



INTIENT SUMMIT INNOVATION IN CLINICAL TRIALS PANEL VIDEO VIDEO TRANSCRIPT

Appreciate it. I felt like we're going to have a great panel discussion now because you dropped a number of different things in there and we can go in different directions, which is, which is there, which is great. So I'm looking forward to that. So I'm going to invite another one of my colleagues up. Quite a schwannoma, who's our Global Head of clinical within Accenture, has spent 25 years in R and D and is a research associate and a Sloan fellow and is looking at how we can make better financial investments in R&D at MIT as well. So very glad to have you here. And please come on up and I'll let you introduce the rest of our panelists. Thank you. Steve.

Peter, please come up here and I'm Greg David.

We have an extraordinary panel today and I think correct. Thank you for really setting us up for a great discussion. I will go to the next 30 or 45 minutes depending on sort of how the discussion goes. Why I'd love to do is invite our audience to also participate, ask questions. Let's actually make this a conversation that's actually have a fun discussion about many of the topics we discussed today. Before I go through and introduce the panel, just want to sort of quickie tied to get a couple of things we heard today. We heard from patients, we heard from Chris Mayer were dramatic in terms of what's happening. Rather the culmination, or if you will, at the intersection of technology and data, I think that there are a number of different things that impact how we're doing patient care, if you will, a participant care. But one thing that stood out to me is that I think a combinatoric made, which was that at the end of the day, clinical development is still the way by which we actually get medicines or devices or solutions to patients. That's the only way by which we do that today. How do we make sure that we go through the process in a manner that's much more streamlined, perhaps more compressed or more accelerated. That might be one of the themes of weeks, weeks.

But before we do that, let me actually introduce this extraordinary panel. Excuse me. Of course, we heard from from Craig and we heard is introduction.

I'll introduce David Barry first because it's going from left to right, my left, right. David is a sea of Vela health Cambridge based companies, also a general partner, flagship, pioneering. And David has gotten extraordinary history both academically and beyond in terms of being an entrepreneur and a disruptor in this industry, started multiple companies. He's actually been somebody who's pushing and accelerating the industry to do things in it in an unconventional way. I'm really glad to have David here with us. Thank you, David.

And their cash comes from data. She's the chief scientific officer, trained as a scientist, spent many years. We were talking during the break working on glioblastoma research, which we heard from Dr. shorter. There's one I think very brings a unique perspective in terms of do we actually have a data problem? What do we have a data linking problem isn't fashion. You have a data connectivity problem. Love to hear from error in terms of what the role of data and technology could be. Github refund of us. Quito sort of makes things happen in real life, right? This is the kind of stuff where in pharma companies we have is one thing to talk in the abstract, what technologies, but it's much more important to see how can we actually make it happen when a child comes up for execution, what do we do? How do we make it happen?

That's part of what good does, both in terms of the technological elements of what Bear does, but also in terms of operationally making sure that that particular pipeline is prosecuted.

And finally, Steve see Geffen from science 37. We've talked about DCT. I think Greg talked about the notion of why DCT is here to stay. And science 37, when Ann has been an early pioneer in this space, you've learned a lot. We've actually made it possible. It's one thing to talk about decentralized stars in the abstract, but Steve and his company had been working on making a video. So I'm really looking forward to an extraordinary discussion today. I'd like to start with perhaps starting with Steve, maybe a couple of minutes. Steve, in terms of your perspectives and won't be heard today. And we can go around the panel just a quick minute or two in terms of what you've heard today and where you think this is going to sleep? Yeah.

Thanks, guys. I appreciate you inviting me here to speak with you today. I think Eric had a great conversation. He has really, you know, things out on the horizon that are coming in the future in terms of digital twins and synthetic control arms. I think what Craig mentioned about the ethical considerations are probably the most near term opportunities that I see. Although that's out there, we're really solving for patient access. And if you think about how we engage with technology today, now look around the room. Half of us have their phone in their hand and we're engaging with our friends and our colleagues and working in social media and whether that's ordering food or procuring services or whatever it might be. We have the ability now to bring technology to the clinical development space. And that really drives access. So access and inclusivity. How to patients learn about clinical trial opportunities when their physician that's treating them might not be engaged in clinical research. Very few physicians actually participate in clinical research. That really drives for participation by patients or potential patients to understand what clinical research opportunities are out there.

So if you have a methodology where you can go to those patients directly and then give them access to clinical trial opportunities even if they don't or that geo-located to an academic medical center, even if their physician doesn't understand or participate in clinical research. Providing that access through technology, I think is really important. And that's really what we're trying to drive. Obviously that impacts the time cost value curve in clinical development. But really it's about inclusivity and the ethical considerations of clinical trials. Actually get up. Yeah, Well, first of all, a DCT is indirectly controlled, is still a clinical trial. So that's basically our assumption. We have started with a bear. So what we see DCT is offering us an additional opportunity actually to enhance the product quotes to enhance and also the way how we act at the end of the day with patients. What I'm, I'm I'm shares you excitement about this is waste what we can do here. On the other hand, we also have discussions about the, the more fundamental question is, so what does it do to the patient? We already said just dumping technology on the patient that makes them happy and that's why the withdraw and more trials. I'm not sure that that's actually true. It's tended to be proven and this is what we are working on. That's why we say, Okay, we need to design now all clinical trials in the future also. More from that, more what we're maybe exclusively from the patient's perspective. So really started with the patient and then working backwards, developing a solution for

them. And what we have seen then, we have a few pilots who did a few parts in the past. It is a positive result I would say, and certainly Google go forward with that. But I think there's challenges ahead of managing the patients. And on the other hand, we don't have to forget there will always be an investigator. You also have to include the sides because dumping the technology and the patient also creates an additional we just heard it in addition to burn on the investigator sights, yet also needs to be managed. Thank you.

Thank you for having me here today. Great conversations throughout the day. As I was listening to some of the previous panelists, I was thinking about some of the things that we believe might change down the line and next time years giving you technologies coming into the clinical trials, but also reflecting on things that should not and probably will not change. So certainly the high bar for scientific accuracy, the high bar for wanting to make sure that we have safe and effective drugs to market that we do right by the participants who end up in our clinical trials. Those will continue to be high bars and then technology will layer on top of that to make certain things easier, both operationally and to get insights out there faster. So when I think about technology for recruitment and retention of patients, There's a lot more opportunity now and a lot more places that patients and interact with a clinical trial and clinical study. So we believe that that's going to open a larger patient population that is eligible for clinical trials. And that is very, very exciting. On the other hand, there's this dichotomy because as we're getting more innovative drugs to market and we're learning more about the biology behind why certain interventions work versus not. There's going to be more personalized medicine, which means smaller and more targeted patients, populations that are eligible for a particular clinical trial. There's going to be a little bit of a balance there. And if we're thinking about some of this more personalized medicine and the data that's included to really define the patient population there, you might end up with studies like oncology studies that end up being rare disease studies.

What does that do to the actual recruitment and retention of patients? What does it do to the ethicality of having various different control arms in the study versus bringing in things like digital twins or bringing in external control arms that are based on real-world data. That's going to be an exciting developments in the space and thus become data. Certainly, different avenues of bringing data into clinical research is going to be interesting. Bringing both passive data and actively collect the data, connecting data together so that you have, we actually have that full view of a patient and that you're getting the results that actually makes sense in the full view of the patients is going to be very interesting.

And then finally, I should say the technology itself is one components for getting more access to clinical trials, but not the be-all and end-all. You still need to when the patient trusts. So patient privacy, patient education is going to be quite at the forefront of what we do in future. Yeah. Thank you Very well said favorite of thank you for first, I just have to say, I always appreciate the introduction using a word like disrupter because in a setting like this, good thing. When my wife uses a different thing. But a context matters Exactly, exactly. So that's a great segue. So at, at vowel, what we've been focusing on is using large-scale human data and computation to pioneer the digital transformation pharma R&D. That is, we see an opportunity where we sit today to use data, human data, across the entirety of the drug discovery and development continuum for the first time in an integrated fashion that is use the same data, the same compute across the entirety of the spectrum. And well, that's very easy to say. We've been working for the past handful of years on standing that up and make it into a reality. And where it ultimately takes you is to stuff that we all know, which is the best way to develop drugs is get the right drugs to the right patient at the right time. And you can have an intervention. But what that does, what that simple statement does is it tells you exactly what we need to do, which is, how do we find the start with the patient, the right patient? That means we need to understand disease. We need the right data to understand the disease. We need the right analytics. The way we define disease today is simply put, not right. That is, we've

taken William Osler style definition for that date back a 150 years and we assume them to be gospel, no disrespect to Osler. My medical education was dependent on him. But that being said, what does it bucket's things into areas that are way too large. We all intuitively know this. But if you look at neurodegeneration, people who have been called as having Alzheimer's have a little bit of Parkinson E types and type symptoms. They have a little bit of a Alessi like symptoms. What is that? Well, it's really all three of them. And we actually need to not call them all three or one. We need to actually define it for what it is. But then we need to understand happening in that patient's journey. So if you take a patient who has diabetic retinopathy, mild diabetic retinopathy, the probability that they will progress over the next three to six months is 9%. Do we want to load them up with therapeutics? Probably not. But do we want to find that 9% and intervene? Absolutely. And this is where we now have the data, the tools, the computation that can allow us to do that. And that's where we can start getting to that rightward, right frontier of the right data, the right patients, the right time. And then of course we need the right drugs and be able to find those right targets and having engineering systems, we'll describe that in a second. That can translate that into meaningful therapeutics becomes the unlock. And we see in the frontier of this with companies like Modern up that happy to say flagship founded. But what we see with that is the ability to systematically take insights and deliver them into actionable therapeutics with precision. And we see the opportunity to do that, for example, with small molecules because of course they have the advantage of being orally bioavailable. So if you can put all that together, what it allows us to do is do a different kind of clinical trial. Get the right drug to the right patient at the right time.

Thank you, David. I mean, that's again, thank you to the whole panel because I think the whole context really matters letting, like Greg said, one of the things that we've been focusing on today is in terms of the last month, in terms of the trials themselves. But there's a lot that goes on for a molecule's ever ready for trial. And we've been having some discussions prior to this conversation about what does it actually take to compress the timeline? Because we heard from our patients, it's not okay to have to wait for a drug for X number of years. As an, as an industry, we're really not move the needle that much in terms of where we can go in this space.

So again, go back to David for a second. David, can you please describe to us in terms of what vowel is doing with respect to your approach towards compressing or accelerating entire timelines.

Sure. So while we focus across the entirety of the lifecycle, drug discovery and development, when you just starts looking at the simple numbers, the impact comes on clinical trials, right? If we reduce hit finding from 30 days to five days, which we have done, the impact to a patient is exactly 0. And we recognize that. So our focuses much more on how we can think about the clinical side of things. And so from that perspective, we like to think about how do you find, for example, the simulations in the right places that can actually replace components or all of clinical trials. We're not going to replace a randomized controlled clinical trial. But can we replace, for example, a trial that's dedicated to drug-drug interactions? Probably. And I think this is where we can start recognizing where does that slope begin? Because the beginning of it is not a slippery slope. The beginning, recognizing where mathematical and computational simulations are actually enriched enough with data that we can have impact. We can take that to the next step and say, can we find the patients for whom we think there's a higher probability that they will respond. And specifically tried to enroll those. And frankly patients for which the underlying biology means that they won't respond. In which case we run into the opposite at the ethical dilemma of if you give a drug to these patients where you believe the risk to them is of side effects and the benefit of them is near nothing. Should you be enrolled in clinical trials? Probably not. Right? And then as I think about it, can we find the right time to intervene? Because in certain club, in certain diseases, if you intervene too late, frankly, there's not that much you can do. But if you intervene at the right time, you can stop progression. You can reverse disease and identifying that exact time and that patient can become very useful. Now if you put all that

together, what that translates into is can you start reducing clinical trial size? Can you statistically enrich your clinical trials? Can you find surrogate endpoints that can predict things like mortality? And the long story short from our standpoint is absolutely yes. And frankly, this is what we've been doing over the last three years. We've had the FDA as a partner that we've been working very closely with and we've been able to incorporate. Each and every one of those components that I just described into active and ongoing clinical trials. And so these are not things of fantasy from where I look at, but things were, were able to see these sorts of benefits that in one study alone we think we've been able to cut up seven years of clinical development in cardiovascular cardiovascular study. Well, at the same time, potentially reducing trial size by 80 percent in something that's not a rare genetic disease. If we can do that systematically. Worksite. I'm thank you again, That's great. It's remarkable. I think the role of technology at all, the data really starts to become clear when we start thinking about technology is much broader than what perhaps we think of today as an industry. Where it to you in a sense, based on what we heard from Craig in terms of endpoint, surrogate, endpoints, etc.

What do you think the role of data is in the amplification of data and the conductivity of data to work with you guys do a date, event. And what sort of technology changes do you think are necessary for us to get full value problem?

So endpoints in the real world and just for everybody's definition of real world data are data about a patient outside of randomized control trials are essentially any interaction that a patient might be having with my health care outside of that trial. Those endpoints might not be exactly the same. I might not be apples-to-apples comparable to the n points at one collects in a clinical trial. But they all have insights that could be relevant to improving medical care. What's interesting is those endpoints are really only valid if the data that you're researching has the right context and these complete enough and is longitudinal enough. And our convention, a date of n has always been that the problem is not that there's not enough data out there. There's oodles and oodles of data that, that's really the exchange and being generated that year over year. We really believe that the problem is one of fragmentation.

So think about even yourselves as patients and now I'll give my example. In the past five years, I've had three different primary care physicians. I've been on four different health insurances. I've moved from Pennsylvania to California and then back to Pennsylvania. And my health care data, even within my interactions with hospital systems, sits in various different places. If a researcher wants us to look at myself and then patients like me, they would have a hard time really collecting, connecting all the data. So a lot of work that's happening right now and a lot of the technology that's datum and is very keen on introducing out there is to make sure that data can be connected, collected in a privacy preserving way to really have that longitudinal view of a patient's. And this can be done for, for various different use cases. But if we bring it back to the clinical study, again, you have a participant population that might be part of your study for, let's say, 18 months. That is just one slice of that patient's life. That trial might not have enough information to talk about the historical medical interactions, about the patient population, What's happening to them outside the trial while the trials being conducted? And then longitudinally, what happens to those patients 35 years down the line is an intervention that you've tested of them still efficacious is it's still safe. So bringing all that data together without disrupting the clinical trial itself can actually provide insights even with the patient population that wasn't the trial. And then let alone what you can do with patients that were in the real world who are getting that intervention post approval.

So when we think about data connectivity, those are types of the types of challenges and opportunities that we have. Can we find the right endpoints in real-world data? And can we actually create the right real-world data, that data assets that help answer those questions. In fact, one of the things you said that really good and having a conversation last night in terms of where the rubber meets the road, right?

Pharma industries, responsibility is to in fact take molecules to the clinical development and regulatory process. And based on what Greg was saying earlier on, we can talk about a lot of things, but one of the key things is a cultural changes that are necessary in an industry that's been resistant, distinct, some change over time. So, you know from your experience with Bayer, so how do we take a lot of what we talked about make it real? How does that actually happen?

Well, there's always a few people. They come up with an idea and then it starts somewhere. Then we have discussions about in the case of East Central US clinical trials, we can say we went back. So I would say 2016 when we had our first discussions about 2800, we built the first platform and for the next two years we're weighting function. We could try to use a platform where you could find one. So we were, we were too fast. What we see now is, I think that's also sex all of you.

There's an awareness also with those people who actually can make the decision. So it's beyond the clinical trials that there's an opportunity there to learn, but this opportunity is, and how we can get, I wouldn't say more data, maybe better data because more data is always wrong. It would be even better with less data and get the same results. But That's kind of growing right now. That's what we see. And I'm a little bit afraid that it turns into an excitement when it is too much already a set, so we also need to manage it. One of the challenges I see ahead of us is when you roll out these decentralized clinical trials, did you use technology? You also need to support somehow. So these are not technical expertise or not medical doctors at home. And then all of a sudden be questions like, okay, I don't know my Wi-Fi password. How do I connect the device now? Or I can charge it or what we have done By the way also in back into THE, we're equipped our self with devices. Now just for two weeks, just to learn how it feels. And honestly I didn't like it. So I had these these sensors attached to me had a wristband. I gotta rush here. Understood, Okay, So I was interested in making my own project a success. But now imagine that's just the patient. The patient was just rip off that thing and throw it into the bin. It's okay, I'm done here.

And this is what we need to learn to manage or how can we also get this excitement on the patient side, I don't know whether it's excitement, but at least a willingness to support the clinical trials to use it. And I think it ends with the question that we discussed yesterday. So what's in it for the patient? And this is where we also see still room for improvement. These stay still. It is that I shouldn't use that term, but it's kind of a Guinea pig approach, right? So we put patients into the clinical trial and then a result comes out. But the patients hardly ever know what the result of the clinical trial is. Because that goes in a complete different way. And how can we embed then also patients without, let's say, impacting the outputs then of the clinical trial. But how can we better integrate and the patient into the clinical trial? And this is what we discuss a lot these days. We want, we want to use the technology, we see the benefits, but as correct set, think we are really at the beginning. So this is just words, thoughts. Thanks Quito.

In fact, so Steve, challenge to year and science 37 guys have built a commercial model on making this real for us. So in terms of many of the things we heard in terms of what Greg described and what good are described in terms of the patients experience and the like. Howe Stick lounge actually allowing us to get there. And from your experience in terms of actually having done this in the real world, what are some of the takeaways here? Think that we have as an audience in terms of understanding how to make this real question. One of the only companies that actually develop their technology and actually uses it to operationalize around studies. So we have our own investigators are on mobile nurses or own clinical research coordinator is using the technology we built. So we have real-time feedback on your point. Does the technology work? And we're really connected to the patients because they work with our clinical research coordinators and our physicians. So we had this real-time feedback loop in terms of is the technology working and isn't intuitive? And does it help? In terms of some of the learnings? I think it starts off with the sponsor side. A lot of times we get involvement opportunities and the protocols already built

and they're trying to retrofit certain things. I think what we saw during COVID was amazing. Think about simplifying the protocol and focusing on the patient. First, we see a lot of protocols that they throw in a lot of different end points. You know, opportunities for data collection, but no one even really understands why they're doing certain things in the clinical level operations team and how that protocol actually arrive there. So I think starting with the patient first and then building the protocol around that. And then thinking about how you bring the trial to the patient and expand inclusivity and access using the technology. I think that's the first step and then you don't, you're developing a protocol and you know, you get to the point of operationalizing it. There's a lot of barriers, There's endpoints, as Craig mentioned, there's the regulatory discussion that has to happen. And I think here in the US also, when you think that global trials, you know, how do you run a trial in an adaptive way where you may have a site in. We're running trials right now where we have a 100 sites in 30 countries were running a virtual site here where patients are identified outside the clinic and the whole patient journey happens without actually attending a physical visit. And we have some sites where they're utilizing technology and mobile nursing to hybridize some of the visits, meaning you could spend some time at home, you don't have to come in for all the visits. And then in some sites where the regulatory constraints are difficult, in other countries, they're not using a consent, they're not using remote data capture their traditionally attending the clinic and as it normally would, but we're doing this all within the same trial. As long as the endpoints support that. And you have a flexible technology platform that could support order of operations that happens in a clinic and also bring that with reliability to a virtual environment. And you could support both of those. I think that's, you know, that's really ugly trials should they give the patient the opportunity about how they want to participate.

So that's great. Thank you.

I know one of our panelists, David has hot stop fairly soon, but one of the things I wanted to ask David before we before we open up with the questions here, is that what do you've done into who preclinical space into a new bringing data at scale and being able to apply you compute lie view. How do we make that happen? Sure, So let me, let me touch on this in a couple of different directions, which is one, I think there's this totally artificial separation between clinical and pre-clinical. Now, it exists for a reason because we do experiments in the lab. And then in theory, some magic happens and all of a sudden that goes to patients, right? But when, when I learned, you know, scientific method and things along those lines, you're supposed to start with the science that you want, the scientific question you want to ask. And where's that question? Start? It starts in the clinic. Which means we should be starting with the patient, figuring out how we translate those insights into something that's actionable and then bring it right back to the patient. And so our mindset from day one. Was reframed the entirety of drug discovery and development into one continuum. With that as the anchoring start with the patient and with the patient, It's all about the patient. And so from that we can redefine targets, we can redefine diseases. We don't need to get stuck in the circa 990 definition of target engagement than at the site of disease. Because who says that a disease is driven by one thing in one location in the body. And if we limit ourselves to that, we're biasing and assuming that patients will be cured by only one way of thinking about disease. So our view is, let the disease tell us what it is. Let us follow that. Let's find the ways that we can control that move from there. So for part of the way that we've, we've accelerated things.

Again, we start with large-scale human data. We've, we've pulled together a very distinctive, long, long-term and very deep dataset that's both longitudinal and multi-tool panel make in its framework that allows us to construct effectively synthetic virtual cohorts and pretty much any disease as long as it's not like child's disease, which I think has a history of two people in the entirety the Earth. We can't do that. And we convert it through computational techniques into one or more targets. We can even do it into robust phenotypes. We've developed a dynamic system that allows us to make small molecules by preference, but we can also make proteins against it. We've built in silico, as well as real-world capabilities to run simulations and predictions in the lab. That is, for example, we have a beating heart in a dish that's very predictive of what happens in clinic. It was used to predict, for example, myocardial clinical trials. It was

used to predict some of what's going on inside of kinetics as well as others. And we translate that right back. So we've build computational models for each and every stage and that creates it into one continue. Now clinical data, we can all talk about where to get. We all have our own biases and that's fine. We're probably all right and wrong as anyone is with different hypotheses. Preclinical data is a little bit of a different beast. And what we focused on is Add Me data. And what we've basically done is we said, Hey, can we become trusted partners of many organizations and work with you and mass? The first thing that people say when I say that is why would we ever do that? And the reality is there's an opportunity when you get to a certain scale that people start saying, wait a second, good for me and good for everyone else can actually happen in the same way because if I get that much more better, excuse that sentence. If I get that much more better on my own and everyone else does, well, I sold everything else I can depend on. And we've been able to transcend from that perspective.

That's been very helpful for us. Thank you. Really appreciate it. And Craig, based on what you described earlier today and what we've heard from all the conversations today. Somebody theory perspective. Where do you think we are as an industry, I'll be ready. Are we ready to actually adopt the technology?

We are ready to think about platforms to make a lot of what we talked about Rio because I'd love to audio distorts, ask questions and looking to see if there are any specific questions coming up, but perhaps you can just address that.

And then I think Tony has a question or two. I think, you know, when when you think about what could stand in the way of adoption, whether it's regulation or the state of available technology, or what other barriers may exist. It, it tends to be ourselves, it tends to be organizational, cultural awareness, readiness to change. Having leaders in your organization that are providing the support. I think the industry, the community is ready. I think that there is a sense of urgency, but I'm not one who's willing to make assumptions here. I don't have a mission accomplished banner for my death. The ability for us to go forward to me is equally strong as the ability for us to slide backward right now. We're at a very delicate point today. In we need we need to maintain confidence, continue to have support and set realistic expectations. Expectations right now. The experiences that organizations have had implementing things with incredible urgency during a pandemic. Your experiences in that situation are not indicative of what performance will look like with proper design, planning and forethought. And so when we look at the pain and the cost and the effort that is required to introduce new. In the middle of a COVID 19 pandemic. We shouldn't let that be the bar that now we're saying is, is how difficult this will be going forward.

So there is a certain amount of expectation setting that I think we need to ensure around what things were like over the last two years versus what we can expect going forward. But I think there were some great themes that I've heard from so many here today. Because that theme of expectations carries through to patients and participants, as well as those sites and understanding and meeting those needs. A digital or a decentralized trial is not the same as a patient-friendly, patient-centered try up. It is very easy to implement a digital or decentralized trial that is anything but friendly, do a rotation or a side? Plank, shoulder squared.

Tony had a question. Yeah. Sorry. Yeah. Thanks.

Well, you know, I thought you were going to go there, but you didn't. So I'm going to try to stretch that thinking just a little bit. We're talking about. Clinical trials and decentralized clinical trials, but hadn't worked in the patient services space over the last decade. I've I've found it quite peculiar that we also kind of, in my view, kind of artificially bifurcate clinical trial and all the decentralized methods. Whether it's IQ and sand, telehealth, et cetera, from commercial use. And when I've introduced this topic in the past, you know, there's a lot of like head exploding, like can't imagine working across that R and D to commercial divide. I'm curious. Maybe, you know from, from Steve de Ghetto, et cetera, do you see a futures where there is less of a divide there and that some of these same tools and techniques that we're developing to

enable speed and quality of clinical research is extended to actual clinical practice. Site. Or I could say, well, yes, it is certainly a topic we are discussing what we think about care. So once a patient leaves the clinical trial, what happens to the patient that would be interesting to see than O2, to know about that patient's well-being after the clinical trials. Well, how can we do the same time we have now built a function like three years ago, which is called digital business, what it means. So we would like to provide solutions which can be a companion to a drug or maybe is really just a digital product. And it would make sense and also to start to use these things right from the beginning and then the patients can carried with them also in the future so that I know it's a topic for us. We haven't gone far yet, but yes, we're working on it.

Thank you. And thanks for the question. 1 question from one of our online participants to David. In terms of, you're going back to comment on using human data across spectrum from discovery to launch. How do you envision using human data and preclinical target ID and validation versus animal data. In other words, what are we doing as an industry to sort of bridge that gap between in vivo and in vitro correlation for sure. And there's a lot of questions actually that are, that are touching on the same, on the same topic, I think 20 your question actually touches directly and indirectly on the same first, any lawyers in the room?

All right. So he's going to be a good answer.

Yeah, exactly. Exactly. Because we didn't win. I don't know what rats are good models for, but maybe I was just a little bit leading there. Sorry, it's a bit too far. Look, if we look at the history of drug discovery and development, There's a couple of trends that I think have come together, right? One is drug discovery and development has been evolved into where it is not out of any malfeasance, not out of any intention, but just because people were trying to do the best that they possibly can. And the way that science emerges as people become experts in things and they focus on those things. And so they focus on the task at hand and they become expert at the task at hand. But in what world do we think that the best way to figure out how to treat human disease is to take some cells from a patient who might have had that disease 60 years ago, lay it on some plastic, put some funky media on it. Take a bacterial enzyme engineer, I put some random DNA sequences on it and see what lives and dies, right? And by the way, that's like standard right now. That is like the cutting edge today. But I just described The reality is people like animal models because they're used to, they liked them because they understand the diff. But we all know if we run an EAA model for multiple sclerosis, we know it has no correlation yet we do it because the degree of comfort that we have and when it's going to require is frankly people getting out of their own way. And I hate putting it that way, but I think you already said that. But the point is that once we start embracing that the best model for humans is humans, then I think we can actually get there and it just, it becomes this notion of familiarity. Now let me say what doesn't get set in these cases? Why do people put up resistance? They're worried they're going to lose their job, right? So the reality is if we can train people, which is it's very doable because I know nothing about computers yet. I run a computer company. Sorry, I shouldn't say that. In turn mine on, I can break it. But the point is that it's actually a skill set that's an enhancement. And when you actually think about what computers do, generalized AI like, that's the stuff of movies that's not happening right now. Artificial intelligence is an enabler, so we can take a chemist and we can allow them to do a lot more. And the more people embrace that, they realize it's going to enhance their ability to translate their skills.

But the other piece, and it goes back to your question, Tony, which is that for whatever reason, and this is the same disintegration that we see everywhere is that drug discovers in the preclinical side tend to forget it but the commercial model. And so if you develop a drug and you're nothing but how it's going to reflect in the clinic I sorry. And the commercial side, you can develop a clinical study that's not meant for it to actually reach patients. And that's why starting with the patient designing your drug and your intent to treat from the patient gets you to the right place, requires a rebuilt preclinical framework, if you will, or post clinical pre-post, post-print, whatever. That allows you to translate that insight and sine that's going to be durably there. And I'll give you, I'll give you a real-world example of something that we do. We have a phase two

clinical trial and diabetic retinopathy. In diabetic retinopathy, the only patients who are treated have severe diabetic retinopathy that has a visual acuity loss. That's the census I leave a vast and which has Patient's favorite treatment ever which is a direct injection into the eye. I'm happy to put it on the screen if people don't believe me how much they liked. But when you when you get into the details of this, ophthalmologists do not want to lose that procedure because they make money by doing it, right? I don't blame them. It's their livelihood, right? But what does, what does the patient want? They want that drug, they want it when they have moderate, they want it when they have mild, they never want vision loss. And so the question is, can you create an orally available therapeutic that you can open up to the primary care physician, the endocrinologist, right? So it's not a displacement mechanism, it's an expansion mechanism. And that's exactly what we focus on here. But thanks David.

I think, you know, we've reviewed sort of we have time for one more question from the audience if you have any. Yes.

Hi Whitney, with Accenture. You've touched on also a great thing. Couple of weeks ago, FDA issued really the first time, not guidance, but really almost a mandate about clinical trial diversity. How does that change the paradigm of whether it's DCT or overall clinical trials to really try and get more representative populations into the trials and get them to the right people that need them.

In many ways, the dog's tail was already wagging. I think that most pharma sponsors, most organizations had already started making some pretty substantial commitments around diversity and representation in their trials. The FDA's document is good. Don't get me wrong, but I don't think it's necessarily earth-shattering. There is a call there that there needs to be diversity plans in place and that will force organizations to have, to have these conversations. Which tools and methods should I be including? Many have already been having them, but for those that haven't, now it's, it's enforced. I think there are some pieces of legislation floating. The diverse trials Act, which adds a little more carrots and sticks. Then that original document which can't have it because it's Security Guidance. And with that, I'd love to have you join me in thanking our panel. It was a great discussion. I really appreciate it.

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