic happens, really. You know, how are you able to generate insights in terms of what you see in the clinical data; the consistency that we see in a real world data, or if you're building a novel endpoint using this data, validating that endpoint with the data that you have captured in here—all of these things you could do as long as you are able to bring them into one place where the teams can

access them. That's the hardest part here.

09:30

TOM: And so then take that even a step further. So you've got the data part of it, you talked a little bit about the digital parts of it fragmented right now, but it's evolving, right? We're seeing the industry evolve. And I think that pace of evolution seems to be increasing at this point. It comes together at the design point. How do you put this together and really see this driving better patient outcomes?

09:57

VENKAT: So, I mean, it's a very interesting question, because we are experimenting certain things now with our patients in clinical studies. As an example, we are launching a particular app which is capturing information about their experience in a clinical study. Now, there are a lot of back and forth conversation that happens between a patient and an investigator during this trial contact. Is there any information in here which indicates lower engagement of this patient, the likelihood this patient is going to drop out from a clinical study? And is there a nudge that can be given by the site, picking up the phone, calling them just to see that how they are feeling?

Keeping them engaged in a trial can go a long way in terms of data collection and ensuring the completeness of the data collection that we have in the clinical study. So those are the kind of places where we are trying to leverage some of the digital and the data that comes in from the digital to enable better clinical development.

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TOM: Do you see the mindset shift happening that I guess changes that conversation from perhaps a reactive, “What happened?” into truly getting to the predictive side and really trying to find those moments that matter or those points of intervention? Do you think the mindset is shifting or there's still some real work to be done there?

11:05

VENKAT: I mean, I would say it's mixed, to be honest. The mindset is clearly shifting. It's going in the right direction because most of the people in the company are aware of what's going on. And then they, you know, in a sort of positive way that happened, that came out of COVID 19, is that people realize that we have to resort to some of the digital means to communicate with our own physicians. We had to resort more to the digital means. So people are starting to ask the question, “Hey, how would we use this technology in our clinical programs?”

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And so there is this two side to it. One is there is a push coming in from the organization. Two our stakeholders, the investigators and others are also asking this question. So it's sort of creating a nice ecosystem for us to innovate.

TOM: And are you seeing the investigators coming along in that journey—because that obviously, as you just mentioned, it's one of the key stakeholders here—are they moving along at the same pace, different pace? What's the experience been?

12:07

So the ecosystem is so fragmented. Just imagine if you have to enroll in a BMS trial, you will have an app for BMS. If you're going to enroll in another sponsor's trial, you're going to have another app. Let alone you're going to have, for your own personal needs that you work within that healthcare system. So that's where the complexity starts to come. If there is a convergence at some point in time, that would be beneficial for both the investigators as well as patients, as well as a sponsor. But we are not there yet. That's the biggest challenge today.

12:45

TOM: Well, it seems we've almost recreated the problem. I think we've all seen that that famous picture up there think there's like 15 laptops all stacked up with all different passwords, depending on the number of sponsors that they're running trials for, just going from EDC system to EDC system and how difficult it is for the investigators. So, again, recognizing as you go through the design part of this, there is an

element here, which is, of course, the patient experience, but also, the other stakeholders in the mix here with the clinical site becomes an important one here. We just don't recreate the same problem that we've been trying to fix now for the past several years.

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VENKAT: Exactly. And I think you're spot on, Tom. I think that's the exact journey that we are going through. But, you know, every innovation like this, you can't expect overnight to be truly transformative. So it is an incremental step.

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But I think we would have certainly learned from what we went through with our EDC. And certainly there will be an acceleration. The ecosystem is very strong, the startup ecosystem, they are very quickly figuring out a way, “How do we integrate this data across multiple different apps and how do we bring that to the patient?”

So I'm pretty positive or at least optimistic that the future state is going to be much more faster than what we went through with EDCs.

14:04

TOM: And what's your sense of just the talent readiness for that? One of the one of the things we've talked about on this series is just the readiness of organizations, broadly the talent, to move decidedly in this data oriented or digital oriented direction. Is the talent, whether it's in your particular area or more broadly across the development functions, is the talent ready for this? And in moving along at the pace we need is there some real work to be done there as well?

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VENKAT: So certainly there is talent and there is a lot of excitement within our organization in order to move this forward. And I would say that broadly, most of these highly passionate individuals, they tend to gravitate towards a startup environment because that's where you really see some digital disruptors, how they are trying to tackle these problems. Certainly the internal talent is also excited about it. We are investing in them in order to upskill these talent within our organization in order to get to that level.

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TOM: Are you seeing the biostatisticians, right, the traditionally trained biostatisticians, are they are they making a natural evolution towards that—I guess the challenges that are ahead of us and the question that you're trying to answer through data—are they trained and prepared for those types of questions or is it a different discipline that data scientists bring that are either augmenting or replacing what has traditionally been covered by a biostatistician?

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VENKAT: So, Tom, I think this is a great question. This is a challenge I face certainly within my own organization. And many of the industry leaders, my peers, also are trying to answer this particular question. So if I think about it, there are two parts to this.

Part A is the upcoming talent. The schools, which are the producers of this talent. When you think about all the academic institutions that we hire people from, there is a clear blend of talent that we see.

15:59

We don't see a strong biostatistician or strong data scientist. We see a strong blend of statistical and computational scientists coming into our organization. So these schools have started to invest really in bringing the best of both worlds up front now. When you think about the existing talent within the organization, this is where leaders like ourselves have to play an important role in investing in our talent’s top skills. So what are we doing with BMS?

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So we have rolled out a program closely working with Coursera about a three-part program with them. These are experiential program, as well as it's a very practitioner-oriented program that enables our organization to really upskill in certain skills is needed for

today's data science world. And I can tell you there are many, many hours invested by our statisticians, as well as the statistical programmers, who are trying to up skill. They are they are understanding within the data science area. And so clearly, it's a journey that our teams are going through. Now, the future state, what I can see is that, I can see some sort of a convergence of this talent coming together.

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There would still be some strong skill set that will reside within the data science team. So, for example, somebody can extract features out of radiomics, somebody who can do an NLP text, somebody can to a very sophisticated, deep learning model. And those skill set will still reside in one part of the organization. The other part of our organization will still have this traditional core skills that we need, such as designing studies for accelerating our clinical program, like adaptive design, and patient study design. This talent will coexist in the future state within our organization. That's the expectation we are all working towards.

17:29

TOM: And do you think our industry is a magnet for some of the best and the brightest in this space? Or we need to do some work to create this as an attractive place for people who have this type of background, who want to then apply it in very complex and challenging ways?

18:02

VENKAT: Now, I used to be of the school thinking that most of the talent migrated towards the tech industry. But, you know, now after hiring a lot of people from other industries…so we have had a lot of talent that data scientists in our organization. They come from very different backgrounds. Some have worked in the finance industry. Some have worked in med tech space.

18:29

Some of them have worked in other completely foreign industries. And one of the things when I chat with them, try to understand what motivated them to join our organization. It always comes down to this one important thing, which is what are we in here for business for, right? It's the patients. It's what impact do we have on patients? And every one of us are somebody impacted by a close loved one, impacted by a serious disease.

19:01

And so these individuals are seriously thinking about what impact am I making to the health care into the society? And that's what is really motivating them to join the pharmaceutical industry more so than the tech industry. I'm not saying tech industry is bad, but the talent coming in there is something about that passion that is driving towards our organization.

TOM: Well, and the ability to then apply their skills, their experience, to something that has just human benefit right? If this past year, year and a half has taught us anything, at some point, every company is a healthcare company in some form. But we've all dealt with this in some way.

19:35

So I think for people really to feel that connection to it, you can certainly appreciate—why there's an understanding why they would want to join this industry and feel like they're having an impact on something that's bigger than just themselves.

VENKAT: Exactly. And the diversity within our team now. It used to be if you worked in pharma, you worked in academia, you have a role within the pharmaceutical companies.

20:01

But then now when you bring in this diverse skill set in the organization, it just opens up a new area of thinking, new way of thinking, and how do we tackle these complex problems. So as we open ourselves more and more to cross-industry talent joining us, I think pharma will accelerate its own innovation.

TOM: And do you think it that takes the next step to not only look at talent at the individual level that has experience outside the industry, but also to look for analogs in other industries.

Are we seeing our biopharma industry starting to look to other industries as an analog for solving some of these big data related challenges that we have? Historically, this industry is almost certainly “not invented here; nothing is as complex or challenging as what we're trying to do.”

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Are you starting to see openness to say, “Hey, what is the high tech industry doing or what is financial services doing to try to solve some of these problems? And how do we learn from what other industries are doing?”

VENKAT: So I think clearly there is a learning coming in from cross-industry that I'm starting to see happen even more. Take a few examples that we have seen in the recent, right. Major academic institutions like MD Anderson partnering with Palantir. So it's a strong tech partnership that they have built in.

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There is also, you see from, Verily from Google, from the tech side of things, along with partnership with academic as well as pharmaceutical company, building that new pipeline to develop drugs. So you are starting to see the partnership starting to happen between tech as well as pharmaceuticals or academic institutions. That's one side. The other side is companies are starting to learn from what the other industries are doing.

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So as an example, the supply chain that we work on closely mirrors what we do, what Amazon does, or other companies do, in terms of delivering products to our consumers. What can we learn from that and how can we be more sophisticated in delivering our products to our patients or investigators?

So there's a lot of cross-learning that is starting to accelerate, not just because of what we went through in the last 18 months, but certainly pharmaceuticals are trying to borrow as much as they can from the other part.

22:10

TOM: And is there an opportunity to also look at—particularly maybe some of the tech companies and their tolerance for risk and—I guess the maybe better said the pace at which they actually introduce change and drive things forward or move towards these new models, is there something for our industry to learn here to think differently around, again, perhaps this cultural aversion to risk that to move faster or towards this type of new model?

22:42

VENKAT: Absolutely. I do think there is an opportunity for us to take a little bit more risk and start, you know, fail fast type approaches in experimenting some of the solutions. The challenge, though, in pharmaceuticals or in the health care sector that we all work in is the regulation. So what happens is a lot of times the regulation is in place in order to protect the safety of our patients. The mistake a tech industry does could be a like button or an unlike button in your app. That’s very harmless. But in case of what we do a lot to our patients, you don't want to be making any of those type of error.

23:11

So there is a lot of checks and balances. There are a lot of steps before we roll or anything to our patients. So that really by itself leads to a delay in how we think about some of this development of these solutions. Now, it's also very similar to how we do drug development, right? So we have early stage gate process that you used to work with phase one piece to a phase three. And slowly we started take a little bit more risk and started to merge these phases.

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Then we started to call phase one/two studies. We started to call phase two/three seamless studies. Then we started to work in that framework. And now we have seen companies go from a phase one, all the way quickly, jumping into phase three. Although rare, but we do see that happening in the industry. So I can see the same parallel starting to happen as the pharmaceutical industry disrupts itself with more digitization, you would slowly start seeing

more risk-taking in how we develop some of the solutions of products.

24:09

TOM: And do you see that also connected to what seems to be a desire here to rapidly accelerate the process? I think what we're hearing this, broadly speaking across a number of different companies in the industry, post COVID vaccine and the perceived pace at which that moved relative to the starting point. Do you see digital data design, as we've talked about in this discussion, really being a key to driving acceleration across development?

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VENKAT: I absolutely believe that the future, any company investing in the area of data design and digital is really getting itself for a very, very strong future growth. And then there [have] been other pharma companies who have been even more vocal about some of the importance of data science or medicines company. And so it is clear, I think this revolution has already started and some of us are very well in the journey.

25:08

But one thing I would add, though, Tom, it's that the successful transformation certainly depends on a balancing act, you're right. So you have to scale meaningful change without disrupting the core that we work on. The core is getting our drugs to our patients in a more meaningful way. You want to be able to disrupt without disrupting the core that we work on. So every company obviously has its own path, but I personally think a winning company is certainly a company which is going to invest in data, design and digital.

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TOM: So let's take that and be more specific then. If you take your biometrics, the data sciences role within the organization—and in particular how that relates to clinical trial design and in this topic of access—so if we can, let's just think about how the parts the conversation we just had relate to that. What do you see as is needed to better design clinical trials?

26:07

VENKAT: I think when you think about clinical trials that are two major areas, I would say. One is from a scientific perspective, there are a lot more innovation that could be applied. So we have talked quite heavily and FDA has played a very important role, as well as EMA in terms of releasing a lot of guidance around patient designs, adaptive designs, complex innovative designs. So there are many different innovative options available today that didn't exist a while back. So the innovation in this area is certainly helping try to accelerate space from a scientific perspective.

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The other area within scientific aspect is around leveraging external data. So it could be historical data. If you all sit on massive amount of data within your own company or through partnership or consortiums, that we share access to some data—how do we leverage that in order to, you know, avoid running a standard of care arm within our clinical study? And obviously you know quite a number of companies talk about synthetic arms or hybrid control arms, which we could use to reduce the need for standard of care in clinical studies.

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So these are a ways we can accelerate some of our scientific objectives that we want to achieve. The second area is more being truly patient centric. How do we engage our patients? Patients are the most important part. How do you find these patients who are more in need of these clinical studies? How do you reach out to the more diverse community to attract these patients and make these trials more accessible to them?

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Making these inclusion exclusion harder and not making this trial accessible to these communities makes it extremely challenging. So we need to do a better job in improving in that front from a operations perspective. And certainly having these digitally enabled apps and other solutions just helps us to accelerate that operational side of things. So those are the

two things that I would say how we improve upon accelerating our clinical studies.

28:08

TOM: Let me come back to the first one that you mentioned: synthetic control arms, which is seeming to gain in popularity, or gain in the volume of conversation about it. What what's your perspective on that? Is that the next couple of years, five plus years, does that become a standard way of operating in certain therapeutic areas? What's your sense of how it's going to play out?

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VENKAT: So the first thing that I would say is, our CTs or the randomized controlled trials will always be the gold standard, because you always need a good comparison. The question is, how can you leverage some of the externally available data? It could be from two buckets that you can borrow information, right?

Bucket one could be your historical data that you collected from clinical studies. The second bucket could be from the EHR environment, where you have access to some of the data, well curated data. And you can borrow from either one of them in order to complement the data that you already are collecting from in our CT.

29:04

And so, in my opinion, in the next two to three years, you're going to see a lot more research that is going to come from both industry as well as from academia. And how do we maximize the value that is going to be generated from these EHR and historical controls. Once that methodology is in place and the regulatory acceptance is in place, you're going to see a lot more acceleration and adoption within the industry.

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I can speak to it even this year, we have had a couple of submissions where we have used external or synthetic cohorts within our clinical program and regulators have presented extremely well and thoughtful on the approaches that we have taken to.

TOM: Do you see from a regulatory standpoint, once a few of the regulatory agencies are supportive of buy-in to this, it will start to evolve across them across the globe and other health authorities, as we've seen with other changes?

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VENKAT: Yeah, absolutely. We're going to see that. I mean, the best part is FDA initiated its own RWE framework and they put together very thoughtful insights on how we can design study, how do we utilize these data in our clinical program, EMA has provide a guidance around it?

And so regulators are clearly embracing this. But I think it's more about—the concern is not on the methodology, so much so than the data itself. How robust is this data? How much of it is of regulatory grade? Was this something that you can infer from an extraordinary setting? I think that's where the distinction is. As the data gets more and more mature to the regulatory grade, you will see a faster adoption.

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TOM: So to enable all of this, what's on the horizon from a technology standpoint? Obviously we've talked about the data, but to do something with that data requires a certain set of technology capabilities, and to your point, certain level of trust in the quality of that data. What's on the horizon? Where are the gaps that you'd see in the space to really be able to enable the vision you've been talking about?

31:03

VENKAT: So, number one, it always it comes down to process, technology and our people. It's always that right when you think about it. So the process is more thinking about, “Is there a system in place?—as and when we gather more and more information or data in our clinical programs, as well as externally bringing a data to our organization—is that a workflow in which this data can decide in one place? So that an appropriate data sharing mechanism is in place so that the organization can maximize the value of it?

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So that's the first thing, which is very important. Organizations are building that. But of course, there are tools and capabilities. There are numerous of tools and capabilities that are available to organizations to access. I don't think that's a major limitation or a cap.

The second is more from a technological perspective. Companies are investing in upgrading our existing system, as I mentioned to you. There is core foundational data capabilities that every company has, but you're also trying to bring in volumes and volumes of data in here.

32:02

Are you prepared to bring those data sets in the organization? So as an example, wearable data, imaging data and other sources of data that you bring into the organization, you just have to have a technology infrastructure in order to access that much more easily.

And the last is people. We talked about it. From a people perspective, there is certainly talent within every organization—but there are gaps. We need to recognize ourselves.

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What we learnt in the past is probably not the best way how we approach some of the newer problems. So as an organization, we do have to invest time in upskilling our own teams. Therefore, they can feel more comfortable and engaging in these innovative approaches to analyze our data.

TOM: And that talent side is a recurring theme, I would say, through this have—just that the need to really take a look at your current workforce and reflect on their skills, the needs of the future. Is it upskilling? Is it a augment with additional talent from outside the organization?

33:05

But it does seem to be a recurring theme throughout this, that the talent that we have was the appropriate talent base to get us the point that we're at now. Now we've got to figure out what do we need as we move forward. And so I think we're going to see a more systematic approach to two new skilling, because I think that the base talent is probably there. But it may just need to be augmented with some additional skills or knowledge of new tools that weren't available, perhaps as they've gone through whatever academic training or whatever work experience.

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But again, it does seem to be a very much a recurring theme through many of these discussions and in industry, I think gets it. And so I think it's going to be an interesting next couple of years as we as we get much more systematic about it and then our approach.

VENKAT: Absolutely.

TOM: So you mentioned two things. I jumped on this synthetic control arm before—you also talked about being more truly patient centric. What's your sense, though? What's the role that digital plays to make that happen? Because we talk a lot about that and obviously its core and central to what we do and why we do what we do.

34:07

What are a couple of things that that really start to flip that? So this industry can actually be more patient centric, recognizing that there is a little bit of distance between a sponsor and the end patient. What role does the sponsor play in helping to make that happen?

VENKAT: So I think—and I've said this before—in terms of the last 18 months has really forced the industry to really rethink, what does patient centricity mean? What I mean by that is that, how can we increase the convenience and the participation of our patients in our clinical study? That's becoming more and more important.

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And I think the first step of it is to understand, do I have to have my patient come to the clinic and go through the step in every single visit? Just to have that thoughtful process is very

important. And can you utilize certain tools and technology that is available today, through which you can capture the same information rather than having this patient return to the site for that particular need? And how do we implement these type of trial models, is going to become very, very important.

35:12

The second is, you try and capture information in a very, very complex way. But is there a better approach in capturing this information so that it doesn't cause burden not only to the patient, but also to the investigative side? Is there a way you can capture this information? I think that's another approach we should start thinking from a more patient centric way.

35:39

The most important other aspect which is coming is a timely engagement with a patient. Today, we see that, you know, we've all gone through it. If we have been as a patient, been trying to reach a doctor's office, be play phone tag, and then we schedule an appointment and then something else comes up and we are not able to make it. But can you make it much more seamless between the conversation that a patient can have with the investigator for a simple question, which could be easily answered through the site coordinator as well as to the physicians there? That's the kind of tools and capabilities that we can build that gives a better experience for our patients.

36:20

So we went through a recent exercise where we asked our team to think through: what would it look like, what does a good industry look like? And so we draw parallels to the banking industry, how we used to go to a bank teller and deposit a check versus now how we submit. We don't really go for everything to a bank. Same way your experience at Disneyworld, how it has changed, really?

36:46

And so all of these different places as a consumer we see a transformation. But the patients are not seeing the transformation, but they're still going back to the old ways of faxing over the trial results or faxing over the blood results to their physician. So that's the part we are trying to transform today.

37:07

TOM: Makes sense, and I think you're two examples there: the rest of our world, the rest of our lives have become much more digitally enabled that we've come to expect a certain way that we interact or don't have to interact, because there's just an ease of use that's out there that doesn't seem to have made its way into health care in a complete sense. So, again, we've all experienced various things over the past year and a half and just things like telemedicine that weren't there before. So again I think that the perspective is much of this is here to stay.

But, I think you said, figuring out when does it make sense to have that versus when does it make sense to have an in-person visit because it's the right the right way to interact at that point.

37:42

And I think there's also some research that people generally enjoy that when handled correctly. And again, it's really, as you look at the design of a trial, what are those moments that really matter from a patient experience standpoint that you have to plan for and make sure you consider as you go through it. And it's not a one size fits all, I'm sure, across therapeutic areas and even indications.

VENKAT: Correct. And, Tom, I would say this: the major question in everyone's mind is about the exchangeability of the data that you capture, right?

38:12

So I can have you and mobile staff collect some of the data at patients home, versus I can go into a centralized lab and provide some information. Or I can connect with you as an investigator site through a text message saying I have a headache. And how does that gets reported somewhere else in the charts?

38:41

Or it could be providing data through my wearable that I've had some AFIB right now. And how does that get communicated to you in a consistent way that I would have captured in a trial level? And so that's where some of the exchangeability of the data, the consistency of the data and how we are able to interpret, is certainly on everyone's mind, who's looking at holistically the picture that is being generated.

39:17

TOM: And I would imagine, in particular, your team having to contend with that is not a minor consideration. Think even just blood pressure, right? If you're taking your blood pressure in three different locations, do I need to allow for any considerations of that? Or if you're having other types of screening that's done at a minute clinic versus in a clinical research site, again how do you how do you normalize that to make sure you're looking at that in a consistent way across the different sources of data collection, is no small challenge for your team?

VENKAT: Yeah, I mean, the most interesting thing is, certainly if you have to look through different types and, you know, it's still this area is evolving. But the greatest experiment we've all had is COVID-19.

39:41

When a pandemic hit, a lot of people had to still take their blood pressure. They couldn't stay without taking the blood pressure. And so they were capturing data and some of those information we were able to capture and, you know, flagged them as something which is collected in a nontraditional method.

And so now there is a massive database where patients had to resort to certain ways of capturing this information. And what kind of differences are we seeing? Are we still consistently drawing the same inference? Those are the type of questions we can answer with the greatest experiment all the pharmaceutical companies that have run in the last 18 months.

40:12

TOM: Without a doubt. And I think that the common thread through all of this is data. A big part of this conversation has been spent on that topic. I think you opened up by saying data is the new currency.

And I think just given the conversation we just had pretty clear throughout all of this, there is there's an element to that. And in currency is probably the right way to look at it, but it's not all necessarily the same currency. So being able to translate across the different currencies becomes really important here.

40:38

So we are at an interesting time, that is for certain within the industry and with the volume diversity of data and the questions we're asking of it. So more to come on that.

I'm going to bring it to a close.

I appreciate the conversation and the insights here across a number of different topics and really appreciate you joining us today.

VENKAT: Thank you, Tom, for having I thoroughly enjoyed the discussion as well.

41:12

TOM: A big thank you to Venkat for joining me in today's discussion. As I reflect back on our conversation, it is evident how a focus on patient centricity is critical to an R&D organization's data, design, and digital strategy. Particularly in clinical research, it is important to continuously ask the question "Are we truly generating a good experience for our patients?"

There may be lots of savvy apps and tools that can collect data from patients in new and exciting ways – but as Venkat emphasized, these should aim to make the experience more convenient and accessible to the patient, not more burdensome.

41:43

We also touched again on the talent aspect in all of this, as we have in many of the previous episodes. How do you ensure you are attracting and upskilling the best talent?

While the biopharma R&D industry may be “behind” other industries with regards to digital transformations, there is a common thread connecting and motivating the talent that Venkat sees in his organization – the desire to positively impact patients which is creating a draw for data scientist to the biopharma industry.

42:09

And so I pose some questions to you, the listeners:

How is your organization working to ensure usability and quality of the holistic dataset that is being captured in clinical research?

What challenges and obstacles have you observed from the regulators’ side in embracing these ever-evolving ways of capturing and collecting data?

Please connect with me on LinkedIn to share your thoughts on these questions, and your thoughts and takeaways on the episode as a whole.

I thank you all again for listening. Please remember to like and subscribe to Driving Digital in Biopharma on your favorite podcast platforms so you don't miss an episode. And until next time, this is Tom Lehmann with Driving Digital in Biopharma.