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AWS WEBINAR: THE POWER OF A DIGITAL THREAD IN PHARMA

VIDEO TRANSCRIPT

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Speakers:
Stuart Henderson: Client Account Lead at Accenture
Barry Heavey: Managing Director at Accenture
Chris Kopinski: Business Development Manager at AWS
Dan Sheeran: Director at AWS

Fierce Moderator: Ross Youell

Ross Youell:
Hello, everyone. Thank you for attending today's webinar, The Power of a Digital Thread in Pharma, presented by Accenture AWS Business Group. I'm Ross Youell, and I'll be moderating this webinar. Our speakers today are Dan Sheeran, healthcare and life sciences director, AWS; Stuart Henderson, global life sciences industry lead at Accenture; Chris Kopinski, business development executive, AWS; and Barry Heavey, managing director, Accenture. You can read their full bios on the left side of your window by selecting the speakers tab.

Ross Youell:
Just a few technical notes before we begin. The webcast is being streamed through your computer, so there is no dial-in number. For the best audio quality, please make sure your volume is up. This webinar is being recorded and will be available on-demand within 24 hours after the event. Time permitting, we will follow the presentation with a Q&A session. Please submit your questions using the questions and answers tab on the left side of your screen.

Ross Youell:
Okay, now let's begin. Stuart, please go ahead.

Stuart Henderson:
Thanks very much indeed, and welcome to this webinar. I'm delighted for us to have this conversation today. I want to start off with a very positive note in terms of what I hop you get out of today. And the conversation today is going to be building upon what is an extraordinary 24 months for our industry in life sciences in terms of the amazing accomplishments we've done in the light of the pandemic. But in the context of that, it's also highlighted some of the bottlenecks that we've got to address.

Stuart Henderson:
And so today, we're going to talk about those bottlenecks and how to address them. Let me start though with kind of just some of the high level views on what's going on, because I think it's important to put it into context of the amazing achievements of this industry that we work in is doing. First, I want to put it just kind of a broader view on the overall portfolio. We take the whole portfolio of the industry and we categorize it into different structures. And one of those groupings is we call new science.

Stuart Henderson:
New science essentially is assets in the pipeline that are new modalities. They are new mechanisms. They have a technology associated with it potentially. There's unmet need, significant unmet need, and there's essentially a classification that with put on the whole of the industry pipeline. And we classify that in terms of what of that will drive revenues. New science, as a part of that portfolio, that

industry-wide portfolio, is growing. And it's increasing the amount of tech in there, and the amount of capability that is going to be driving that revenue.

Stuart Henderson:
So we see almost 81% of biopharma revenue is going to come from that ... Growth is going to come from that group which we call new science. And the net present value's increased. This is a real reflection on the scientific advancements that the industry's made. And it's extraordinary. And so in terms of science, especially tech in there, it's important because six to seven times, companies, they're excelling in new science and spending six to seven more in terms of dollars, six to seven X more in dollars on the digital side of their portfolio. So that's the first is new science, more important than ever. There's much of that research that's available on our website for you to look at.

Stuart Henderson:
Secondly, there are way more treatments in development, but they're way more complex. We're looking at biomarkers. We're looking at far more stratification disease. And so in terms of phase two and phase three, we see the number of procedures that are in those have increased by 44% since 2009. So it's really important that not only we've got great new science, but it's way more complex. But despite all that, treatments are coming to market faster than ever. It's an extraordinary time, more complex, more science, more tech, but yet it's coming together faster in the market.

Stuart Henderson:
So this is, from an achievement perspective, for you as industry leaders, it's an extraordinary achievement, and we wanted to kind of just start off with a highlight there. But I want to put it in context of, in actual fact, what did you need to do to overcome and achieve that. And there's really three orthodoxies that we've seen you as industry break in the last 24 months. The first orthodoxy is that drug discovery is a process you can't change. We can't change the way we discover medicine. I'm going to use three examples to tell you and show you how industries change that.

Stuart Henderson:
If we look at three companies, Recursion, Insitro, and Escientia, Recursion defines itself as the industrial revolution of drug discovery. Insitro talks about itself being the convergence of human biology and machine learning. And Escientia is an AI-based company, which is actually delivered the first AI drug into clinical trials. These three companies have done an extraordinary job of taking what is an enormously difficult process and bringing tech into it. If we think about every cell in our body has 21,000 genes, and we talk about how many proteins they code for and how many proteins they interact for, it's a great example of where tech and scale tech can make a difference. But you've changed that orthodoxy, and we've seen those deals happening, and we see these companies making great strides.

Stuart Henderson:
Orthodoxy two is we can't deviate from in-person clinical trials. It's very clear at the beginning of the pandemic we had a lot of clinical trials that were either all virtual or all in-person. We had very few hybrid. In actual fact, the concept of hybrid clinical trials really only penetrated to any great scale during the pandemic. And so what we're seeing is a far more thoughtful approach to the increase in terms of the number of clinical trials that will be done with a virtual aspect to it, even at premier sites.

Stuart Henderson:
You see companies that were kind of in the wings pre-COVID, pre-pandemic, now very central to the strategy of every single clinical trial organization, whether it's the likes of Science 37, whether it's the DASO metadata, whether it's Medable, Viva, or THREAD, we're seeing just an extraordinary progress in terms of the capabilities they have to enable clinical trials to be virtual. And by that hybrid, what we mean by that is of a certain number of visits, some of those will be in-person, some of those will be in-person at a local site, and some of those will be

entirely virtual. So we've seen orthodoxy two blown up.

Stuart Henderson:
Where we're going to focus today is on orthodoxy three. And I'm going to hand you over in a moment to Barry Heavy who's gonna kind of talk about this. And the concept is we can't rapidly scale manufacturing for new modalities. Now, in some respects, we would argue that we've seen an extraordinary achievement just in the last 12, 24 months with the scaling of vaccine supply, especially in the mRNA space. We've seen hundreds of millions of vaccination treatments, or vaccine treatments rolled out around the world. It's extraordinary to think how quickly that scaled and how rapidly it is. But there are bottlenecks.

Stuart Henderson:
And the conversation today, I'm going to hand it over to my colleague, Barry. He'll talk about those bottlenecks and how you can go about addressing them. So without further ado, I'm going to hand it over to you, Barry.

Barry Heavey:
Thanks very much, Stuart. Great to be here. And yeah, I mean, to pick up on that point, I think there's been enormous progress in challenging that orthodoxy three that Stuart mentioned. But there's also continues to be challenges. New science never sleeps, so there's constantly new modalities coming to market. Companies have a wider and wider variety of products to handle. And there's been high profile cases of companies in recent years where they've had big challenges and delays in launches because of issues in manufacturing, or delays in just ramp up into the market, the addressable market, because their ability to actually scale manufacturing was somewhat challenged.

Barry Heavey:
So there's been a lot done, but there's a lot more to do. And I guess we want to ask the question today, what if we could do things like accelerate early process development? So it can take six months to a year to just even develop the early stage manufacturing process through your pre-clinical studies, or your first in-human trials. And then when you've got that done, you've got to start again and start scaling up the process and understand all of the variables that might change when you do that. And that keeps happening, that kind of re-development of your manufacturing process has to keep happening as you scale from clinical production through launch and into commercial production.

Barry Heavey:
And what if you could accelerate the pace which you can do each of those incremental step changes in either at the scale of your process or the efficiency of your process? Taking three, six, eight months off what might be a twelve months normal cycle time. And when that adds up, you're seeing potentially enormous value in terms off taking process development and manufacturing of the critical path that it may come on because we're seeing the acceleration that Stuart outlined in the other orthodoxies in drug discovery and clinical development.

Barry Heavey:
What if we could rapidly scale up the efficiency of manufacturing? There are companies now, biotech drugs, protein-based drugs with monoclonal antibodies happening in the market for over 30 years now. But we're only finally seeing companies really maximize yield of the manufacturing process. And there's a small number of companies who are running at 10X the yield in their manufacturing process as the rest of the industry. Those companies have really understood the biology of the manufacturing process and got to a better control of it using data.

Barry Heavey:
And you can imagine if that happened in the car industry, if one automotive company was saying, "We can produce 10X the number of cars per month from the same square footage as all of our competitors," it would be an enormous disruption in the industry. But that's what's happening in this industry at the moment. And I think it behooves all of the companies to try and kind of accelerate the rate at which they're increasing efficiency, even if nothing else, for the sustainability of manufacture.

Barry Heavey:
What if we could have a Turbo Tax kind of approach to making filings and interaction with regulators who are getting approval for these chemistry manufacturing and control dossiers associated with our manufacturing process? And in actual fact, in some cases, the regulators are leading the industry on this. So the FDA in 2019 already launched their CASA program, which is around the management of knowledge, and the sharing of knowledge, and structured applications for CNC filing.

Barry Heavey:
And finally, a constant pain point in the industry is that handoff between different teams as the process, as we described, evolves from pre-clinical to small scale clinical batches, to large scale clinical batches, to commercial. And every time there's a handoff between those teams, these complex, delicately controlled processes that maybe not all of the variable are fully understood yet have extremely high risk of changing and not performing as expected and causing concerns from the regulators and so on.

Barry Heavey:
So the solution that today has really been kind of really heavy and of human intervention and managing those challenging transfer points between groups, either internally in companies, or between companies and their third party partners, either CMOs or collaboration companies. So our question is how can we address these?

Barry Heavey:
So it's a nice aspiration to talk about these priorities. But we want to talk next about some solutions that we think would really help accelerate these. So we talk about this idea of the digital thread in life sciences, which is effectively our definition of this is that it's a truly digital solution that accelerates the scale in the supply of complex treatments, from the clinical trial right through to commercial launch and production, and right through the life cycle of the product.

Barry Heavey:
So again, we can only achieve this kind of acceleration and see this handover between groups by harnessing enormous amounts of complex scientific and engineering data on the process from inception, right through, perhaps 10, 15 years of supply of the product in clinical and commercial manufacturing. Furthermore, we would say that, again, it's a nice aspiration, but we believe there is a solution. And we believe that this solution can be developed by building on established tools. We're not coming saying there's a new magic bullet solution, a single solution that can suddenly solve this problem, this orthodoxy that's persisted in the industry for all time.

Barry Heavey:
Or rather, we believe that the technology now exists to harness the existing systems that companies have invested in, like their ERP systems, their backbone systems, their GXP manufacturing and quality control systems, but then on top of that, using modern tools, like cloud, like AI and ML to really unlock value and help make faster decisions in extremely complex contexts, and lower the risk of noncompliance and under-performance in the supply chain.

Barry Heavey:
So again, somewhat aspirational you could argue, but let's look at some examples. So this slide is really ... I touched on, in one of the earlier slides, the stress that exists in handoff of these complex, delicately controlled, manufacturing processes for these exquisitely complex molecules from one team to another. And this case study really touches on that. And this is with a company that really were a kind of ... They epitomized the embracing of new science. It's well kind of chronicled that this company has one of the most exciting pipelines in the industry.

Barry Heavey:
They've gone from bringing in about 70% of their revenue from four or five products. Now they have almost 15 products bringing in 70% of their revenue. And they have a huge growth in novel modalities like biologics and so on. And actually, our friends at FiercePharma have shortlisted for a number of awards in recent years for a number of their new molecules that were launched that

were in the most exciting new launches of the last few years. So really a company that's embraced new science.

Barry Heavey:
But also, to some extent, their supply chain group, clinical and commercial, has been something a victim of the success because they are effectively creaking under the weight of the number of new molecules that they're moving through the pipeline and having to handoff from one to the other. And providing that hyper-care at the point of handoff is distracting from the day-to-day business of running their day-to-day operations in each of those groups.

Barry Heavey:
So they really were looking for a digital bridge to support that handoff, especially between R&D and manufacturing along the value chain. And they decided, particularly in order to eat this elephant, particularly focusing on the area of tech transfer at the point of moving, handing off the product from the last clinical supply into commercial production when the product is approved, or is expected to be approved. And so that's where they focused, because obviously that's a huge pain point. There's a huge amount of focus from shareholders, from the C-suite and so on in that area. And if they can fix that point, then they can spread the thread of capability right along the pipeline.

Barry Heavey:
And traditionally, that handoff in tech transfer was at start extremely paper driven, with a huge amount of checks and controls for hyper-care, and an extremely human-intensive effort that, as I mentioned, kind of created ripple effects in people's day jobs where that hyper-care given to this one asset being transferred took away from focus on other products. And fundamentally, it was creating risks of delays, risks of errors in that handoff process that the company just felt were unacceptable in the context of what they saw coming at them in terms of the new modalities.

Barry Heavey:
So this company, at the moment, has more than 50 tech transfers in flight across their organization. So we worked them to, as I touched on earlier, leverage existing tools. But mainly where I should start is the more important thing is we worked with a very multidisciplinary team from this organization. The old joke, or the old cliché that you can go fast alone but you can go further together. But this teal really wanted to bring together people from R&D, people from their regulatory affairs group, people from manufacturing, from quality, from supply chain, to really solve this together and to speak each other's language.

Barry Heavey:
And so they utilized the language of science and regulatory affairs around manufacturing, around the quality target product profile, and the critical quality attributes of their complex products, and they utilized tools to create effectively a digital product profile. And equally, they embraced, the whole team, the multidisciplinary team embraced the language of the process engineering, the SAV8 batch control process and language and approach, and created a digital process profile.

Barry Heavey:
And that's where the magic happens is understanding your relationship between these complex processes and these complex products. But they built those connections on their existing systems that were relevant to their engineering teams or their quality teams or their regulatory affairs teams. And that kind of digital thread that they've created really has helped them kind of transform, at least in their early stages, transform the way they're done. They've been able to eliminate enormous amounts of paper from this process.

Barry Heavey:
And for their first trials, their first monoclonal antibody that they did tech transfer on, they were able to cut the effort by more than 20% for that product. The company's now looking at scaling this out across their portfolio, and they actually expect that they're going to see even more positive returns on this over time as it's utilized in a wider variety of products with greater complexity over time.

Barry Heavey:
So with that, I'm going to hand over to Chris Kopinski to talk about how we're taking this even further now with the modern tools of cloud and AI and ML. Thank you very much.

Chris Kopinski:
Thank you, Barry. Truly exciting example. And for those of you in clinical supply, tech ops, or commercial supply, you know the value that a digital product profile can bring to your organization's success, whether it be accelerating clinical development, speeding up your filings or approvals, optimizing and creating more efficient manufacturing operations, or executing flawless tech transfer between your teams.

Chris Kopinski:
And the COVID-19 pandemic has proven we can move quickly as an industry. However, the product portfolio complexity and the pace of new product introduction continues to demand a new paradigm. That's what we want to talk about. The digital tools and capability that enables such an innovation, they exist now. That couldn't necessarily be said 5 to 10 years ago. And it may not even been possible. And what we're finding, at least from an AWS perspective, is customers that innovate with digital thread do so by leveraging the best that the cloud brings. By moving to cloud, our customers are able to migrate applications such as LIMS, MES, quality management systems, to free up their IT resources.

Chris Kopinski:
This additional capacity allows their teams to create an environment of innovation such that you can leverage data generated in the process of bringing those new therapies to market in order to scale your manufacturing process globally while ensuring the necessary security, compliance, and resiliency measures are in place. And in doing so, companies are able to evolve their business policies in order to help break down silos between functions, and truly create an end-to-end data strategy.

Chris Kopinski:
So what's really changed during COVID-19? Well there's been a tremendous amount of focus, and rightly so, on the industry's ability to discover and develop new vaccines and therapies in a small fraction of the time it normally takes. But our ability to scale up global manufacturing has been equally important and impressive. If someone had told you two years ago that a company that had never before commercially manufactured anything could go from zero to a billion doses in one year, you'd have said that's impossible, and I would too.

Chris Kopinski:
And there have been similarly impressive scale ups of antivirals, biologic therapies. And here's the key. The same cloud and machine learning technologies that made this possible are ... The same cloud and machine learning technologies that made these gains possible are available today in many other therapeutic and vaccine areas, unrelated to the pandemic. So combined with other recent advances I will describe, we are increasingly able to apply the digital thread to clinical and commercial manufacturing, and thereby take manufacturing out of the critical path for getting new medicines to market.

Chris Kopinski:
I'm going to focus on five key areas and advances made possible by the cloud. One such advance is using machine learning to identify the key parameters that predict how easy it will be to manufacture a given molecule before you've even begun clinical manufacturing. While the machine learning part is critical, the less glamorous but equally important advance making is making it possible is our ability to get data about the molecule and the similar molecules out of those many data silos that are spread across research, clinical, and manufacturing divisions.

Chris Kopinski:
A second advance is the ability to immediately, and in some cases, automatically transfer learnings about manufacturing challenges back into molecule design process. Our customers are now applying both of these advances by leveraging cloud-based technologies like IOT, data mesh, machine learning, and knowledge graphs.

Chris Kopinski:
Third, let's talk a little bit about SAP. SAP is the core manufacturing system for nearly all of our life sciences customers. While most customers have already recognized the business agility

gained by moving SAP to the cloud, COVID really demonstrated how you never can be sure when you'll truly need that ability the most, so you better get started now. Several of our customers were only able to meet the rapid scale up of manufacturing for their vaccines or therapies because they had already begun moving SAP to the cloud before the pandemic hit.

Chris Kopinski:
So a fourth advance relates to the use of advance analytics and biologic manufacturing. Where a bad batch can cost millions or tens of millions of dollars, while also delaying patient access to a critical vaccine or therapy, traditional statistical modeling is often not able to identify the likely causes of those bad batches, or predict them in real time because of the vast complexities that exist in these processes that make data too hard to model. So our customers are now combining real time data capture with machine learning in order to identify process or environmental changes that increase the probability of a bad batch.

Chris Kopinski:
Furthermore, combining that data with historical information related to process deviations, our customers are now able to mitigate risk to normal operations, which carry that additional impact of delays or the ability to incur unwanted costs, which our companies can have.

Chris Kopinski:
My fifth and final point is I want to spend a minute on cell and gene therapy. For these incredible life-saving medicines, manufacturing and supply chain visibility are more important and more challenging than ever. Patients, providers, clinic staff, many people within the manufacturing lab all need real time information and predictions about the location and the status of both the patient cells and the therapy manufactured. The same technologies that enable Amazon to show you when a package can be delivered to your home can also help to show you and all those stakeholders when the drug product is likely to arrive, and to then make real time changes to your plan manufacturing or infusion at the hospital or care center.

Chris Kopinski:
So those are the five key areas in which the digital thread is helping customers scale manufacturing quickly, increase predictability, and lower risk of shortages. So I'm not going to hand it over to Dan who will touch on a few of the organizational and people changes we have found that were needed to make these advances possible.

Dan Sheeran:
Thank you, Chris. So those changes that Chris described in what's possible today with manufacturing from a technology standpoint are incredibly exciting. And we're seeing the results of that with many of our customers of all sizes. But as Chris mentioned, if they're not implemented with the right model in place for people, change management, and sustained executive commitment, then we have seen in many cases attempts to reap those benefits fall short. So I'm just going to talk about five area to have in mind as you begin this journey that are not about the technology, they're about the people, the process, and the culture.

Dan Sheeran:
The first is I'm sure many of you have been involved in proofs of concepts, or POCs. And there's POC fatigue at many of our customers, particularly among the people who are funding the POCs. And it's actually been called something by many of our customers like death by POC because there's not an overt plan from the beginning about what's going to happen, what everyone's committed to make happen if the POC proves successful. So having a linemen on that from the beginning is critical.

Dan Sheeran:
The second point is that there's often stakeholders who are critical to the success of the program that are not identified until too late, and then their buy-in is not there. Typically, many of our customers will start with somebody from IT and somebody from operations who develop a shared vision and get going. But then they discover too late in the process there's a brand manager, there's somebody in finance, or there's a technology transformation team elsewhere in the organization that controls key budget or decision-making authority on policy that .

they did not have on board from the beginning. That will slow things down by months. In some cases, it's actually killed critical projects

Dan Sheeran:
The third thing to really focus on, not just for manufacturing transformations, but really any significant digital and technology transformations at your company is to make sure you have top-down executive commitment to what you're attempting to do. The reason this is so important is that inevitably, when you're doing things that are new, you will encounter roadblocks. And lots of people will treat those roadblocks as an opportunity to slow the train because change is scary. Sometimes change is threatening.

Dan Sheeran:
Now, even with the best of intentions, people may start asking questions that will slow you down, that if you don't have the right executive sponsors to help you unblock those challenges, your project will grind to a halt. Now, typically, in a manufacturing program, the most important executive sponsor to have is of course the leader, oftentimes an executive vice president of supply chain and manufacturing at your company. But it's equally important we have found to make sure you have support from the commercial side because it's the brands that are counting on those therapies and vaccines getting manufactured and distributed on time, into the market, that will really be an ally for the manufacturing advocates to make sure that the changes are adopted.

Dan Sheeran:
This is particularly true of high profile therapies, where the company has very visibly committed to certain revenue targets for newly launched therapies, or therapies that have been launched before but are accelerating in the market.

Dan Sheeran:
The fourth thing I would talk about is the critical role of getting the buy-in from the actual plants where the initial change is going to be tested and then deployed. We have had customers learn the hard way that if they don't involve the plant manager and even the staff line managers for the specific factories where a given pilot or commercial production roll out of a new manufacturing technology and digital system is going to take place, if those folks are not bought in early enough, they will slow things even if everything else is working according to plan.

Dan Sheeran:
And then the final thing I'd touch on is we need to spend a minute on GXP. Now GXP, of course, is incredibly important. And everything we do with you needs to respect all the GXP obligations that you operate under. But at the same time, we need to make sure that GXP does not become the boogie man that is out there vaguely in the dark, preventing anybody from doing anything differently. When we have dug into significant challenges related to GXP with many of our customers, it's oftentimes the case that we can make significant progress with a customer increasing visibility, increasing predictability, many of the benefits that Chris and Barry have been talking about, through systems that live outside of the GXP regulated environment.

Dan Sheeran:
And by starting there, you can get quick wins that give you the momentum that you need to then focus on the things that may require working with GXP systems. This is particularly true with therapies that are already launched. Of course, it's a quite different situation when we're focused on greenfield opportunities. And that's an important thing to think about as you consider your digital transformation is to think about both your greenfield and what we call the brown field, which is modifying systems that are already in place.

Dan Sheeran:
So those are a handful of things to have in mind at the start of a digital transformation in manufacturing, this digital thread initiative that we've been talking about today. I'm now going to transition and talk for a minute about the things that make working with AWS and Accenture in particular really a unique opportunity.

Dan Sheeran:
We are two organizations that are in an incredibly fortunate position of seeing a quite broad array of advances from quite different types of companies. We both work with many of the largest manufacturers in the industry, and I know some of those companies are represented on our call

today in the audience. But we also have the benefit of working with many of the industry disrupters and seeing how companies that are what we call born in the cloud are able to create some of the advances that you've heard about on the call today and really be pioneers, and take those learnings and then help bring those learnings to our larger, more established customers, and do so in a manner that actually works with the culture that those customers have.

Dan Sheeran:
The second thing that we are able to bring, both Accenture and AWS, because we've worked with so many particularly large scale customers for so long is we have a deep appreciation for the realities of what you're dealing with. We understand that many of the largest companies are the results of multiple acquisitions with a factory footprint that is quite heterogeneous, both in technology and geographically, and the challenges that that creates in terms of trying to create standardized programs that can be rolled out globally.

Dan Sheeran:
I think it the kind of change management experience that both Accenture and AWS have, and the high trust relationship we have between our two organizations, allows us to deal with each situation and meet the customer where they are.

Dan Sheeran:
So there's a lot of opportunities that we are pursuing together today and really pioneering ways across the spectrum. And we're able to bring the best insights of those to each engagement, really at an accelerating pace. So with that, I think we're just about ready to open it up for questions. But I thought I'd share just two closing observations. The first is as you're considering going forward with this, you really need to ask yourself, "How do I get started?"

Dan Sheeran:
And the answer is quite simple. Just contact your account representative, for either Accenture or AWS. And they can begin the journey. They can share some reference materials with you of what we consider some of the most interesting work that we're seeing happening in the industry today. Oftentimes, we're involved. Sometimes, we're not involved. But we're happy to show you what we think good looks like.

Dan Sheeran:
The second thing we'd encourage you to think about is, "Who are the critical people in my organization that we need to be working with? And am I in particular somebody that can take up the mantle and get this started?" Now, in most cases, the answer to that is yes because step one can be taken by any number of types of people at a life science manufacturer. So you might be in clinical supply, you might be in technical operations, you might be in commercial supply, you might be in CMC regulation. Really anybody in any of those groups that has a passion and some degree of authority, or at least credibility to get the process started is a great person to get the process started.

Dan Sheeran:
So please don't make the mistake of thinking, "Oh, this is somebody else's project." We have seen wonderful programs initiated by lots of different types of people across our customer base. So thank you again for spending time with us this morning, letting us share these initial thoughts. And why don't we now open it up for questions.

Ross Youell:
Yeah, and we will do exactly that. So now let's move on to the Q&A. Note that there's still time to submit your questions using the Q&A tab to the left of your screen. We have lots of great questions already, and we'll try to get to as many as possible. So the first question is for Barry. Digital thread for life sciences sounds like a product lifestyle management tool. What is the difference?

Barry Heavey:
Yeah, I think it's a very fair comment. I think one of the reasons we're a little bit cautious of using that phrase, quite frankly, is that PLM and PLM tools carry a lot of baggage in the pharmaceutical industry. As tools, they have been around for a long time, and have been very successfully deployed in other industries, in particular in discrete industries like aerospace and automotive, where the fundamental data model is the CAD file or the computer aided design file,

and where the manufacturing process is primarily dominated by physics, not necessarily so much by complex chemistry, and certainly not by complex biology.

Barry Heavey:
And so the challenge with taking existing PLM tools and trying to apply them in pharma is that simply today, there hasn't been much evidence that we've seen that they've really worked, they've really added much value. And for that reason, they carry some baggage. And I think we need to think about a new paradigm where we utilized, as we discussed, the systems that are already in place, and that work, and companies trust from a GXP perspective in terms of controlling and monitoring and batch processes that have complex chemistry, or complex biochemistry inside those black boxes, reactors.

Barry Heavey:
And then creating a solution that then leverages more modern tools like cloud and AI, ML. so yeah, I think what we're talking about digital thread is close to the concepts that are talked about a lot in PLM. But just have that caution around not having people come along and go, "Uh-oh, we tried it with this before and it didn't work."

Ross Youell:
Great. And our next question's for Dan. Our organization will be migrating to S4/HANA. How does the concept of digital thread increase the value of my S4 investment?

Dan Sheeran:
Well, customers move to the cloud, whether it's their SAP systems or really any other systems. They migrate to the cloud for a variety of reasons. Often, the initial thinking is around cost. And in fact, the cost savings are absolutely tremendous. We have one customer that's forecasting well over $100 million per year in annual operating costs by moving their SAP systems to the cloud. However, most of our customers find long term that the even more significant benefits come in the business agility that they gain.

Dan Sheeran:
So Chris gave the example of having an Amazon-like ability to track where everything is in a cell and gene product, the cells, the therapy itself, between the clinic, the lab, et cetera. It's quite common that customers come to us and say, "Boy, if I could just track all of my manufacturing and know my supply chain, and monitor it with the same fidelity and flexibility that Amazon's able to handle packages, wouldn't that be incredible?"

Dan Sheeran:
And we say, "Well yes, it would be incredible." Now, the first thing that you need to do is you need to make sure all of your data is immediately available for you to analyze instantly and make immediate, real-time, typically machine learning based decisions around. Until you have your SAP data in the cloud, particularly using HANA, you do not have the kind of real-time, highly scalable, highly elastic access to that data that you need to build out these types of capabilities that we're describing.

Dan Sheeran:
So I would say business agility is the most significant long term benefit that our customers gain. Cost is the initial focus. But then the third thing I would touch on is elasticity's just purely in terms of scale. As Chris mentioned, nobody knew, nobody could predict two years ago that you might need the ability to go from zero units to a billion doses in a year. Well, if you're not discovering how much capacity you need until the time you need it, you have a problem. And so by moving your SAP systems, your S4/HAHA to the cloud, your just buying yourself insurance for a whole bunch of different situations that are hard to predict.

Ross Youell:
Great. And our third question is for Stuart. Are there any specific areas in a new science realm where you see the digital thread for life sciences being more beneficial than others?

Stuart Henderson:
Thanks. Barry and I were just pinging with each other. Actually I think Barry's better suited for taking that question. He's going to bring a much better answer than I could. So to you, Barry.

Barry Heavey:
Thanks, Stuart. Yeah, my perspective is unless, yes, I mean, I think digital thread is applicable to all types of molecules and all types of modalities. It's something that no matter what the molecule is, you want to be able to scale it up quickly and get it to market as quickly as possible, and not have manufacturing on the critical path.

Barry Heavey:
However, I would say that obviously the more complex the molecule, the more risk you have that something is going to go wrong, or something is going to get delayed in that scale up, tech transfer, optimizing yield, so on, so forth. So kind of going after the products that are more complex, where your organization maybe has a little bit less experience of, may be the ones where you'll get the most immediate value.

Barry Heavey:
There's a little bit of a goldilocks think here because if you go after really complex products that really nobody understands in your organization, or if it's the first time, it may not be the place to start. So I think the example I gave was a company who did this with a monoclonal antibody, which are complex molecules. They're 6,000 carbon atoms. They can vary quite a bit. They have all these interesting post-translation modifications that can vary from batch to batch.

Barry Heavey:
However, the company did have some experience with them, quite a bit of experience with them, knew what they were doing, and could see very quickly that they were moving the needle and making things better by embracing them. They probably would have moved the needle less far with more traditional synthetic molecules, the small molecules, but not to say there wouldn't be a benefit there. So it's about trying to find that sweet spot of product where you're going to get a big bang for your buck by reducing complexity and reducing risk by using these kind of tools.

Ross Youell:
Got it. And so this next question is also to Barry. Our organization has made several attempts to bridge between R&D and manufacturing. These initiatives haven't delivered for us. So how can we approach a new initiative to increase the chances of success?

Barry Heavey:
Yeah, I mean, that's a great question. I mean, that's the kind of, getting back to the old thing of orthodoxies. And it is always been thus, so we're never going to be able to change it. And it's a tough kind of point of view to deal with when you have people who have been through this and it hasn't worked before. And it's a little bit why we also steer away from this use of the terminology PLM that I mentioned earlier.

Barry Heavey:
I think this is kind of an eat the elephant question. You need to ... Fundamentally, you're going to have to, as we discussed, bring very multidisciplinary group of people together to make this work, reg affairs, R&D, manufacturing, quality, supply chain. And really have that kind of the right level of sponsorship that Dan talked about, and people with the credibility and drive to push this forward. But if you try in that context to boil the ocean and try and fix this for every part of your supply chain and every modality, you're probably going to end up getting beached.

Barry Heavey:
So we would often advocate ... Companies have talked for a long time about doing lighthouse projects and pilots and so on, so forth. We're not talking about doing that, but maybe picking a specific product or modality. As I discussed with the case study gave where they took a monoclonal antibody, but when they saw they could move the needle there, that immediately means we can make this work for all of our monoclonal antibodies and build out from there. So you get that bridge point.

Barry Heavey:
The other thing was focusing on a particular pain point in the life cycle. So again, that client focused not on like every digital thread from end to end, but really focusing on that tech transfer from clinical to commercial, where shareholders and the CEOs focused on results, so the project that you're doing gets a lot of sponsorship and gets the appropriate level of investment behind it.

Barry Heavey:
And then finally, it's the old cliché, but you really have to think big about change because you're getting lots of busy people who are doing things traditionally in their silos, trying to get them to step out of that. So really bringing people along t

he journey to place an emphasis on how this is going to make their life better and make better for patients and so on. So putting a big emphasis in organizational change management, as well as the technology, I think is a big success factor here that we sometimes see companies forgetting about when they take these things on.

Ross Youell:
Great. So this next question is for Chris. I definitely see the value in applying digital thread during tech transfer. Do you see any other opportunities for the digital thread?

Chris Kopinski:
That's a great question. In the United States here, we're in the middle of a baseball playoff, so I'll use a baseball analogy. We're really, I think in my opinion, only in one of the first or second innings of this game, which is the digital thread and what the potential is. So we see a lot of opportunities. I mean, Barry spoke to what is possible in tech transfer. I mean, reducing effort by 20%, even more. Creating that digital thread that can be used across different parts of the value chain I think is a huge benefit.

Chris Kopinski:
But we're also seeing areas where ... Stuart talked about examples about what's happening with drug discovery, or what's happening with clinical trials or clinical development. Healthcare and life sciences organizations are really seeking opportunities to reinvent how they collaborate. They're also trying to make better data driven decisions, either clinically or operationally. And by using the digital thread, it gives you let's say the plumbing that allows you to bring that data together in a meaningful way.

Chris Kopinski:
And not to mention the advances that we're going to be seeing here in precision medicine. I mean, the original launches of these CAR T therapies have been truly amazing. But the tight integration within the industry of the customers, the clinics, the operations, the payers, the potential to actually bring these different parties together to solve new problems in meaningful ways are very, very high.

Chris Kopinski:
So I think we do see that, especially as these advances are happening in each of their functions. Stuart shared a lot of great examples, but I'm just thinking of another example in my head, Propeller Health is a digital health company. They're essentially providing or allowing providers to monitor their patients remotely, stratify those patients on risk, and make data driven decisions on the treatment. So if you just think about what they're doing there, imagine what you could do if you bring in additional data about how those therapies were produced, or how those therapies were manufactured, or how those therapies were discovered. So yes, I absolutely do see that we do see a vast amount of opportunities for the digital thread.

Ross Youell:
Great. And so this following question will go to Barry. What is the potential of new science in synthetic/small molecule drugs? Could we see disruption yielding small molecule drugs redundant, maybe from a [decadle 00:46:35] view?

Barry Heavey:
I think we are seeing a little bit of a decline in the number of new drugs that are of the small molecule modality, and growth in biologics is outpacing small molecule, but I don't see small molecules going away at all. I think there's still a huge potential for synthetic chemistry to produce amazing molecules that do wonderful things in lots of different therapeutic areas.

Barry Heavey:
I think some of the molecules that are emerging for medicinal chemistry are more complex now to synthesize and to formulate than the molecules that were coming out. A lot of the low hanging fruit molecules have been picked. But there is still some amazing new small molecules coming through pipelines all over the industry. And I think, yeah, I don't see new science disrupting that.

Barry Heavey:
New science is not just about moving to new modalities like CAR T or gene therapy or biologics. It's sometimes just about understanding the disease more completely and identifying the right enzyme that needs to be targeted with the right small molecule or whatsoever. Or it can be about taking, Chris's example, taking an inhaled small molecule for a

certain disease and combining with a patient monitoring outcome, like the technology used from Propeller Health, to give patients better control of their asthma or COPD.

Barry Heavey:
So no, I don't think synthetic chemistry is going away any time soon. Sometimes when we talk about the digital thread, we emphasize the biologic space because the industry has been doing a great job manufacturing and formulating small molecules for over 150 years or more you could argue. The biologics, and CAR T cell, and mRNA space is newer, so it has a little bit more challenge and risk and complexity, so it's the area that maybe will benefit more in the near term from this kind of digital solution.

Dan Sheeran:
Could I just add to that?

Ross Youell:
Sure.

Dan Sheeran:
So I really want to second what Barry just said. I think that the future is bright for both biologics and small molecule. I'd ask us all to reflect on the incredible news out of Merck recently about the potency of the new antiviral, COVID antiviral small molecule, just really extremely promising. We increasingly see opportunities for small molecule development that used to take many, many months to happen extremely fast.

Dan Sheeran:
In fact, we did see this during COVID with a number of the antivirals that were developed through the use of machine learning, where instead of needing to use wet lab experiments to confirm hypotheses, our customers, be they startups to the very largest biopharma companies, are able to model, using artificial intelligence, the likely behavior, manufacture-ability, as Chris referenced, the efficacy, the potential side effects of small molecules, which is in some ways more readily available, of course, to small molecules than to biologics, given that with biologics, all the potential side effects and other interactions are so much harder to predict with living systems.

Dan Sheeran:
And so we think it's actually an incredibly bright future for both biologics and small molecules. Again, once the data sets, as Chris was indicating, once the hard work is done to make sure that the incredible data sets that are available, that are right now already resident inside of the companies, are made liquid, and are able to be accessible, and query-able, not necessarily just by data scientists, but by clinical folks and research scientists.

Dan Sheeran:
So we're seeing a tremendous acceleration of that just in the past few quarters. And think that there's probably going to be a quite rapid intake at the top of the funnel. And what that's going to do is create pressure on the development parts of our organizations to figure out, "Okay, now that early research has doubled, or tripled, or more than quadrupled the number of candidates, how do we scale up our systems so that we can keep pace?"

Ross Youell:
Fantastic. Thanks, Dan. So kicking it back to Dan for this one as well. Are you seeing any players use specific AWS or cloud capabilities as part of the solutions that disproved these orthodoxies?

Dan Sheeran:
Yes. Chris mentioned a couple of them. In particular, a step one, as I just mentioned a minute ago, is getting access to the data. We have most of our customers have acquired many different companies over time, and as a result, they've got different data sets from different assays they've been doing for decades sitting in silos that are only accessible to the people who happen to be in that research department. Or they're accessible to all of research, but they're not accessible to people in clinical.

Dan Sheeran:
Step one is breaking down those barriers. Now, that's easier said than done, but there's several new generation technologies, data lake house approaches and data meshes that we're finding increasingly useful to make the data available. But then you have to be able to query it. And so

we're seeing increasing success with knowledge graph technologies, but also other natural language interfaces so that non-data scientists can query the data.

Dan Sheeran:
So there are AWS services like Kendra and QuickSight, this new QuickSight Q service that we've introduced that many of our largest customers are seeing great success in essentially turning their scientists into citizen data scientists. That is the way we like to call it. And that's really where the acceleration happens, where the scientists don't need to get in a queue and wait for a data engineer to do all of their work to get the data ready for the assay.

Ross Youell:
Great. Thanks so much. So our following question is for Barry. The digital thread is a great tool for companies with newer automated facilities. What I see in the field over the last 20 years is a chronic lack of investment leading to facilities with major regulatory issues, including major data integrity issues. What step-wise changes would you recommend for a digital transformation like we described today?

Barry Heavey:
Yeah, that's a phenomenally important point. And I think it's not an easy one to address because there's been a lot of focus in the industry is on the greenfield investment, the investment in the new sites that are making the new products, the new modalities. They are kind of sucking up a lot of the attention and capital within the organization, investment capital within a lot of organizations.

Barry Heavey:
So kind of going back to fix the data gaps in other organizations and kind of value chains for other products is not trivial. And yeah, I don't think there's any tried solution to that. There are places to start, but I think the concern I have is that to do this correctly, create this digital thread correctly, you want to make sure that you have the sponsorship from the organizations that this is going to deliver a large return on investment because there is some skepticism in the organization that this is just more of the industry forded hype machine and so on, and we haven't seen it, we don't need it. We've managed without it before and so on, so forth.

Barry Heavey:
So I think proving out the value to the business of this approach in specific areas, where it's very clear, will then create that momentum that can then drive it across the organization. So it's really a little bit ... We're not going to fix Rome in a day. And this has been a long-held orthodoxy that GXB manufacturing is done the way it's done, and it's very hard to change it. But picking the areas where you choose your battle, eat this elephant, is going to be important. Maybe, I don't know, if Chris or Dan want to kind of follow up on maybe some examples of what you guys have seen in the brown field space as well.

Chris Kopinski:
Yeah, I can answer that, Barry. And I think they're great examples, and it's a challenge that many of us face. I mean, I would add and kind of bring in something that Dan said, which is really around the importance of that leadership top down support, first and foremost, because I do think that even where technology can be a barrier, it also can be an accelerator. And so this problem isn't solved by a single point solution. It's going to be the collaboration between parties that are in this process of working from the development side to the manufacturing side to supply chain.

Chris Kopinski:
And so even in those let's say environments where there's maybe a historical lack of adoption, I think there's actually a lot of opportunities to also accelerate that given the right drivers. So one of the steps we like to take here with our customers is really deeply understand what the challenges are in that opportunity and work backwards from that and truly, deeply understand what needs are there and how we can look at technology as an accelerant, even while we consider, as Dan said, we still have to continue to comply with the regulations, continue to bring in the right SMEs to make sure this happens in a productive way.

Dan Sheeran:
I'd like to suggest a pretty simple rubric for how to think about this question. Is there an existing therapy ... Sorry. Is there an existing therapy, brown field situation, that either a bad batch or insufficient ability to keep up with demand will cause the company to potentially miss earnings? Something like that. Is this an executive level, is

this an executive board level issue? Has the company committed to go from 2 billion to 10 billion for a given therapy? Is it flu season and we got to make sure this vaccine is ramped up, because even though it may not be the most important thing financially, it would be a very significant problem for society if this one product can't be made in sufficient quantities.

Dan Sheeran:
If it crosses that threshold, you can absolutely go and get the executive sponsorship you need to try something innovative while respecting whatever the GXP requirements are. If it doesn't cross that threshold, it's a bit of pushing a string. So that's a rubric I would encourage you to apply.

Ross Youell:
Great. Thank you so much, everyone, for that wonderful answer. So that was actually our final question. We had a lot of great questions today and couldn't get to them all. But we will try our best to get back to everyone who submitted personally after this webinar. And with that, thank you for attending this FiercePharma webinar and submitting so many great questions. I'd like to thank all of our speakers for participating, and Accenture AWS Business Group for presenting today's webinar. This webinar has been recorded. You will be able to access the recording within 24 hours using the same audience link that was sent to you earlier. Thank you again for joining and we look forward to seeing you at future events.