

Orchestration in Clinical Trial Versus Commercial Supply: Key Insights and Opportunities

Supply chain digitalization and orchestration can transform the commercial supply chain, improving key supply KPIs, reducing risk, and increasing agility. But how will digitalization impact the clinical trial supply chain? In this video, Antonio Tramontano, Digital Strategy Leader and Life Science Supply Chain Consultant at Genpact, takes a look at:

- How clinical trial supply is structured and organized from the perspective of the life sciences company/clinical trial sponsor.
- How clinical trial supply is both similar to and different from commercial supply.
- Key supply chain challenges faced by the clinical trial sponsor.
- What leaders in clinical and commercial can learn from each other.

Tramontano also provides actionable steps to enable clinical trial and commercial supply chains to collaborate on innovative digitalization solutions that improve visibility, intelligence, and control. Watch now!

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TRANSCRIPT

Antonio Tramontano: Let me start by saying that usually, the clinical supply is a little bit unknown to many people. Perhaps this is obvious for you guys in this room, but every pharma company runs two types of supply chain. You have the commercial supply chain and you have the clinical supply chain.

The complexity from clinical supply chain is that it deals with a lot of stakeholders that typically are not the traditional one that you deal with in the commercial supply chain. On top of this, the clinical supply chain has to deal with patients, hospital, physicians, and so on.

If you look at one pharma company having both commercial and clinical supply chain, the network that the pharma company has to connect is way bigger than we usually think. The complexity coming from this is exactly what Jitendra said.

The input from the forecast come from the physicians. The forecast of clinical trials is a patient, is not the drug that you give. Sometimes you need to connect, this and this with manufacturing. This connection goes through many, many nodes and is complicated.

Sometimes you need to make sure that the logistic providers ship the drug perhaps at home. Also there, is a lot of complexity that really require for a strong effort to improve orchestration. Having a digital orchestration, I believe, is an imperative because as Jitendra said, do you really want to manage all this complexity on Excel emails? It's not sustainable anymore.

Let me take a step back because people say, at the end of the day, is just supply chain. Here, you deal with commercialized products and big volumes. Here, more or less, it's drug products anyway. Not really because clinical and commercial supply chain have different scope, different structure, different focus area, and of

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course, their own challenges.

The scope, the clinical supply chain deals with clinical trials execution, not with commercial and approved drugs. The regulatory and compliance element in that is super strong, and the real customer, so to speak, is the patient. Sometimes we are talking about life-saving drugs.

On the other side, the commercial supply chain has to make sure that everything which is commercialized [laughs] goes to the market and so on. The structure. The clinical supply chain is way smaller than a commercial supply chain and deals with small batches, as also Jitendra said, but has to achieve the highest precision possible in the delivery.

When I was in clinical supply and I was managing this type of challenges, we were measuring our own time in full delivery. For clinical supply, it was 99.8 percent. Honestly, it was seen like, "Oh, we need to achieve 100 percent. We've seen room for improvement."

If you would have 99.8 percent in commercial supply chain, I can tell you they will drink champagne every month. You can understand how different it is because if you miss an appointment with a patient, you are going to get a division. FDA is going to be on your neck. You need to put a lot of actions in place, and this could even delay the launch of a drug or make the trial more complex.

The reason why it is so expensive to launch a drug is because you need to deal with all this type of complexity. This is why in terms of key focus area, while commercial supply chain is more focused on efficiency and scalability, the clinical supply chain is really focused on operational excellence to deliver drugs on time, in the right place, at the right moment.

Clinical supply chain is definitely strong in execution, commercial supply chain, to achieve efficiency, I would say, is stronger in planning. I was in IT commercial supply chain, so I dealt with a lot of projects in this area.

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I'm not going to repeat what you already heard, but you can see challenges in clinical supply related to the forecasting. How you can forecast according to patients when you have such dropout rate. How you can really get the full [laughs] trial demand and visibility across all these nodes and all this change. How you can deal with all the costs, regulatory needs.

All those are daily challenges. On the other side, you need to deliver big volumes, you need to deliver drugs fast, and so on. The demand and supply balancing is more the challenge that every day, a commercial supply chain has to foster.

Remember what I just said. Commercial supply chain is a little bit better, much stronger in planning, and clinical supply chain is way stronger in execution. What are the opportunities that those two organizations working within the same company can have to learn from each other?

When I look at clinical supply, clinical supply is very strong, as we said, in running operation, but there could be new ways. They can learn from commercial supply chain how to do planning, for example. Think about how enhancing demand planning by having more data, for example, patients enrollment and so on, to improve the quality of the forecast.

At the moment, I can tell you a pharma company is looking at the number of patients, and in order to avoid any type of stock out, is adding 100 percent average [laughs] on top of their number of patients that they think they are going to have. I believe there are better ways of managing with this way of planning.

Of course, they could also implement functionalities that in commercial supply chain are mature. For example, what if scenarios or scenario planning, constrained and unconstrained planning.

Those are something that today, very likely are managed in Excel [laughs] in clinical supply, whereas there are sophisticated advanced planning tool that do this since long time, for example, Kinaxis and so on.

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On the other side, commercial supply chain can really learn from clinical supply. I love the examples that Jitendra made. Think about personalized medicine cell therapies. The business model also for commercial supply chain is to deliver the drug to the patient.

This is a new business model for a commercial supply chain, but they can learn from clinical supply chain how this can be done.
They can become a little bit precise in the delivery timelines and also learn from clinical supply how to scale up or scale down based on the...Because we are not talking about, especially for personal medicine, we're not talking about large batches here. We're talking about doses.

Sometimes it's an autologous cycle. You take some blood cells, you do some magic, let's say, and then you re-inject them into the body of the same patient. Imagine if you get the blood of another patient. You will read [laughs] on the news the name of that pharma company the next day, I can tell you.

Both, although they have different needs, they have different strengths, they have one common need of creating a real supply chain infrastructure to connect all these stakeholders in one because also the transition from clinical to commercial has to be smoother.

Today, it's more like throwing things over the wall. If before, we said that [laughs] the slide was confusing, actually, I feel that today, the integration between one pharma company and the suppliers, and IRT vendors, and so on, it looks more of a spaghetti architecture with point-to-point.

If you expand this even to the full environment of life science, it's even more complicated. Look at the Thermo Fisher of the situation. Perhaps they sit here and they connect to more than one pharma, and then perhaps both pharma have to go to the same clinical sites.

All these things are managed with point-to-point interfaces. This means that there

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is lack of supply visibility, the handoff of the data is complex, and of course, is very costly. Every time you have a regulatory inspection and so on, to be compliant is also very heavy. Of course, there is a limited traceability.

That's why the future has to look different from point-to-point integration. I loved what I've seen this morning from Shabbir. We should move to one agile and integrated supply chain network where the same integration is happening seamlessly. This will create value for all the stakeholders.

Instead of addressing the same challenges in silo, let's join together our forces to do it in a way that the customer of a Thermo Fisher and the Thermo Fisher itself are addressing the same challenge at the same time. This will create value. It will eliminate key pain points and also will unleash new opportunities.

Today, it's very difficult to manage the data. Imagine when you will have the data at your fingertips, what type of analytics, what type of information you can derive from this data? Perhaps we can open a new era of, for example, analytics running on clinical data, which can help also the time to market for commercialization of drugs.

Let me then give you the main takeaways, and at the same time, also some food for thought. As we said, clinical and commercial supply chain, they belong to the same organization. They might be seen as one, but not the same. Clinical supply is stronger in execution, commercial supply chain is stronger in planning.

They can really learn from each other, becoming better respectively in execution and planning, but building a unified infrastructure need is essential for both. At the end of the day, if you want to have an Andover from clinical to commercial, having one extended supply chain beyond the four walls is really important to achieve, especially end-to-end visibility.

That's why I loved what Shabbir said in terms of building a network of networks because at the end, you don't need to build every time a point-to-point interface,

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which is difficult to build and costly to maintain.

If it is already there, it can allow things to move faster and data to be more trustworthy. This can help also to manage all the risks that are with the launch of a drug together.

Let me give you another example of one figure that for me is astonishing. Because of the way of operating in clinical supply in terms of adding average or not having visibility, or to do all the best to avoid a stock out, 70 percent of all the materials that the clinical supply is dealing with is waste, ends into waste.

One of the reason why launching a drug costs 2.6 billion is because there is a lot of waste produced. Definitely, there is more production than actually the dispensation of the final drug. Imagine if you can start to have information along the chain, better information about the data, better traceability, and you can react much faster if there is a supply chain breakdown or crisis.

You reduce the amount of waste. It means less cost to launch a drug, and perhaps faster access to the market. You can do this only if you really are able to orchestrate every single node in your supply chain. To do this, you can unlock, again, new opportunities, and you can foster better operational efficiency.

I believe that what I just said and what you heard before in the previous session really resonates. They also explained why digital orchestration, especially for clinical supply, it's something that every pharma company needs in order to improve.

The ultimate benefit will be for the patient, rather than for the pharma company itself. If you have questions, I'm open. Yes.

Audience Member: I think Jitendra, I have a question. Maybe it's for both of you.

Antonio: Sure.

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Audience Member: Jitendra, you mentioned GS1 and identification of clinical trial medications. In commercial, we have the famous for the product code, and the batch, and the X-ray and the serial. What's the thinking for identifying clinical trial medications?

Antonio: GS1 is a standard that I think is pushed to be adopted in the clinical trial operation. When I was in, let's say, in pharma, the challenge was to adjust every system that we have to [laughs] have that terminology.

This means going, for example, to SAP, you change all the tables, all the fields. Guess what, expensive, it will take years, and so on. I think the secret would be to have a platform that can do this translation.

I can still keep my source data in the way I know I'm more familiar with, but make sure that when I move the data from one party to another, perhaps there is an integration layer that can adopt the GS1 layer. The data that is reaching my stakeholder on the other side is translated according to the GS1.

Especially for compliance reason, if we can give already the data to our regulatory organization...

[background music]

Antonio: translated according to the GS1 would be, I would say, a very good opportunity to save money.

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