What's Coming? Clinical Trial Supply, Transportation, and Cell and Gene Therapy

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Tereance Puryear: Is anyone in here in the clinical space, been in the clinic clinical space? Companies are, of course, [laughs] even they've been there, or anybody's companies who are exploring the clinical select space. The clinical space for MINT, I didn't say this in our previous talk because we are moving some things around, but MINT in of itself was not initially meant to be an execution system.

When I say execution, we never wanted to initially replace an ERP out of the box. We didn't want to be a TMS system. You guys have these things in-house, and our initial goal was to bind them together. The same applies with the clinical supply chain. If you've ever been near it, my friend in the back has, it is a very complex process that involves a lot of people, players, entities, and systems as well.

There are a lot of adjacent systems that go into the clinical trial process. One of the big systems that comes to mind are the IRT systems. Those are the systems that randomize the trials for the studies. I think RTSM is one of the newer variants of that, more improved on the technology side.

The idea is that if you think about supply chain as we talked about the orchestrations before for the CMO, MH idea, there's typically a sponsor or the manufacturer who wants to do a trial. When they start the trial process, their idea is that they need to randomize it themselves if it's a double-blind study. If it's not a double blind, they can do the randomization themselves internally.

The data passes through the system, and it follows the same logic of integrate once to do those transactions that sit in the box to my left. Where we found some traction with MINT was that, remember, I mentioned that every pharma company may not want to be an IT organization, they may have IT functions that support the internal work, it's the same concept.

Nothing in the supply chain works inside your four walls unless you're a vertical company, which those ended in the 1930s in most worlds. The idea is that you need to exchange data

with multiple parties outside of your four walls. MINT can be overlaid into this use case.

As we work with the downstream where you get the blinded study going down to the dispensing location and upstream to the manufacturing process of this, we can exchange data similar to the purchase order, similar to the idea of more so around inventory balance, the ship order request, move their product from A to B, what are the inventory balances in these locations?

As we look to connect them, we leverage the same logic. No matter the data from the system we're supporting, we build the maps and the transforms to support it. The data gets added to our canonical model. We're now able to easily transact that data between two entities.

This is just an extension. We enable companies that we talked with today. They have a massive IT organization in-house that are doing a lot of things around the clinical trial space, but that's just an internal. That's in-house. That's only their own systems they have to manage.

The simple thought of now having to turn to the left, create 20-plus integrations, the IRT systems as they're called, they can multiple IRT systems in a space. One manufacturer can use multiple IRT systems to share clinical data. The IRT systems can be a support system for multiple manufacturers. Every time you do that, that's a new connection that you have to make to support this process.

As I'm speaking about clinicians, not a lot of people here are on the clinical trial space. Even think about that application to the rest of your supply chain, you have multiple customers. You have multiple suppliers. You have multiple warehouse locations. The sheer idea of integrating every last one of them, that point-to-point idea, it is cumbersome.

In clinical trials, and we'll talk about cell and gene therapy a little bit afterwards, time is of the essence, and a lot of dollars are invested in these processes. The last thing that people want to do is spend more money to make it work and it's not going faster, and also to waste money on investments that are not improving the clinical supply chain.

We want to take again the burden off of these companies to say, manage your internal systems, show what you're experts at, let us handle the integration between two parties to share information around the transaction. Some of the transactions, like I said, are very much similar to the ones we've talked about before.

You get to the bottom, you see the receiving advice, more so the dispensing advice, drug return order, the destruction confirmation. Again, all of these are transactions that can be digitalized, but these are also actions that happen today over email and PDF, destroy this, move this, do that.

If my inbox is backed up like mine is every day, I'm not doing that in a timely manner, and I'm not making this supply chain speed up any more than what it is today. Again, if you're in the clinical trial space, we're going to have a conversation. We're definitely open to it. We are moving a lot in this space. GS1, for example, the global standards, they are starting to roll out.

If you go to their website, they are starting to roll out standards for some of these transactions to help the industry. There are some industry leading companies who've sped ahead of that because they want to get ahead of it in a digital space. Again, they're still working internally.

They want to get outside their four walls, but the idea to digitize, I think for whatever reason, this space caught traction really, really fast. I think because of the nuances involved in it, people want more time to focus on the actual business as opposed to connecting the

dots to get the data faster.

Moiz Khanbhai: Transportation transaction. The earlier conversation when we're talking about logistics, there wasn't any questions around, what about where's my goods physically? Is it on a truck? Is it going by plane? We hear a lot of companies wanting those transactions to be brought from TMS systems into their own environment.

We've got a few examples here in terms of booking requests, the booking confirmation, bill of lading manifest, etc. Whilst this sounds simple, actually, in the actual transportation world, depending on the mode of transport, there's, I think, in total, 40 different transactions that cover that specific area.

Just out of interest, again, show of hands or feel free to speak out, does anyone get these transactions from logistics 3PL companies today, whether your goods are going on by rail, road, sea, plane? No?

Audience Member: It's sent by email.

Moiz: It's by email. Is it just a very simple email that just gets sent to someone within the team around this batch, or this number of goods is going by this this carrier?

Audience Member: I just know that the request follows a certain email type with the references, but then I don't know how they get the answer. I suppose it's the same. It's quite standard, but it's an email with each topic. The air waybill number, the flight numbers, and ETD, ETA.

Moiz: That information, then you type that manual back into maybe an ERP system?

Audience Member: In another email to the customer.

[laughter]

Moiz: Would you see value of having that information digital directly into your ERP that can group the whole order together?

Audience Member: Yeah. Also with the price which might be forecasted, and see if it is actually invoiced, what was planned.

Caitlin: Yeah. That's a really good point. Sometimes the weights change. Maybe they added an extra pallet or something, and so the weights change, which means your cost of the shipment, the tariffs, or the taxes that come along with the fees of processing things. For our next event, there's going to be some more handouts. I'm your fun handout person.

We ordered them from the US, but they were manufactured in Canada, and then they were shipped here to Spain where they got stuck in customs for a couple of days because our Spanish office needed to work out some kinks. Then someone had to go down to the office and pick it up.

Logistically, it would have been really great if we had some tracking numbers on these things to track them through the system to get them here. Nowadays, even flying here, how many of you have air tags that you put in your suitcases? Just a show of hand. I know I've seen them. As soon as you land, you're opening your phone, where's my suitcase? You're hoping it's on the plane.

You're hoping that the dot's going to show up in the country that you're currently standing in. Is it in your airport? Or even better, when it gets lost and then you're showing whoever the TSA agent is, no, it's here, it's on the other side of this wall, I can see it.

To have that sort of insight into something that arguably is more valuable like the pharmaceutical industry, not that your luggage isn't important, of course it is. From that perspective, if we can do it with our suitcases that's assumably in the plane, which is also

traveling with us across the country, wouldn't you want to have that information on your drugs as it's transported through the entire network?

Moiz: It becomes more complicated when you have temperature sensitive drugs. You want to know your goods are sitting on a tarmac in Dubai at 40 degrees heat or 50 degrees heat. Again, you just want to know that because either that complete batch needs to be disposed of, or you can get on it straight away to make sure that it's moved to a container which is controlled by temperature.

Audience Member: This will not help identifying where the pallet is, for example, if there were two flights and it's in transfer.

Moiz: Sorry.

Tereance: No worries.

Moiz: With transportation transactions, again, what we are looking at is also doing integrations to other systems with the tracking IoT devices that are within that shipment so we can actually monitor the temperatures, if it goes +/-2 degrees, whatever it may be, whatever tolerances are set up, you can send information back to you to alert you of that fact.

Audience Member: Invoice number or with the [inaudible] number...?

Caitlin: Through the documentation. This is not all the fields. This is just some of them that are commonly seen, but we can certainly add or remove fields that are relevant to you and your business.

Audience Member: Oh, just to understand how we can ensure that the product was shipped at the right temperature, for example.

Tereance: IoT, yeah.

Audience Member: The error ID?

Tereance: Well, the IoT devices allow you to do that. A lot of companies are implementing them for temperature, is the first piece, time out of refrigeration is another one that's very common in this industry. If you look outside of pharma even, IoT is a big thing, road speed sensors.

I can't remember the term properly in my head, but if a pallet's been bumped, there's a sensor that determines how much the pallet may have moved from a bump or damage. There's lots of ways that we are able to integrate and grab that data. From my prior life, this transaction set was used in conjunction with a lot of APIs where you get real time along with the status update.

The status update may have come with a geofence, the IoT of temperature at any moment in time, so you can actually physically track. A lot of that's dependent upon the carrier and the mode type. There's a lot of ways you can leverage the transaction to pull in more data and feed the system. Again, we can bring it all together, and Josh is in the room.

We can bring all this stuff together, but the idea also is what carrier are you using? Do they have those capabilities, or is that something you would, as a strategic partner, want to invest in them and say, for all of my shipments, I want temperature sensors embedded in mine? I want geotracking to know where it's going for certain shipments and things like that.

A lot of 3PLs and transportation companies, those are accessorial charges where they upcharge you for more features, bells and whistles. They nickel and dime you, essentially, but it's capable through this transaction set. It gives you a lot of information down to even

the stop level.

If your pallet is on a large trailer with multiple other stops, what stop number are you in line even? You can go that far down, but it's dependent upon the carrier and the mode that you use to tell you. If you get into ocean, tons of other bits of data that can be baked into, that's actual transaction set.

Audience Member: Maybe one step back, because it's nice that we can track everything, but when you think about that, even if we have not...I don't think I'm long enough. Otherwise, explain to me. We need to think about to serialize also clinical products not by legal law because we need to have the possibility to trace them.

Therefore, you need, for sure, a serial number or something like that on it. Therefore, also, this is what I discussed with your development team that you need to implement or to think about, don't use a GTIN because it's not a logistic product anywhere.

You need to have the possibility to mark your products from a internal material code, I would say. Build up a pool based on these numbers, and then have the possibility to trade them through the whole supply chain. It's like COI, chain of identity from the start of manufacturing until dispensed to the patient.

This is not possible right now to speak about transportation. It's quite OK, but it's not really a traceability because it's based on an SCC, something like that, but you don't know which product exactly moved that way. Here, Boris, maybe what is your solution here to implement TraceLink to have this capability?

Moiz: That's a tough one.

Tereance: Yeah. I would say it's a deeper conversation. I follow where you're going. I've had some of those chats before from one of our other products called supply chain work management, which was slight predecessor to the current version of MINT.

It was more about the people to people, but there was a use case that came up where they said, I want to track true end to end, I want to know every step in the life cycle. To your point, that does require the entities. Outside of maybe tracing, we can, of course, support, I think, that conversation.

Is the plan to serialize every single product, even ones that don't require serialization, and use that as an identifier? I can tell you, and Josh can correct me here, I think any bit of data can be stuck anywhere to be used in any kind of purpose if we really put our minds to it. If you told us there's an identifier that you want to send somewhere, we could make that actually work.

I think from an industry perspective, it's a good conversation to have of, do we serialize top to bottom to be able to track end-to-end and even back up? It's got an identifier on it in the transportation world, in the ASNs even. In ASNs, there's a space for a serial number in a traditional transportation ASN.

To ask the question I know a retailer I used to work with, they have flex fields in a lot of their schemas for their transactions that allowed custom data fields. We will receive that custom data field. We knew where it mapped to, and that gave visibility to whomever needed to use it wherever they need. I think it's an industry conversation.

I would argue TraceLink can support it, but I am not the product owner, so I won't say we'll do it today or tomorrow. If you've raised the conversation with our development team, they're probably working on it.

Audience Member: You mentioned the GSBEM membership, the group is also creating for clinical trials or also personalized medicines, something like that, but there's no stand up

right now set. Nonetheless, you're speaking a little bit far ahead from my perspective to trace something, but you don't know what you trace exactly. Certainly, these products are very cost intensive.

For these degrees/diseases which are related to, it really makes sense to invest here something a little bit more and to go in a little bit forward. Therefore, we need also the solution designer to have capabilities, I would say, to rate your system to have such flexible, to have this capability to do it not on a legal law base, more as an advantage to have the whole traceability in the supply chain.

Tereance: Yeah. I think that's the easiest case, I would say, we're open to talk about it in documenting because the industry drives a lot of what tracing is. Caitlin and Moiz have been here longer than I have. The industry drives a lot of tracing. Caitlin has been in it more than I have. The industry drives a lot of innovation that we've created across our products, I would argue to say.

Caitlin: We're involved in the conversations too. Speaking of the GS1 clinical trials, it's not just a transaction we've heard about, we're involved. Personally, I was last year. I spent a lot of the time on the GS1 calls talking through the clinical transactions. Elizabeth Waldorf is another representative. You're nodding your head. You've probably met her. She's in a lot of our GS1 talks.

We're involved in a lot of the organizations around the world just to be involved in that conversation. Not only can we learn from it, but help inform it as well, especially in the clinical trial area. I know we're on the transportation side, but it sounds like a similar PO, but it's not.

With the randomization the blinded studies, there's a lot that goes into it where you still need to track very granular what goes in it, but you can't tell people. It's a blinded study, so you need to know what's going from [inaudible] , but I can't tell you what you have.

Tereance: It's pretty identifier driven.

Caitlin: The way to associate all the information back to each other so that it's all nested from the owner of the study or the IRT, they need to know what's going where, but to the recipient, you need to know some of the information, but not all of it. How do you convey that in a way that's standardized but also informative? That is what the GS1 group is working on. We're very involved in that conversation as well.

Tereance: I'll touch highly on cell and gene therapy. Anybody involved in cell and gene therapy, has been, or is planning to be? Somewhat similar to clinical trials, minusing the idea that this isn't blinded, this one does look at the idea of chain of custody. From when it leaves here to go there, to go there, it has to be tracked and followed.

The interesting thing about cell and gene therapy is time sensitive. The vein-to-vein time is just extremely, extremely short, and so it's very, very key to lift yourself out of the manual space. Everything I talked about before on manual, it's less prevalent, I would say, in cell and gene because I think the industry understands that it's time sensitive.

However, if you're still doing things mainly, you have an opportunity to expedite the process. We have done the research. Our VP of product, Lucy D'Souza, who was not able to be here this this week, has done extensive research on this with our product team to understand, again, where we sit. We're not trying to be a cell and gene therapy orchestration system for the actual patient side.

The idea that the transaction sets you see on screen are very much relative to what you guys saw prior to in our earlier discussions, it's the same concept. Someone has to initiate a purchase order. Once that's done from the hospital level, even that idea of a purchase order

has to go out for manufacturing processing to come back into the hospital system.

I'm circumventing the processing in the interest of time. The idea is that we're able to work with the various systems in the cell and gene space, connect into them, and start that conversation to understand, we know the transactions that you guys support. We understand the systems that are out there. We know we can connect to them.

How do we best do this to support the industry and fill the gaps? The gaps that we've understood have purely been around how to get the data to move faster and simpler without me sifting through an email box. It's almost an identical conversation with the rest of the transactions. What we're looking at is being able to track the chain of custody through the datasets we're able to support.

We hope to have better on time supply. I say hope too because I'm the optimistic pessimist of the group. I always say in salute, technology is also an enabler. I'm giving you a better way to do your business. Hopefully, the people involved on both sides are doing it, but we support the idea for on-time supply if you digitize the transactions having to go into the right parties and players.

You minimize the, again, the manual interaction of bad data. Did it go to the right box? Moiz has a favorite, with someone on holiday or had to leave the office, that's that single point of failure. If it's not in the system, I can't log into Moiz's' inbox to see the emails he's had. This is a common problem.

Again, cell and gene therapy, since it's time sensitive, we've seen a lot of traction in conversation around the space to support the transactions on screen. As we learn more and as we get more into it, I'm sure there are going to be more transactions that are going to pop up our ways we can leverage data to speed up the cell and gene therapy process.

There's two conversations I know, I think, Thursday and Friday or two on Friday around cell and gene therapy. I'm part of one of them. They go deeper a bit. This from the MINT perspective, is how we look at supporting this process. Again, if you look at the visual from what we spoke about before, MINT is positioned to enable and connect.

Again, let the cell and gene therapy experts do the work and end in the supply chain. Take the manual data work out of their way. Get them some consistency, as I'd like to call it as well, but also the visibility of what's going on. Where's the product? What's the timeline to get it back? Do we have proper production status and information that's been passed across the entities?

Is everyone aware of what's going to happen? Because when that patient in this space comes back in, the process is get them in the hospital and get the drug and the cell and gene therapy process closed on the other end, vein to vein.

I'm a big non-bloody talk person. Very squeamish, so I dance around some of the terminology. The idea is that they can leverage the platform, and not even on the system-to-system, but also use the system-to-person or person-to-person to digitize as best they can where they are with the systems they have.

[music]