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Establishing Direct To – and From – Patient Clinical Trial Supply Chains (Part 1)

Intro:
I'm Chris Riback. This is Logistics Live, Conversations and Insights on the Global Supply Chain. Few aspects of our lives and routines changed more significantly over the last several years, or more rapidly and permanently than supply chains. Virtually overnight protocols, border requirements, flight schedules, regulations and more shifted as standard operating procedures went out the window. Post-COVID, much of life returned to normal, but one important area of supply chains found a new normal, in semi-miraculous ways and very much for the better. These are direct-to-patient and direct-from-patient clinical trial supply chains. Known as DTP or DFP, these supply chains have become essential lifelines. Medical patients relying on life critical cell and gene therapies or participating in revolutionary clinical trials can participate without having to leave their homes. But with this clinical trial model comes new challenges around time, temperature and logistics. Further, these DTP and DFP supply chains extend to patients' homes and apartments in nearly any location in the world, moving far beyond hospitals and clinics.

So how do you set up these supply chains? How do you mitigate risk?
And how do you ensure they're resilient? Mike Sweeney can explain. Mike is QuickSTAT's Global Head of Strategy for CGT and direct-to-patient products. He joins me now to discuss how to safely transport life-saving and life-changing shipments no matter where in the world the patient may be.
Mike, thanks for joining. Really looking forward to talking with you.

Mike Sweeney:
Happy to be here, Chris. Look forward to the discussion.

Chris Riback:
So let's start out with a little bit about you and your background and your role at QuickSTAT. I know you joined the organization fairly recently. What have you done and how did you get here?

Mike Sweeney:
Well, it's about 30 years in clinical trial logistics. I was with World Courier for many years, and happy to join QuickSTAT after a short stint doing consulting back in March of this year.

Chris Riback:
And how has it been? Everything you expected?

Mike Sweeney:
It's been better than I expected. I really came in looking for a new opportunity after many years, and it's been wonderful. The people are fantastic, the organization has a great culture. I couldn't have landed at a better place.

Chris Riback:
Or in a more challenging place or a more important place in terms of individuals and their health and their wellbeing. They and many others, I'm certain, thank you for that. So why don't we get into the topic at hand: direct-to-patient or DTP. It's fair to say, I think, you correct me if I'm wrong, that the pandemic forced companies in the biopharmaceutical community to really rethink their operations. Some might say it's the only good thing, DTP is, that came out of COVID. Talk to us about that. First, if you would, maybe let's just start at the highest level, what is direct-to-patient? Direct-from-patient is a component of that. Maybe you'll touch on it. What is the process and how does it work?

Mike Sweeney:
Well, direct-to-patient is typically involving a patient's residence or somewhere outside of a commercial hospital or similar setting where they will be having drugs shipped to them, potentially administered to them. A lot of this is based on residential settings, so it is a bit newer in terms of bringing the clinical trial or medication and treatments to the patient's home. So that's, in a nutshell, what it involves. And there's also materials that are shipped out from the patient's residence as well.

Chris Riback:
And how much of that shift to residents was because of COVID? For those of us who follow healthcare and the pharma industry less closely than you do, we certainly read about and hear about the push to at-home care and the push to taking care of various components of – whether it's clinical trials, various testing, or whether it's actual care itself, but pushing it out of the formal hospital-like conditions and into more, whether it's one's home or local areas. Could you help me balance the impacts on the process, that overall trend, and then what did COVID do to perhaps accelerate it?

Mike Sweeney:
The good thing is there was a start to this before COVID. There were many organizations, including QuickSTAT, that were heavily involved and building out services to serve the patient where they are. And again, that's typically at their home, could be at their place of business, it could even be a child's school. So it is pretty flexible in terms of the way that it was set up. So there was some history here, and frankly we've been doing, one way or another, deliveries to patient homes for many, many years. But the formalized service has really been something that is geared towards clinical trial recruitment and retention and looking at patients that struggle in some cases to get to the hospital site for their treatment. Maybe the nearest hospital site that's enrolling patients is very far away.

So there's a number of reasons why this is important, but COVID without question forced the issue. It really made us all work together very quickly and respond to situations where patients were expecting medication and their treatment doses were due in certain numbers of days, and that had to happen or the trials had to be suspended. In some cases, that was probably more difficult to manage from the pharmaceutical viewpoint of which trials do we continue, which trials do we suspend, how can we create processes that will accommodate this? So there was a lot of very fast action and work that had to happen to really preserve that continuity for patient treatments.

Chris Riback:
And to really home in on this re-engineering, let's call it, what had to happen on the fly with, I'm certain, no rule book, no 1-800 number, how do you re-engineer this type of life and death process during COVID? You are having to, with your partners, create new protocols, I'm certain, on the fly. That has to take such effort. And for the biopharmaceutical community, the fact that it takes a lot, they must be at the top of that list of industries that would really find that a bit of a challenge. What they're doing involves life and death. What did it take for them to execute this re-engineering, and what role were you able to play in that?

Mike Sweeney:
That's a great question because I think that there were certain organizations that made decisions, and it is largely the biopharmaceutical industry that was trying to figure out how best to engineer this. And they really had to consider it from a quality standpoint and really the patient's safety first, and then everything from there trickled down. And there was a lot of collaboration that went very deep, really looking at what was possible. So my role in a lot of ways was really consultative and really looking at what's possible, what's risky, and then having these discussions about, do we want to ship controlled substances to patient homes? Do we want to ship vaccines and other drugs that may be not as stable or maybe have higher risk upon dosing?

Or maybe in some cases, certainly organizations made decisions not to do certain things, and then they would kind of look at the pool of areas where they could apply this service. And then it was very difficult to kind of shift the protocol, shift the drug supply chain and accommodate as much as possible that patient or those patients at home. And the other issue really, or the challenge was that it did still involve the hospitals because a lot of this medication was being stored at hospital pharmacies, which obviously had restraints, everything from very limited hours to the access to that drug.

Chris Riback:
Who could access, I'm sure. Yes.

Mike Sweeney:
Exactly.

Chris Riback:
I heard you say just a moment ago, and it really must have been on one level fulfilling, a consultative role that you played with these firms. If I look at your job description, I'm assuming that every day you are worrying about logistics, you are worrying about these life and death materials getting to and from where they need to be. What percentage of what you do is consultative, you want the clients to call you up, talk through challenges, talk through opportunities, talk through their new ideas, how can we make this happen, versus you're worrying about logistics and did the plane arrive, did the truck arrive, did that pickup arrive, and really, really thinking about that client picking up the phone, that consultative role that you play?

Mike Sweeney:
It's something that we strive for all the time. We're looking for ways to be as helpful and informative, based on what we see as the best practices, based on experience. We've lived through a lot of these situations where... some of our customers have as well, others not as much. And during COVID, there was a lot of uncertainty. There was a lot of, "We need to get this done, we're not really sure how to do it." So I think it was really just a deeper level of that consultation, but we really do need to look to do that as much as possible.

And to be fair, it's probably a big thing that we wish for, but don't always get. Time is limited and it's challenging. But during COVID, it was a little bit different in terms of, I think, there was this thirst for knowledge. And frankly, customers knew that they were really short cutting some processes that they would normally do much more in depth, whether it was quality reviews and analysis, audits of all of their suppliers, which obviously couldn't be done on onsite anymore anyway. So there were just a lot of shifts in terms of the way that our customers were approaching this and it was a learning process for everybody.

Chris Riback:
What a wonderful phrase, thirst for knowledge. Yes. I'm certain that there was in that time, particularly when none of us really knew what was next. But I'm certain, and we'll get into this a little bit, that continues, that thirst for knowledge never stops. I'm certain it never stops with your clients, and particularly this field with the boundaries that are being pushed every day. Thank you very much to the scientists who are doing that boundary pushing on our behalf. That thirst for knowledge must never end.

I'm finding myself wondering as well, moving a little bit out of just that COVID era and into the day-to-day challenges that you face, with the level of seriousness of the business that you are in, the range of individuals depending on this process, your processes working perfectly every single time. Talk to me about the challenges, but also, of course, then the advantages of direct-to-patient and direct-from-patient, those challenges and advantages that they provide in clinical trials, specialty medicine delivery programs, getting them in the hands of patients in their homes.

Mike Sweeney:
The real challenge is just you're taken out of your comfort zone of a known commercial medical setting, and now all of a sudden the drivers have to go to a home, to a neighborhood, and they have to deal with a number of potential parties that are going to open the door. It could be the nurse that's visiting the patient, it could be the patient themselves, it could be a family member or another caretaker. So it's all of a sudden you're working in a residential, typically, format, which is very different, and obviously it comes with its own challenges, but also the scheduling of that and the expectation of when the shipment will be delivered. And a lot of times we're talking about temperature-controlled materials and the thing that we do not want to do is burden the patient in any way. And some of these packages are a bit bulky and have temperature-controlled materials in them. And we certainly want to make sure that that's something that's not left at the home. They're not going to be able to get rid of that. And it's usually in a reusable shipper as well.

So it's really an interesting shift and something that thankfully a lot of people had been more accustomed for really any types of materials being delivered to their home suddenly, even if they hadn't used Amazon too much or had been used to that more so in the past. But there's a lot of communication and coordination and a lot has to happen to make it go without a hitch. But I think the advantage is that the patient no longer has to go to the hospital. And it's no secret that hospitals are still overburdened in many locations around the world. And I don't see that going away immediately. That entire industry was really already struggling, I think quite a bit before COVID. And now for them to get some extra help and have patients that they don't have to schedule every single time, every single patient, is a bit of an advantage.

But for the patients themselves, and the pharmaceutical companies that are sponsoring clinical trials, I think it's just a very interesting way to look at getting access to more patients, allowing them to have access to more treatments, more possibilities. And I think the other part of it is that patients have the choice. This is not something that's all or nothing, so it does just give them another option. In some studies, I think now, there are all virtual scenarios happening, but a lot of them are some sort of a hybrid, some visits done at the home, some at the hospital. So it really does give a lot of flexibility and I think overall satisfaction. It's been proven by patient advocacy groups routinely that this is one of the top two or three things that patients enjoy about being involved in a decentralized clinical trial. It really does speak to where we have landed after COVID in a lot of respects.

Chris Riback:
What about the pharmaceutical companies? What are the benefits for them?

Mike Sweeney:
They're able to really sharpen their recruiting times and they're also able to close out their clinical studies a lot faster. And I think another advantage that is interesting is they don't necessarily need to have as many sites involved for hospitals to recruit the patients. So that can cut down costs, but one of the ways that it can cut down costs is it eliminates or reduces a lot of the protocol amendments that are happening to clinical trials. The more sites you have, the more feedback you're going to get, the more changes you may have to that protocol, and that's painful. So I think there are a lot of advantages that are definitely seeing the light of day. And it's been very interesting, but I think there's a long way to go on this journey. We really don't know how big this could be or where it goes next. There's definitely some disruptors that are out there looking to make the technology better than it has been. I think there's going to be some continual challenges going forward as well. But I think the positives far outweigh the negatives as far as where we're headed.

Chris Riback:
Are there any specific technologies that you're seeing coming down the pike? Anything that's foremost on your mind? Or is that something for another conversation?

Mike Sweeney:
No, I think that there are already things that are... Some of the things that we already know and probably many of us experienced during COVID was the basics of telemedicine. That's something that's going to be required to support this. But wearables and other devices that patients are able to reflect how they're feeling, or their diaries which are being done outside of this in technology that they don't control, sometimes not technology at all the way that that's recorded by nurses and other caretakers. But I think the really interesting thing is that it's something that will continue to flourish, and the technology needs to be invested to manage the supply chain better as well. But I think the advantage of what's already happening in the home is something that we couldn't do this without that. We couldn't do everything that we're doing just on the physical delivery and pickup sides from patient homes without the technology that's been supporting that and their journey. And really it's all about their safety and their satisfaction.

Chris Riback:
You just said two magic words: supply chain. I took you as describing yourself as being in the communications and coordination business. I might add to that the choreography business, which of course all leads to the supply chain business. As far as setting up successful direct-to-patient or direct-from-patient supply chains, what are the must haves, the information needed by an organization's clinical trial logistics provider?

Mike Sweeney:
It's a great question, and there's a lot of parts to this, but I think generally we need to understand what the temperature requirements are of the drug, how much is needed from us in terms of packaging and temperature management. And that goes all the way down to proving that the drug was shipped at a certain temperature within a certain temperature range, which is pretty standard. And the other big pieces of this are the geographies. Where are we looking to do this and what does the supply chain look like? Is it simply a drug that's coming from that pharmacy that the patient would go to that hospital pharmacy? Or is it being shipped somewhere else centrally? Is it being shipped across borders at all in the US? It matters in some cases if it's crossing state borders, if it's going directly to a patient home, in other situations as well, this is being applied internationally.

So there are a lot of considerations, I think any special requests. So you're going to have problems, you're going to have delays. And I think when those things happen, you have to have a communication plan in place. There needs to be escalations. So the last thing we want to do is go to a patient's home more than once. We want that to go off without issue. So it does have to be scheduled and coordinated. So there's making sure we know who is actually making that communication or contact with the patient and making the schedule. I think again, there's just a lot of communication and consideration around the temperature control and exactly what the plan's going to be. And then if there's any deviations to the plan, who do we communicate with and how do we communicate?

Chris Riback:
Each of those touch points, and I'm thinking here about what you were just talking about engaging with the customer, the patient, but each of these touch points are so sensitive and so integral. Really help me understand the logistics, maybe just as literally as you can. How does QuickSTAT help set up a successful DTP or DFP supply chain?

Mike Sweeney:
So the logistics really does get down into the weeds, and we need to understand exactly, first of all, are we going to be supplying any package? Because these temperature-controlled shipments, again, they're often going to be stored somewhere in refrigeration or other temperature-controlled depots or pharmacies or similar. And the key for us is to understand where that journey is going to begin, and is packaging from us required? And if packaging is required, temperature monitoring devices are required. All this technology has changed quite a bit and gotten very sophisticated, but the shipment can't start if there's not proper packaging and temperature control at the time that that's needed at pickup. So that's sometimes challenge number one. How much notice do we get to be able to supply that packaging to that pharmacy? And then from there, we need to hit that schedule to deliver when the patient expects it.

So there are a lot of nuts and bolts and a lot of really planning to make sure we understand exactly what's expected. And the simple thing is really having contacts. We need to understand who at the pharmacy we need to speak to, where we need to go to pick up. We don't want to have our drivers get lost in a large hospital institution somewhere that the drug could be somewhere where we would least expect it to be. And I think that's been kind of the interesting thing. We've learned a lot about the hospital settings we're serving as well as the home settings that we're delivering to or picking up from.

But I think the challenges come from not having all the information that we need and have a plan right at the beginning, making sure that everybody is kept in the loop as they're needed. And sometimes it's very loose and light in terms of communication. Other times our customers want to know immediately. “If there's a five-minute delay, I need to be notified.” So there's a lot that's loaded onto the drivers and the service and they need to be trained well, and they need to be responsive and respectful. It's a challenge without a doubt. These are not easy shipments.

Chris Riback:
No, they don't seem like it. And your story just a moment ago about, so they're in the hospital, but trying to find exactly where the medication is or the pickup point is, that last mile of anything, and sometimes that last mile is actually only about a hundred feet as a human being in our own lives, those last mile, last hundred feet transactions, if you want to call it, are always so, so difficult. What about coordinating that exact timing with home health nurses and your drivers?

Mike Sweeney:
That's a great question because it's a daily routine that we all need to dance a little bit around this, because we're looking to hit a window that's within roughly 30 minutes. Sometimes it's going to be tighter.

Chris Riback:
Wow.

Mike Sweeney:
Well, you have to think about what the patient is actually experiencing. And we want to be invisible unless we're delivering directly to that individual. But if there's a nurse in the home, what are they dealing with? Are they just going in and checking vitals? Is there a lot more going on? And what are they even dealing with in the home, in the home situation? We have no idea, but we need to be conscientious of that and we need to be patient because in some cases they may be running late as well. They're on the road and moving from patient to patient in a lot of situations, and sometimes they've traveled quite a distance just to get to the patient's home, as well as our driver.

So any delays that occur with either side just need to be communicated and we need to work out any alternatives. It does happen where there are delays and maybe the arrangement that was first planned needs to be adjusted. I think that, again, is the key, and the technology can enable this communication and needs to help us with that more going forward. But trying to standardize that where we are today, and every nurse knows exactly how the communication will work, and there's just not a standard right now. It's a lot of different methods that are being used. And some of it's personal preference, which maybe that's something we need to look at trying to standardize and drive forward as an industry. It will be challenging to get that all on kind of the same page.

Chris Riback:
Well, if you can standardize personal preference, I'll read that book of yours. What about privacy? What about abiding by HIPAA or other rules of other countries?

Mike Sweeney:
So HIPAA is the big driver in the US and GDPR in Europe, and they're both, I think, a microcosm of a much larger picture. So we need to consider the patient's health and their status and what we know about their situation, what therapy are they being treated for, what therapeutic area, for instance. But the privacy part of this is critical. So there's personal privacy, which is what I was referring to, GDPR, which is just we don't want to be using anybody's information without their consent. And obviously in our world, we're just looking to make a delivery or a pickup from an individual and have no interest in really, frankly, even knowing who they are, we just need to make sure that the logistics and the contacts that we have are who we should be seeing for pickups and deliveries.

And the privacy part of this or the challenges, there are consents that are happening for patients when they are enrolled in clinical trials. The issue is that that consent is not being trickled down to all the service providers. So I think we're looking at this at the highest level of risk, where in many instances the patient's already consented and know that the courier is going to have their information. But what we need to do to manage that information today, hopefully, will be a bit more reasonable going forward just given that obviously anybody scheduling these shipments or delivering them or picking them up needs to know this information. And we also need to be able to verify legally that we delivered something to somebody somewhere.

So there's a lot of things that we could be blinding, and we do. We don't share this information on our tracking. There are a lot of controls that are required for this, but I think we really need to evaluate how much needs to be done and how much is practical and safe. Obviously, we do not want to use the patient's information or that residential information for any reason other than the logistics, but it is an issue and it's something that I think we need to consider going forward.

Outro:
That was the first part of my conversation with Mike Sweeney on establishing direct-to-patient and direct-from-patient supply chains. In part two, Mike offers specific system design ideas and tactics for any industry player to establish processes and overcome inevitable roadblocks. For more information on clinical trial logistics, visit our website at quickstat.com.