GENENTECH EPISODE

AUDIO TRANSCRIPT

VO Stinger
You're listening to Driving Digital in Biopharma, a podcast from Accenture. Your host is Tom Lehmann.

Tom Lehmann
Welcome back to the Driving Digital in Biopharma podcast series with me, Tom Lehmann, America's Life Sciences network lead at Accenture. For those of you that haven't joined us before, welcome. It's great to have you here, and thanks for joining. For the returning listeners you might have noticed a few changes to Driving Digital in Biopharma on your way to listening to this episode.

Tom Lehmann
We've been running the Driving Digital in Biopharma podcast series for a few years now, and in that time, we've seen a natural evolution of the topics that we cover and also the guests that have joined us. And given that change, we felt that we needed to refresh the title of this series to reflect a broader intent for the conversations that we want to have with industry leaders. Digital will certainly still be a feature, but just not the centerpiece. We want to further expand our discussion topics and the guests that we include and also have a name that reflects that intent.

Tom Lehmann
We'll continue to have thought-provoking conversations about the big changes happening in Life Sciences organizations, and we'll do this while showcasing the progress that has been made and the challenges that were faced along the way. We also want to open the door to having cross-industry discussions to enrich the takeaways from our episodes. So, with that in mind, let's hit the rewind button and start again...

VO Stinger
This is the lens Life Sciences Reinvention in Focus, a podcast brought to you by Accenture. Your host is Tom Lehman.

Tom Lehmann
Welcome to The Lens with me, Tom Lehmann, a podcast that puts Life Sciences reinvention in focus.

Tom Lehmann
Hi Christian. Welcome to Driving Digital in Biopharma.

CHRISTIAN F. _ Roche Genentech
Hi. Tom Good morning.

Tom Lehmann
So maybe for the benefit of our listeners, why don't we start with just a brief introduction about yourself and how you got to your current role.

CHRISTIAN F. _ Roche Genentech
Yeah, absolutely. And thanks for having me. I joined Roche Genentech in 2019 as digital transformation lead, and more or less, from the beginning, focused on the cell and gene therapy space, because we started to identify certain gaps that need to be filled with innovative digital solutions. And from there it actually evolved into a functional role. I'm heading the orchestration and exceptions management team in PTC, which is our cell and gene therapy unit dedicated to cell and gene therapy...and we are responsible for orchestrating the virtual treatment journey—so all transactions, sales order, purchase order and so on that are required to really manage the flow of funds and related transactions in the ERP system, which is our core operational system.

CHRISTIAN F. _ Roche Genentech
And we are also setting up the master data in those systems, and we are driving certain innovations in the digital space to realize automation and the overall orchestration of the journey. So that's what I'm currently doing. And yeah, I have three teams that I'm working with that are driving those topics. My background actually, is in supply chain management. So I studied Supply Chain Management in Cologne, and I've spent seven years in consulting before joining Roche Genentech in 2019.

Tom Lehmann
Excellent. So why don't we start with some foundational pieces around cell and gene therapies. You mentioned that's your current focus, and I would imagine that many of our listeners are unaware of the differences between cell and gene therapies and other treatments that are out there. So maybe just a little bit of a crash course, if you will, in cell and gene therapy for the benefit of the listeners?

CHRISTIAN F. _ Roche Genentech
Yes, absolutely. So I will do my best, because it's a very complex field, but comparing it, I would like to start with, actually, briefly describing the more classical space, how I see it. So in the classical space, pharma space, you have something that we call small molecules. Those are chemical products, typically small that act in certain cells to provide benefit to the patient. Typically the sample would be ibuprofen, for example, that almost everybody knows. So that's small molecules. That's kind of where all things started. And then in the 90s, we moved towards biological products, which is the second area with antibodies, and those are proteins produced by cells that typically act on the cell surface by connecting to a cell receptor, and then they flag certain cells, or they up or down regulate the cells' activities. And that started in the 90s, where Genentech, the company I'm currently working for. Genentech, as part of Roche was the key innovator in that space.

CHRISTIAN F. _ Roche Genentech
I'm just mentioning it because more or less that means that, for example, for Biologics as that one key technology how those products are produced, and there's one typical supply chain setup that is used to run the therapies, and that is a big difference of cell and gene therapy.

CHRISTIAN F. _ Roche Genentech
So cell and gene therapy, there are different ways to structure the field. I would simply structure it into two key areas. One is the gene therapy space. There the purpose is to deliver a healthy gene or a gene variant to a patient that has a gene defect, typically a single gene defect. One example would be Elevidys, which is a gene therapy for Duchenne Muscular Dystrophy. And there we are delivering a smaller version of the Duchenne's gene, which is then more or less used in the cell and delivered via a virus, more or less to actually then create certain functionality or function in the cell, which allows the patient to maintain their health status, or even it's even possible, in some cases, with some therapies, to cure patients, because this gene effect is more or less addressed.

CHRISTIAN F. _ Roche Genentech
There are fixed dose gene therapies and variable dose therapies. And then we have the individualized and cell therapy space, where we differentiate two key groups. So one is the allogeneic space, where you typically start with

cells that are provided by a donor or that are derived from a cell bank, a stem cell bank, and those cells are then the product that is actually delivered to the patient. And we have the autologous space, where we have cells that are coming from the actual patient, and then we alter the cells, equip them with a new receptor. So that's very roughly speaking, the overview. Like I said, it's not very easy to structure the space and to give a full overview, because cell and gene therapy is not just one thing. There are so many different technologies and products in the market that it's quite diverse.

Tom Lehmann
That's helpful. And even in that just brief description, as you said, just touching the surface there, you can start to see that the complexities that start to naturally show up with cell & gene therapies versus a much more established way of working with the small molecules. And we'll get into more of that as we go through our conversation, but that's a real helpful starting point for us.

Tom Lehmann
So maybe just if you can maybe bring it to life a little bit more so Roche in the cell & gene therapy space. What are the specific indications that Roche is focused on, just again for the benefit of how does this translate into real medical treatments?

CHRISTIAN F. _ Roche Genentech
Yeah. So starting with gene therapies, typically, they are in the rare disease area, or they are in the neuroscience area ophthalmology. So for example, we have for neuroscience Elevidys for DMD, which is the gene muscular dystrophy. So that's one example. We have Luxturna with Spark in the ophthalmology. So treating genetically caused eye diseases that can lead to blindness. So those are two areas for the gene therapy space.

CHRISTIAN F. _ Roche Genentech
And really the big difference, which I didn't mention in your previous question, is that here we are really trying to cure the patient. So it's not just about treating the patient as the disease evolves it's really about curing the patient, which, as you can imagine, has a big impact for the patient, but also for cost of society, for example. Because, for example, Duchenne's is typically used for young boys at a certain age, fairly young, and you really expand the expected lifetime. But also cost of society is reduced by treating this disease. So those are two key areas where we are working, and that's all publicly available information. We are also working in the oncology space. For example, with Spark, we have products going into the hemophilia area, or we have cancer therapies that are targeting solid tumor. So those, I would say, are roughly the key areas and oncology, neuroscience and ophthalmology.

Tom Lehmann
Okay, all right, that's very helpful. And again, not only a basic understanding of what are these therapies, but also the benefits that they can produce. And certainly, as you said, that the ability to cure rare diseases is a significant opportunity, specifically with this type of therapy, which we take as we get into a little bit of what does this actually look like, as far as the treatment, I want to come back to that here in just a little bit.

Tom Lehmann
So if we look at the traditional research and development process, and then manufacturing—and manufacturing, of course, is going to take on a little bit different flavor than a mass produced small molecule, something in a pill form, for example—talk to me a little bit about what does that process look like. So if you think about prior to getting into a clinical trial, what are the major activities that are occurring, and then let's just walk the process through to manufacturing. Let's start with what happens, maybe before you get into human clinical trials.

CHRISTIAN F. _ Roche Genentech
Yeah, absolutely. So I'm in pharma technical operations, so I'm not deeply involved in pre-clinical activities. We are mainly involved in clinical and commercial, which is already unique, because typically in pharma the clinical world is very different from the commercial world. So typically you have your clinical teams working on the clinical trials, then you perform a tech transfer and launch the product, and then you have a commercial environment that is actually running the therapies in the commercial

space until the product is phased out. And at Roche we have a very unique approach where we cover clinical and commercial—so I think we are already with the teams that we have covering a very wide space, but I will still try to briefly describe how preclinical looks like.

CHRISTIAN F. _ Roche Genentech
So I would say there are two key phases. One is pre-IND, and then the other one is more or less IND-enabling phase in preclinical... and IND means investigational new drugs or more or less a new drug that we want to bring into the market. So pre-IND, the focus is heavily on like process development, analytical development and feasibility and these types of things. So more or less what we are trying to do, we are trying to identify a target that we think that works, that provides a benefit over existing standard of care and that we can produce. And then at some point, we also should have expectations about whether or not the product is something we can actually produce at scale, from a financial perspective, from a manufacturing perspective, and so on. So that's kind of pre-IND, where very fundamental research is done.

CHRISTIAN F. _ Roche Genentech
And then as you come closer to filing an IND, you would go into this IND-enabling phase where you really start to conduct engineering runs, where you set up a manufacturing process, run engineering runs, and try to make it from we are able to produce the product somehow with variants and so on, try to try to make it from there into a more or less stable GMP—so Good Manufacturing Practice—compliant manufacturing process that is ready then for the clinical trials. And all that happens as it indicates preclinical, so outside or without the involvement of humans. So there are animal models, for example, that are used, and other things to validate the process. So that's kind of preclinical, and from there, it goes into the clinical trials.

Tom Lehmann
So keep going, then, if you get into clinical trials, obviously, if you're talking about rare diseases, your patient populations, by their nature, will be much smaller. So, how does that play out then? Because partly now you're starting to not only test the therapeutic effect, but also thinking about the end to end supply chain, which is a very different view of supply chain. So maybe if you can put those two pieces together, because this obviously is what we'll be scaling up when you get into the commercial side of things, but let's just stay in the clinical stage for now.

CHRISTIAN F. _ Roche Genentech
Yeah, absolutely. So if we look at this point, actually, there are already a few things that are quite interesting, if you compare to classical biologics, for example. So one is that, typically, the partner we are working with, they are not really experienced in that field. So this can be like a university, or can be a small company startup that had a smart idea and found something that potentially can lead to a product. So we are working with in-licensing, for example, we are partnering with other companies, and we also have our own R&D departments. However, in most cases, there's some sort of collaboration with partner. This can also be labs that we are working with, or a smaller manufacturer that are working in that space.

CHRISTIAN F. _ Roche Genentech
So because, as I mentioned earlier, in the biologics space, there is more or less one standard way of producing antibodies with cell banks and so on, and there's one supply chain. But here, more or less the whole technology, more or less needs to be designed and put in place. And the whole supply chain needs to be designed and put in place. And that is very diverse, again, so more or less in the CGT space, we have, I would say, 8, 9, 10, different versions of supply chains. We have various manufacturing technologies that we are using so—and the partner we are working with are not really experienced in that space—and so that's why there's a lot of foundational work that needs to be done and the collaboration with a partner is different than in a biologics setting.

CHRISTIAN F. _ Roche Genentech
The other thing is that typically, as soon as you set up the supply chain, as soon as you select the partner, you would be more or less sticking with them until you go into or even including commercial space. So over the course of the clinical trials you also have to evolve the supply chain, evolve the collaboration and help the partners, in some cases, to really make it to those commercial stage. In some cases, we are moving the product in house. So there are different ways how, not just us, but also others, are then evolving from "we made it to clinical, how do we come to commercial?" So there are a few things that are quite interesting around that.

CHRISTIAN F. _ Roche Genentech
And on top of that, as you mentioned, we are working with lower patient volume, and there are different pathways. There is not just one pathway from clinical to commercial. There are different pathways, more or less accelerated based on the risks related to it and the potential benefit the authorities see for patients. Overall, however, the clinical trials are always similar, so you start with more or less a Phase I, where it's mainly about safety and dosing. You go into Phase II and III, whereas it's mainly about efficacy, and then you start to file. And then Phase IV is actually the commercial phase, where you have the product in the market. And then, more or less, the product itself is ready to be sold. However, specifically in the CGT space, because the cost related to producing and doing research for the product is quite high. There are typically also country specific reimbursement discussions that need to happen before you can actually sell the product to a patient.

Tom Lehmann
As you look at I guess that maybe the final part on that walk, and then I want to get into a little bit of the role that digital has played. But before we go there, when you look at the manufacturing side again, you're learning a lot through the clinical process, right? As you said you're establishing a partnership that will likely continue beyond clinical into manufacturing. Tell me a little bit about that handover, though, as you go from clinical to manufacturing. Historically, there's this big tech transfer handoff from one to the next, and it's about scale up and getting to manufactured scale, commercially manufactured scale. How is that different in the cell gene therapy space, as far as that transition point?

CHRISTIAN F. _ Roche Genentech
So typically, when we start in clinical, that is the biggest handover. So from preclinical to clinical, that is the biggest handover where we are starting to be involved, where we more or less take the molecule from research and then try to bring it through clinical into commercial. One of the differences to biologics is that, as I said, more or less, typically you are stuck with your partner, you are stuck with your supply chain. And there are some things where we have flexibility. So the level of automation from a manufacturing perspective, there are some variances we can we can play with as we go through the three phases of clinical trials. However, the goal, typically, is that later in Phase III you have, you're more or less running your commercial setting, because only then you can really show it's working, it's safe, it's providing the benefits. And so that's why, typically, like I said, you're stuck with your setup for the most part, and unless we make a decision that we bring something in house and we take it over from a partner that we that we used with, so it's in licensing model.

Tom Lehmann
Alright. So let's, let's pivot a little bit then to talk about the role that digital, or broadly, technology, has played across that life cycle that we just went through. So give me a sense of what you've been focused on; what are some of those interventions that have helped to facilitate that process? And then we'll pivot maybe to then what's on the horizon... But let's start with where you've been and what role digital plays.

CHRISTIAN F. _ Roche Genentech
Yeah, absolutely. So I think digital plays actually a quite big role here. And there's always the discussion of when should you actually start introducing digital technologies? Because you need to have a certain understanding of the process. For example, you need to have a certain standard in place to then automate the process or use digital technologies. But overall, I think in the R&D

space there are huge opportunities for technologies that can cope with huge data sets. So for example, for therapies where we conduct sequencing of the genome, which is like the genes of patients, you can for a whole exome sequencing, which is sequencing all genes that are producing a protein, you can easily end up with a data set of eight gigabyte for one patient, for one screening. And so analyzing this data set, finding certain information in the data set that might help to improve the treatment, is one example where more modern technologies, like data science approaches and AI can really help.

CHRISTIAN F. _ Roche Genentech
The other thing is in that space that is more about R&D, I think, is a big opportunity is also in everything that involves pictures, because everything, if you do a cancer screening, for example, pictures, analyzing them with algorithms, is something where I think artificial intelligence as well can really also provide benefits by just classifying but also by showing certain correlations in the data or even causality. So if this, then that will happen with what's happening in the patient.

Tom Lehmann
Hi folks. This is Tom Lehman, your host, jumping in here because Christian has mentioned the concept of orchestration a few times, and it's probably not a familiar topic for most of you. So I've asked Sanjay Srivastava, Accenture's lead for cell and gene therapy to provide some context for you. Sanjay, help us out here in the cell and gene therapy space. What is the significance of orchestration?

Sanjay Srivastava
That's a great question, Tom. unlike traditional pharma, as Christian has said here, in autologous cell therapies, we have to manage both patient journey and the cell journey, and it's a very complex, multifaceted and multi stakeholder engagement journey that we need to orchestrate just in time from end to end—from the time the patient walks into the hospital to the time the drug is administered and they walk out. And in order to manage that journey, we need the capabilities to orchestrate that just in time patient journey, as well as the supply chain journey of the cell, and that's what orchestration is really about.

Tom Lehmann
All right, thank you. So let's get back to the episode

CHRISTIAN F. _ Roche Genentech
So from my perspective, digital really starts when we start to set up the clinical trials, where at the very beginning, we would still try to run manual processes, but as early as possible, we are trying to prepare for scale with the therapy. And that's actually also where my role started at Roche Genentech, where we identified certain gaps in the orchestration area. So being able to orchestrate the end to end process, being able to introduce a certain level of automation, but also introducing capabilities that are quite unique compared to biologics. So slot scheduling, for example, where you have to work with various partners, is a unique capability in that level of detail, where you more or less need to know who, which specific lab colleague is working on a specific device, and is he trained, and so on and so on. So it's really very sophisticated.

CHRISTIAN F. _ Roche Genentech
Another example would be chain of identity, chain of custody, CoI, CoC, capabilities that are typically not there. And we identified those gaps and started to specifically invest in those areas, to build capabilities that allow us to orchestrate the end to end value chain. So there's a co innovation with SAP to introduce a new product called SAP CGTO to orchestrate the value chain and provide certain capabilities. And we have a collaboration, also a co innovation with Accenture to provide a treatment center front end, because this direct collaboration with treatment sites, healthcare professionals is also not something we are doing in the classical space. There is more a wholesaler business, so we are selling into the market. It's Make to Stock. Here it's in the individualized space. Make to Order products that are ordered by a specific treatment site. And they have to provide, for example, cells. They have to provide data. And we need to capture this, because the supply chain there is what we call a closed loop supply chain. It starts with the treatment side, we do something, we do our magic, and then we deliver the product back to the treatment side. And that is a new model for pharma as well, where we identify those digital gaps. And as I said, there we are investing.

That's something my team is driving, and that is something where, also the industry is still very young in that space, with digital capabilities.

CHRISTIAN F. _ Roche Genentech
But long story short, if you want to be successful and scale the product globally, you need to have digital support, because it's impossible to do all that with paper and Excel. You need to have the capability to really run it at scale and also in a way that you can repeat it and it's compliant, especially because the complexity between clinic and commercial is increased in the way that as soon as you go into commercial, you're already selling the product. So you have all the financial activities, like I said, like a sales order, purchase order, across various entities that need to be managed in time to really be able to ship a product, to get it through customs and then treat the patient in a very short period of time, from order to treating the patient.

Tom Lehmann
And I think what's important to understand, as you say, product in there, it's different than what people would probably be thinking about as a mass produced product; as you said you're shipping it to a distributor, to a wholesaler. This isa patient of one, if you will, right? So the product is a byproduct of your process, and the input coming from a treatment site, and ultimately a very tailored outcome for a patient. I think it's really important to understand because that's a very different, nuanced process versus we're doing a mass production and we're shipping something to a site, and then it's produced. It's then distributed to a number of individuals. And that orchestration part is so important to get this right.

CHRISTIAN F. _ Roche Genentech
Absolutely, also the impact. So for example, and what you just described, is for us, like a made-to-order supply chain, a closed loop made-to-order supply chain, starting with a patient, ending with a patient. And you're right. That's not what we do in biologics. Biologics, we sell into the market, and then we have the market more or less selling it out. We don't even see the treatment side. Here, we do. And so that's really a big challenge and new area for us, but we are building capabilities to address it and to be able to scale.

CHRISTIAN F. _ Roche Genentech
The other thing is that, for example, if you provide the wrong cells to the wrong patient, then the patient might die. That's it. So that's why chain of identity, chain of custody, are so super important. You must not really mess this up. Sorry to say that way, but it's super important that we have a strong chain of identity, chain of custody, we always deliver the right product to the right patient, and in a very complex supply chain setting with strong turnaround requirements, that's really a challenge you have to think about when you commercialize those therapies.

Tom Lehmann
I also think, as you noted part of this is getting that interaction with the healthcare provider, that site, correct as well, right? Because it starts there it ends there. Are there other things that are unique that you have to work through? Because this is very different than, as you said, biologics and other products that are out there.

CHRISTIAN F. _ Roche Genentech
So yeah, there are some things that are different because of the nature of the product. So for cell therapies, we are working with living cells, which means they have to come from somewhere. So we have to source them, more or less, like purchase them from the treatment side and the patient, and then we manipulate them and send them back as a treatment. Other therapies, like in the gene therapy space are not individualized or personalized. So for example, Luxturna, which I mentioned, which is a treatment for a retina disease that can lead to blindness. There we are delivering one gene via a virus vector. So the virus like an infection, more or less, the virus doesn't include the virus gene. It includes the gene that we want to deliver. So it's a vehicle we are using, and there it's a pure Make to Stock therapy. You still have challenges around reimbursement, you still have challenges around cold chain and certain regulations, which are different in the cell and gene therapy space compared to biologics. But there are different flavors. It's not all about purely individualized therapies.

CHRISTIAN F. _ Roche Genentech
Actually, the biggest trend that we see in the industry is a shift more towards products that can be donor derived, or that can be stem cell derived. So if you want to have a cell that is an immune cell, which is a product to fight cancer, for example, a T cell, for example, then you would probably take this from a healthy donor, or you would use a stem cell bank, where you have cells that can be manipulated so they become that target product. So again, there are different flavors in that area.

CHRISTIAN F. _ Roche Genentech
Some challenges are due to the nature of the product. Some challenges are due to reimbursement things, and some challenges are just due to the nature that this is a very new field we are working in. And there is not like there's 40 years of experience of how to do things. That's why I really like this space. It's, for me, like being in a startup, although I am part of one of the biggest pharma companies in the world. So there's a lot of fundamental work we have to do. There are a lot of new things, new capabilities we are building to make this work and that is really exciting.

Tom Lehmann
So as you look at where things are right now in that evolution, as you said, you don't have decades of experience in this space, certainly not in the on the commercial product side. As you look at how it's evolving, how it's maturing, what role are you seeing for some of these, these intelligent technologies? Right? The rest of our lives, we hear about AI all over the place, and generative AI and these types of things. What do you see, either of our current state in that space or maybe on the horizon, as far as the role that some of these technologies can play to help with that evolution that, as you said, is naturally occurring?

CHRISTIAN F. _ Roche Genentech
Yeah. So, as I said in the R&D space. My guess—is I'm not really involved there, so just by knowing roughly what's going on—there are massive data sets we have to cope with. So everything that can work with massive data sets and they are data science approaches, machine learning models, which are classified as artificial intelligence, decision tree models and so on, is something that are beneficial and can be used and are already in use. Where I'm working, where it's mainly about commercializing a product, covering clinical and commercial, we are already using a few technologies where you would say it's kind of new. So for example, robotic process automation, are things that we are using where we don't have a technical interface between systems. Things like automated testing, are things that we are using for our IT projects to reduce the human workload in the testing area, or specifically to repeat certain tests that we did automated testing.

CHRISTIAN F. _ Roche Genentech
And those are kind of new technologies when I compared to like where we were 5 or 10 years back that were not really used on those on those projects and initiatives. Also the topic of chat bots. That is something where I think there's a big benefit, specifically about collaborating with treatment sites, that they are able to actually put certain requests in and get support via chat bots. There are still some challenges when you go into global scale. Not all languages are covered, and so on and so on, but that is definitely something that I would say is ready to be used in the industry. We are not using it, but we are considering it.

CHRISTIAN F. _ Roche Genentech
And then one big topic that is, I think, in everybody's mind, is our topics around ChatGPT, so more or less content creating artificial intelligence, as you could tell. At Roche, we have our own version of it that is sometimes used, but that can help more or less, more from a business side, as we run certain projects. So it's not something that the patient would directly see, but it's helping on those projects to accelerate them, and by doing so, it's reducing the cost, which is then beneficial for the society and the patient. So there are definitely a few technologies that are ready to be used that we are starting to use.

CHRISTIAN F. _ Roche Genentech
But long story short, so as this space is very new, and as the capabilities that we that we need, are very young, most of the investments that we are driving are like fundamental IT

projects where we need a new software piece to orchestrate the value chain, as I said, or in the manufacturing space to set up an MES system for a new site. So those are more classical IT projects that we are working on. However, like I said, it's also in the exception management space, because exception—again, another example where CGT is way different to classical biologics—exceptions is more or less a standard, so you have to be able to cope very well with exceptions. And for that, we are driving the exception management framework where we try to identify exceptions in advance, classify them, prepare with playbooks so that the response time is as short as possible to not impact the overall turnaround time of the product. 32:54

Tom Lehmann
Hi there, jumping in again here to make sure you have the background on another topic that Christian's been talking about. This time, it's exception management. Sanjay help us out with this one.

Sanjay Srivastava
Yes, indeed. The exception management is really unique here for cell therapies. The reason is that these therapies are being administered to very, very well treated and sick patients. Its implication is that as we go through this complex journey that we were trying to orchestrate, patients' situations change, often change, and when they change, that results in an exception that we have to manage more often than not. In fact, if you look for our experience, we see about 90% of the time, and during the orchestration of this, of the journey, we are managing exceptions—exceptions in schedules, exceptions in patient situation changing, not showing up where they need to, because the medical condition has changed, or some technical difficulty in manufacturing or or in sales themselves. Hope that helps.

Tom Lehmann
Yep, great. Well, thank you. Back to the episode.

CHRISTIAN F. _ Roche Genentech
And in this space, I think there are definitely opportunities to use more novel technologies to have an eye on what's going on overall in the world that has a potential impact on supply chain. So for example, if we know that we have to ship a product likely next week from A to B, are there certain environmental factors that might impact our delivery commitment or overall lead time, and by sensing them, potentially predicting them, can we make adjustments in our value chain? For example, fly a product in not via Frankfurt, go via Amsterdam instead, because we are expecting a strike in Frankfurt. So that can really have an impact, like a real-life impact, on how smooth the execution of the treatment delivery works. And that is also something we started to look into.

Tom Lehmann
Well that last one is an interesting area, right? Rewind the clock three or four years ago, as we were working our way through the COVID pandemic. Supply Chain resilience became a very popular topic across a number of different industries, including ours. As you look at the ability to not only predict, as you said, but also to have the ability to react and react quickly, so that you can alter your path, does feel like it's an opportunity, whether it's in the cell and gene therapy space or just broadly, where you're thinking about biopharma supply chains, it's a necessity, right? All the geopolitical activities are going on, as you said, it could just be a strike in one location, which is not a big event, but it's a big event that could be disruptive to a supply chain. It does feel like, increasingly, we need to get better in that space,

CHRISTIAN F. _ Roche Genentech
Absolutely. And that is one example where I think actually we can partner up with classical supply chain or biologic supply chain, because, as you said, they have similar challenges, and the biologic space is also evolving from a supply chain perspective. Classically, it's really like the wholesaler business that we are doing, but there are also trends towards direct to patient delivery and something like that. It's not that we are the only innovator in pharma, so there's a lot happening there as well. And then those topics are interesting, and there are synergies between those two areas.

CHRISTIAN F. _ Roche Genentech
Another example would be really assessing the supply chain. So assessing your partner, your CDMO, assessing the supplier of that CDMO, assessing the supplier of the supplier from a risk perspective, from a financial perspective, to overall improve resilience of the value chain. So those are topics where we can definitely partner up. And yeah, we also at Roche, we started to talk to our colleagues to partner up on this. Actually, in some areas, like in this specific one, they are more leading than we are.

Tom Lehmann
That makes sense. Well, and maybe I'll jump to a different question off of that, just reflecting on where this field is. You've mentioned it's new, yet there's a lot to be learned from some of the other areas in the business, or other types of treatments. What's one thing that you're most excited about in this space over the next few years?

CHRISTIAN F. _ Roche Genentech
Yeah, so I think it's really the potential impact that these therapies have. So it's really life changing impact. Because, as I said at the beginning, we are with some therapies really trying to cure the patient instead of just treating the patient. So seeing this becoming more, I don't want to say standard of care, but becoming more broadly used, is something where I'm really proud of that I'm part of it, and where I'm really looking overall, like big picture to see a higher impact of cell and gene therapies in pharma, in healthcare. So I think that's overall why I'm excited about it.

CHRISTIAN F. _ Roche Genentech
I think the other thing is that, as I said earlier, also the industry and cell and gene at Roche Genentech is still very young. So I really, really like this entrepreneurship environment where, if you have an idea, it's very likely, if you can sell it and convince a few people that you can start working on it, if it provides value. And the other thing is that you have the benefits of a big company, like as an individual, which gives you... I'm a family father, I have three kids and a wife, so that's why working for a big pharma company provides a few benefits that we really enjoy. And this combination, I find that quite interesting. Honestly, even if I think about it, I have to say, working in cell and gene therapy, in a setting where you are building something new, like we did at Roche with a new business unit that is established, is a one in a career or one in a lifetime opportunity. I don't think that in pharma, I will have the opportunity to jump on something like this again. So I think it's really a great opportunity, which has a lot of interesting things. There are also challenges, so you need to be able to work in such an environment. There's uncertainty. Portfolios are changing every day. Almost all technologies are uncertain. So if we summarize it, I mean, we are building new processes based on new technologies for new products in a new business unit with new people. So there's almost in every area, new or innovation involved, which is exciting, but also comes with certain challenges as far as maturity, uncertainty, ambiguity and so on are concerned. But that's, yeah, why I really like this space, and what I'm excited about looking forward, what I would like to see from CGT moving forward.

Tom Lehmann
And maybe I'll wrap with the final question here... given all of that novelty, is there one thing that you wish people knew about your role and function that people probably don't know?

CHRISTIAN F. _ Roche Genentech
That's a good one. So not specifically for my role and function. I think the biggest, or the thing I would really like to share is that it's not hard to start in CGT. So it's really not hard because it's so undefined space...and it's really fun to work in. So I would really encourage people that are thinking about going into cell and gene therapy to just do it. I mean, if there's an opportunity, grab it and just do it. That's how I more or less landed in cell and gene therapy. I didn't have 20, 30, years of background in that field, and I would challenge that only like a few people have, or even like nobody has at this point in time. So it's really, if there's an opportunity in that field, and you like being on the on the forefront as far as innovation is concerned, and you like working in an

entrepreneur-like environment, then grab the opportunity and just do it.

Tom Lehmann
I think it's a great place to finish a great discussion and I appreciate that encouragement, as you said, that the degree of novelty that's there creates all sorts of opportunities for people. And you certainly have found your way into a space that it's very clear you're passionate about and is on the on the leading edge of some really new and interesting science. So I appreciate your thoughts today. I appreciate you joining this discussion.

CHRISTIAN F. _ Roche Genentech
Yeah, thanks for having me.

Tom Lehmann
So a big thank you to Christian for sharing so many interesting aspects of his role and his experiences to get to where he is right now, including some of the challenges he and his team have faced and are currently trying to overcome—as was as the insights into the incredible work that is being done and the future that lies ahead with Cell and Gene Therapies. And also a big thank you to my colleague Sanjay Srivastava for joining the conversation and the extra information he provided.

As always, remember to like and subscribe to The Lens podcast on your favorite podcast platform so you don't miss an episode. Thanks for joining.