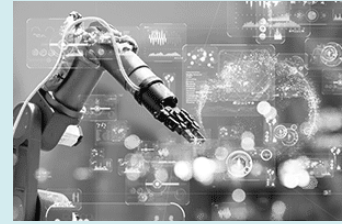




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Podcast Episode 18: David Northrup on Patient-Centric Lessons Learned in the Clinical Trials Supply Chain



Key Takeaways

- The clinical trials supply chain has always been highly focused on the patient; therefore, it can serve as a model for patient-centricity in the commercial pharmaceutical supply chain.
- Building closer relationships with downstream partners can help you gain a better understanding of the drivers behind patient demand.
- Looking beyond the walls of the supply chain team and sharing data with other areas of the business can help you significantly improve demand forecast accuracy.



What can the clinical trials supply chain teach us about getting products to patients on time and in full (OTIF)? A great deal, according to David Northrup, Head of Supply Chain at Theravance Biopharma. In this episode of The Agile Supply

Chain Podcast, Northrup shares the important supply chain lessons he learned while working in the clinical trials supply chain, as well as some sage advice on how to increase patient-centricity and improve OTIF in your organization.

Transcript:

David Northrup, Head of Supply Chain at Theravance Biopharma, shares supply chain lessons from the world of clinical trials and sage advice on how to increase patient centricity and improve OTIF, right now on The Agile Supply Chain Podcast.

Roddy Martin: David Northrup, welcome to the next edition of TraceLink's supply chain leadership and thought leadership series. You're a very able and capable addition to this.

My experience with you building the clinical trials hierarchy of metrics way back in your Pfizer days, through your Thermo days, through your Axiom days, and now to chief supply chain officer, you've gone through an amazing roadmap of roles and getting closer to the patient all the time.

Welcome, and talk a little bit about yourself, and also the clinical trials supply chain hierarchy and how it's a good proxy for all supplies on the supply network side of the patient-centric supply chain. Welcome, David.

David Northrup: Thanks, Roddy. It's great to see you again. It's always nice to have a conversation with an old friend, especially around supply chain topics. The bulk of my career has been in the development space, with clinical supply chains really being at the heart of what I've done.

One of the key things I think when I look at the credo and what it means to me and how you guys have framed it up, it's really about the patient. When you look back at how clinical trial supply chains have started to grow and evolve, they have been always focused on the patient.

The patients for clinical supplies are very niche patients. These are volunteers. We

know who they are, and it's very important to us to meet their needs on a day-to-day basis. As you started to move back into commercial supply chain, you can see the evolution of that, the start of being patient driven in commercial supply chains as well.

I'm looking forward to the opportunity to talk about the patient centricity across both clinical supplies and commercial supplies as well.

Roddy: David, what's really interesting about the clinical trials' supply chain as a proxy to the supply network is that the results of nonperformance are a disaster. If you don't get clinical trials' supplies to a clinical trial's site on time in full, they may have to cancel that whole portion of the trial.

Unlike pharma, where you've got 2 to 300 days' worth of inventory to play around with in some companies, in this case you don't.

You've made very precisely labeled batches for very specific individual patients. If you don't get that on time in full, you may have to cancel a very significant part of the trial. That puts that the angst back in supply chain in so far—as patient-centric.

David, you are now Chief Supply Chain Officer in a new commercial venture, and that must be really exciting. Talk a little bit about patient-centric and patient-driven. Let me clarify what I mean by that.

Patient-centric is the big strategic view. It's almost the P&G started the shelf. It's the healthcare started the patient. Patient-centric says everything I care about is the end-to-end patient-centric supply chain.

Patient-driven says in the supply network, I can no longer rest on 2 to 300 days' worth of inventory. I want to have really precise amounts of product. The product that you're commercializing, you don't need to go into detail about it, but it's focused on a very specific niche of patients, and that's patient-driven.

The accurate demand forecasts translated back into the patient-driven supply network gives you the whole new supply chain. What are the really big challenges? What keeps you awake at night?

David: It's a really good perspective, Roddy. Part of way that I've always looked at clinical supplies and the patient focus on clinical supplies is that it's always been there as we've talked about. What we're starting to see is when you build up that cohesiveness within a supply chain and within a focus of an organization, technology starts to build in.

Clinical supplies always used IRT as a way to track drug and drug use at a patient level. If you start to expand that out and actually look into commercial supply chains now, that's really the track and traceability aspects that are being involved within companies like TraceLink.

It's really looking at how that patient of a model is really starting to build out in commercial supply chains as well. When you look back at the experience I've had within clinical supply, it is almost mirroring the deliveries that we want within a commercial supply chain as well.

At the top of the hierarchy, its demand forecast accuracy. At demand forecast accuracy, you're starting to see clinical organizations and commercial organizations start to look at data and start to look at analytics to help them find these patients.

To become more accurate in terms of where they're located. How they're going to be dosed? How they're going to be supplied?

The demand forecast is going to become much more accurate. Really the supply chain organization has started to become much nimbler in terms of what they're driving at. As you pointed out, we're not going to have that excuse anymore of demands being off. Demand is going to be very accurate. We're going to be able to provide the supplies in a very effective and efficient way.

Roddy: That's a really interesting point of view. I would imagine that as you now have a overarching patient-centric versus just a patient-driven role, getting that demand forecast accuracy as accurate as you possibly can is probably one of your biggest challenges.

The industry still lives in the hangover shade of a few of the big \$1.6 billion fines that pharma companies got for sharing patient data across the community.

What are you doing about that demand forecast accuracy? Because not only is it key to what you're building and commercializing, but to all the clinical trials processes as well. Thirdly, to all the suppliers that are feeding into CMOs that are making your product.

It's got to be the one factor, the one capability that keeps supply chain officers like yourself awake at night.

David: It does. There's also a way to look at it from different levels. I typically look at process, people, and technology, when I look other solution like this. The connection with the demand generators in our case, it's clinical or commercial.

They need to understand why it's important for supply to understand the demand forecast accuracy. We build relationships with those organizations so that they become more attuned to why that information is so critical to downstream activities.

Roddy: That's a very powerful point. I'm going to harp on that a little. You said, "Build relationships with downstream partners."

Now traditionally, and you know the story, but it's a big pharmaceutical company in Europe, where I was standing with the head of tech ops. I said to him, "Why don't you work more closely with the account managers on the sales side?"

He looked through his window and he said, "Roddy, you see that building over

there?" He said, "That's the sales building. I'm not really welcome in that building." That used to be the perspective for the chief supply chain officer.

When you talk about building closer relationships to understand the drivers of patient demand rather than just the numbers of usage, that's got to be a huge new scope for a chief supply chain officer. Who do you have and who do you work within the organization to make that happen?

David: What we've been doing recently is we work with, not just the commercial organization and the program leads, to help them understand. Also starting to dig into the informatics, the data scientists, and really start to build that relationship so that everyone really understands the importance of where we are and what we're trying to do from a supply perspective.

It's really interesting because obviously we are in a COVID type environments, so a lot of these relationship building is occurring via just like we're doing now, Zoom meetings and webcams. It's working.

We're able to connect up individually with the teams that are located in Europe, East Coast US, West Coast, all over the world, and have these types of dialogues to help us understand the importance of this information, the demand forecast accuracy. How that translates into a supply plan?

That's really been a part of the missing elements for the sales and clinical organization, is understanding that translation. Why it takes so long to receive medicine over a period of time?

We've really been able to articulate that in a way before the demand starts to hit, before the supplies are needed at large, so that we can start to build in a good plan in terms of what we're establishing, and how we're going to deliver the supplies longer term.

Roddy: Great points. You leave me piece by piece into the next part of my

discussion. If you think about outside in, and building AI, and machine learning models around patients and the data to desensitize patient privacy, etc., and not to bring out individual patients.

The point is, when you can build a model of patient demand and use that in your planning systems to go back, you can actually start looking for questions you could never answer before, because you look for the patterns on the patient side. You can very quickly through the model, analyze what is the impact on all the various suppliers.

My point is, we're going to see this exact scenario, play out with vaccines. It's one thing to have an approved vaccine, but it's another thing to get two vaccinations of every dose to every patient, and every person on this planet, including all the labeling, the track and trace, the supply, the vaccine material, etc.

That's how we're going to have to think about it. It's interesting to note that you work so closely with the informatics and the point being, let's try and formulate the questions that we never knew we could answer before, and how they translate back into the supplier network, and to the CMOs who are doing various things for us.

Dave, if I was an investor or a leader looking to sponsor any new commercial venture in patient facing supply chain in the newest cell and gene therapy domain, what's the one piece of advice that you would give me to say, "Look very carefully at this capability"?

I'm conscious that I'm throwing too much into this, but the five-stage maturity model you know really well. If you're sitting in a stage two reactive project organization, you're not connecting the dots.

Tell us a little bit about the advice you would give a chief supply chain officer starting in a cell and gene therapy operation. I know you've just started, so it's advice to yourself.

David: Roddy, what I've been looking at, I think you've done a good job paraphrasing it. It is trying to take a demand and convert it into scenario planning. We're fortunate that working with our IT organization, there already are a lot of great data platforms that can enable scenario planning for a variety of supply plans and demand plans.

That's where we are. The first investment is around making sure that our data connectivity is in place, making sure that we're able to look at our scenario plans and convert some discussions that we have in terms of what markets we want to go into first, second, or third, into actual models that then can translate into supply planning as well.

That's one of the key areas that we've been involved in. We're then looking at the people that are associated with each one of these areas, and how do we integrate the people who manage, for example, external manufacturers into those conversations?

How do we bring in extra manufacturing, to sit at the same table, as we're talking about scenario plans, so that there won't be any surprises? We want those guys to have the same level of information that we do as a sponsor, because it's so valuable for their response time to understand what we're looking at.

To get the true and actual demand data that we require for them to actually provide the supplies. It's been very advantageous so far.

Roddy: That's a nugget. I'm now going to paraphrase you because you've left us with a fantastic closing thought. We all, in the technology industry, we pay a lot of attention to use cases. Rightly so because if you don't start off with use cases that are applicable, then you're probably on the wrong ship.

If you start off with a use case, and then within the use case, you look at the personas and the stakeholders. You talked about the people. Agile is people process technology leadership. You have to connect the dots back to the

leadership and back to the people, and then you talk about scenarios.

You talk about all the various scenarios within that use case involving the different groups of people, and what they're going to do in connecting the dots around the same table, around planning. That is a fantastic nugget.

Whilst it sounds very simple, I know it's not. I know that somewhere lurking in that stakeholder group, our procurement people who're working to a budget, and I know you have a background in that as well.

As a last statement, how do you manage those procurement and sourcing and hardcore numbers and metrics driven people who are going to say, "Hey, that's not in our budget"? How do you manage that?

David: Roddy, that's a good perspective, and a good question as well. I think part of what it becomes is, if we look at what we're trying to build, it is something that hasn't been done before.

It's really around change management and being able to bring all members on to the team before they happen. Here I am looking at building out a commercial supply chain, and one of the first folks to actually bring on is procurement.

I want those guys to be able to be embedded at the very beginning of the process, because of what you indicated. We want a lot of the data sharing. We want the informality, if I can call it that, of trying to meet demand and supply, somehow negotiated into the contract so the participation is in place.

We'll be more apt to get available capacity. It's those types of things where we will want to bring them in early. We do the same thing with our finance folks as well, to make sure that our fees and our payments are in accordance with not just what we want, but what they want as well.

They're going to be building up a different relationship with us than we've had with

other partners, and that's what we want to do, is build them in early on and make them part of our almost like an external team, but more internal than external, if you understand what I'm trying to say with that.

Roddy: Dave, given your new role, and this is obviously a new organization, new product you are commercializing. I think that must be a really interesting challenge. Talk a little bit about how that is different.

David: Roddy, I am incredibly fortunate to be able to start a new supply chain without any baggage, without any leftovers or hangovers from any other challenges or any other opportunities that existed before us.

I find it to be an incredibly exciting time to grab on to the technologies that currently exist and build an organization and infrastructure on, what I believe will be, the platform of the 21st century. Probably one of only a handful of companies have been able to do this.

I'm looking forward to taking advantage of all of that technology to enable our business processes to become incredibly effective.

Roddy: That must be really exciting, as a last comment before we close out, because you get a chance to get outside the box. The problem when you're in the box in a 20-year-old company, you're going to hear, "We never did it like that before. We can't do it like that, because we're not set up." You don't necessarily...I'm not saying it's easy.

Let's simplify ourselves. You don't have to live with those old cow paths. We can't do that. You have a leadership organization that wants to be successful, is prepared to get out the box, look from the patient back at the supply chain, and build the supply chain as it needs to be.

Roddy: That's got to be massively exciting, and I really hope that you are hugely successful in that role.

David: Thank you, Roddy. Now I'm really looking forward to taking part of this journey.

Roddy: Awesome. Thanks, Dave. Thanks, everybody.

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