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Establishing Direct To – and From – Patient Clinical Trial Supply Chains (Part 2)

Intro:
I am Chris Riback. This is Logistics Live, Conversations & Insights on the Global Supply Chain. Today we continue our conversation with Mike Sweeney, QuickSTAT's Global Head of Strategy for Cell and Gene Therapies and Direct-to-Patient products on how to set up robust direct-to-patient and direct-from-patient clinical trial supply chains. In part one, Mike outlined how sensitive, precise, and flexible one must be in handling and transporting these CGTs that hold such incredible potential for improving if not saving lives. Mike also explained many of the challenges, the strict timing and deadlines, maintaining the required temperature throughout transport to name a few to ensure product integrity and patient safety. In part two, Mike offers specific system design ideas and tactics to establish processes and overcome inevitable roadblocks. He breaks down extraordinary case studies and gives his views on what's next, particularly around regulation.
I'd like to ask you to put your consultative hat back on again. For a new client or a client who is looking to set up a successful supply chain process, what would you advise? What are the steps? What should they be really thinking about? What are the potential roadblocks they should really be aware of? What do you say to clients who want to do this?

Mike Sweeney:
I am an advocate, obviously. I think that this is something that is fantastic for both the clinical trial organizers as well as patients. It has a lot of benefits, so I'm always going to be of the mindset of we will help you do whatever is possible and whatever we can do under the regulations. And that's really where it starts. Our customers need to make sure that what they're doing is something that is legally allowed in each country, that they're aiming to perform it, and that their supply chain doesn't have any regulatory issues. And that's not really our job to manage that, but we do inform them, look, if you're going to be running any of this clinical trial in a direct-to-patient manner, you need to make sure that the protocol approval considers that, that your competent authority is aware and understands. Sometimes there's back and forth on these applications and before the approvals are submitted or gained, there are sometimes conversations and adjustments that have to be made.

So the bottom line is, most regulators are not looking to stop this from happening, but obviously, they want to ensure that there is a safe manner to have a drug delivered to patients. Most of what we saw prior to COVID was there was literally nothing out there on this in any country that really was doing this routinely, US included, many countries in Western Europe and Asia Pacific region as well as Latin America. There are many countries where this had been happening even prior to COVID. Obviously, the number of countries has shot up. But I think the key is that our customers need to understand there is a proven successful history of doing this, that there is a process that works and we just need to help understand what are their concerns. So one of the things that we really need to understand is if there is, for any reason, a temperature deviation enroute that's discovered, what are we going to do?

Is the protocol something that requires us to return the drug immediately to the pharmacy that we picked it up from, or is there some way we could potentially look at that deviation and the severity and the time of that deviation and preserve that drug and even potentially that delivery and that visit for that patient? There needs to be thoughtful processes involved in terms of how are we going to get to where we need to be in terms of supporting these patients. And again, on the logistics side, we want to be invisible. This is something that it's an advantage for them to be able to have this, but at the same time, it shouldn't be ever painful for them. To experience this at home, it's all about the convenience because we know in some cases that's their only option. I think it's really just a conversation about the goals of the customer. We have sort of a template that we run through, a battery of questions, and make sure that we consider their special instructions or requirements.

Chris Riback:
In listening to you and I am certain that you would never for a second even characterize this as a complaint on your part. It's the business that you're in. It's the service that you are looking to provide. But there's almost a math equation that's going through my mind of increased convenience for the customer requires a transfer of complication to you. You are having to deal with it. And to me as a lay person, that temperature requirement and the way that that can change and you're thinking about so many different touch points now because, in a certain sense, the number of potential households out there is... Well, it's not infinite, but it's a really big number. And that level of exponential complication that transfers from a customer to you from simplifying a customer's experience to creating or bringing that complication onto you. I mean, no complaint, that's the business you're in, but that's the image that's going through my mind in listening to you. Am I kind of imagining that, right? Is that how I should be thinking about it?

Mike Sweeney:
You are, but I think the thing that I always look at is a lot of others in the supply chain have it a lot worse than we do. And that's typically at the hospital setting where they have to make a lot of tough decisions and they're being pulled into different directions that a typical patient visit onsite wouldn't require. Again, there's a trade-off. There's not that scheduling and everything that goes on with treating that patient when they come in, but then there's this trust of what type of treatment and how is that going to be delivered to their home and how are we actually going to manage this extra leg of logistics, which they're in the middle of in a lot of cases.

Now, it isn't always up to the hospital because sometimes more and more in direct-to-patient, we're seeing a distribution that's happening centrally from a centralized pharmacy, for example. So that is something that again, takes that storage burden away from the clinical study sites. And it also allows, I think, for really to maximize in some cases the inventory management as well of the drug. There are some drugs that are in shorter supply than others, some that are much higher value than others. And not all, but most that we deal with are temperature control in some nature.

Chris Riback:
We've gone through the challenges and one could get caught up in that, and how difficult this challenge is that you have chosen to take on. On the other side of that are those positive stories, it's the successes. Any examples come to mind?

Mike Sweeney:
Absolutely. I think there were many heroic stories during COVID where it just didn't seem like reaching a home in a certain area, whether it was in China or Italy or wherever was going to be possible. And through perseverance and maybe begging the authorities, pleading cases, things happened that a lot of people didn't think could and it became almost normalized for a while there. What I see is just a shift of patients that are not able to be recruited today for a trial that requires them to come into the hospital every time. And there are instances prior to COVID and well before that where patients would fly to their nearest hospital, you can imagine, and taking a drug back home with them from the hospital when they get there.

So I think that when you think about the advantage this creates in a lot of ways and it creates more control as well of the supply. And certainly when I talk to customers, one of the greatest things I can hear is, "Well, we used to just allow a 40-mile radius roughly where patients would be recruited from, now we're 250 miles or maybe limitless."

Chris Riback:
Incredible.

Mike Sweeney:
Yeah. I mean, so the rare disease situation, you're not going to have patients that are all clustered around that hospital or that location.

Chris Riback:
No, certainly not. Rare disease does not choose patients based solely on their proximity to hospitals for sure, and the ability to extend that radius as you just described, that's really remarkable. What's next? Don't misinterpret. We are not dissatisfied with what you've been able to do to date. So thank you very much for that. But we're all curious as well about what's on the horizon. What do you see?

Mike Sweeney:
Well, I think one of the good things that's happening now is the regulators have actually said, "We know this is going on both in the US and Europe." The authorities have come out with guidance this year, which is helpful just again, endorsing the fact or acknowledging the fact that this is happening and that it can be done safely and effectively. But I think what's really next is another trend that's happening within regulatory arena and that's on diversity and expanding clinical trials to diverse populations, which is necessary to make sure we understand what's effective and what's not. And I think that that is something that we'll continue to see driven forward, and that could be very interesting. When we look at the countries and we look at the locations and which patients are being recruited, it's going to really open things up, I think even more.

There is a lot of work to do. There's no question about it. I think the typical clinical trial patient is somebody that probably looks more like you and me than a lot of other people around the world, and it shouldn't be that way. There's a lot of opportunity for us to do more, and I think that that's the idea and why I really fell in love with this service and supporting it is because it is about giving people opportunities and access that they didn't necessarily have before. That includes anybody that has a relative and you're searching for clinical trials. A lot of us have done this. And it's a very tough situation if you can't find a trial that fits in a location anywhere near you. So I think that this is just hopefully going to open up some doors and create more of an inclusive environment, which will also give the research community better, stronger results.

That was one of the issues on the COVID vaccine studies, if you recall. I know that Moderna did an excellent job in getting a diverse population run through those trials, and that was really helpful. It's great that we are seeing regulators like FDA and others around the world that are coming out and looking at these aspects because they are important. Equally important for our service and our future in this and where we need to go is the technology. I think that QuickSTAT has done a really great job. They have a terrific online portal that our customers are using routinely and really taking advantage of that in terms of communicating in a lot of ways instead of phone calls or similar. So I think that there's more to do in looking at the technology, whether we're talking about real-time tracking GPS, which comes with some really great positives for nurses and patients to know where drivers are, for example. But it also wreaks some havoc on the privacy concerns of a clinical study.

So there's a lot that we're looking at and I'm excited about, and I do think that we need to continue to work hard because this is delivering packages from point A to point B. It can all be done through technology, but a lot more can be aided by technology. And I think especially as we scale the service more, and I do expect that it will continue to grow, there will be more opportunities for us to really look at the best way to manage the supply chain and automation of that as much as practical.

Chris Riback:
There is a lot to do. There is a lot of work. I'll let you get to it. Mike, thank you for your time.

Mike Sweeney:
My pleasure, Chris. Thanks so much. Appreciate it.

Outro:
That was my conversation with Mike Sweeney on establishing direct-to-patient and direct-from-patient clinical trial supply chains. My thanks to Mike for joining and you for listening. For more information on clinical trial logistics, visit our website at quickstat.com.