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Reduce DSCSA Costs and Accelerate Supply Chain Digitalization with a Network Approach





DSCSA will require organizations across the pharma supply chain to implement a fully interoperable system for EPCIS data exchange by the end of November 27, 2023. How will you cost-effectively achieve secure, electronic interoperability before the deadline? The **TraceLink digital supply network** is the answer.

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- Discover the business benefits—including significant cost savings—of executing EPCIS transactions on a digital supply network that uses a canonical data model.

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Transcript

Dan Walles: Good morning, everyone. It's good to see everyone again as we move into the next topic of our deep dive session, deep dive topics related to DSCSA the 2023 requirements.

Today, what we're going to be reviewing is how to reduce the overall cost of DSCSA. Particularly around the integration challenges of working with your trade

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partners, whether they be your suppliers or your customers. In doing so, being able to accelerate your opportunities for supply chain digitalization.

Today, I'm joined by one of my colleagues, Bharath Sundararaman, who is our general manager of the intelligence supply network solution area within TraceLink.

My name is Dan Walles. I'm the general manager of the track and trace and compliance business here at TraceLink.

Just as a reminder, the Deep Dive Webinar series, which happens every three weeks, really tackles topics that are common across manufacturers, wholesalers, and dispensers. We had a session a few weeks back talking about the importance of standards within the industry.

Today we're looking at the overall costs for DSCSA. Right before the holidays, we'll be taking on a topic where we dig a little bit deeper into our product, where we look at compliance on TraceLink's OPUS platform, and then at the beginning of next year, starting to look at some product demonstrations and doing some end-to-end demonstrations around DSCSA exchanging data, verification, and exception management.

We hope that you join us for these upcoming events. If you weren't able to make the previous one related to standards, that information is available on demand through tracelink.com. As we dig into today's session, there's a couple of key things that I hope folks walk away from today's session with.

That's around digging more into this move to item-level traceability as we head to the November 2023 requirements for DSCSA.

As we move into item-level traceability, it's really creating a pretty substantial set

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of requirements as we think about exchanging data with our customers whether they be wholesalers or retail pharmacies, or if you are a wholesaler, or retail pharmacy or health system, receiving information in from your suppliers.

What we want to spend some time digging into is really looking at different architectural approaches to solving this challenge, which is...those that take on a point-to-point architecture versus those that are more network-oriented.

Then we'll follow up that topic area with what we believe is TraceLink's differentiated advantage and value, which is our network architecture, as well as our network services team, which for many of our customers that are on the line work with on a regular basis.

Point to how the combination of our network architecture and our services organization can help you reduce the cost and time and maybe more importantly the risk associated with DSCSA and the ability to be able to accelerate your supply chain digitalization or supply chain transformation efforts.

Before we get started, let me just recap TraceLink, for those of you that are new to us. TraceLink is the largest digital supply network in the healthcare space. We were founded in 2009 offices globally. Our customer base is approaching 1,300, probably will exceed 1,300 by the end of the year. As I mentioned, we are a global organization.

One item I'll call out specifically here is the experience we have today across all segments in serialization. We have close to 900 customers today that are serializing product using TraceLink or managing serialized product in their operations through TraceLink.

Those range from pharmaceutical manufacturers to 3PL, CMOS but also wholesale

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distributors, as well as health systems and retail pharmacies. Another item that I'll call out here is this concept of a ServiceLink.

What we mean by active ServiceLinks is, this is essentially the integration and connection if you will of partners across the TraceLink network. The vast majority of those ServiceLinks are companies that are exchanging lot-level DSCSA information.

What we're talking about as we move to 2023 is expanding those integrations and those ServiceLinks with customers to incorporate the requirements for exchanging item-level information, EPCIS transactions, and the like.

In terms of size of our company, close to 800 employees, many of them over half of them focused on supporting our customers, developing our products, organizations like our network services team.

When we look at DSCSA, we paint this in the landscape of the supply chain challenges that our industry is facing. Whether we're participating in the receivers of a global supply chain that has requirements and challenges around traceability and transparency, better visibility into material shortages, shipment delays.

We see some movement in certain markets around moving to digital leaflets and in trying to provide more information in digital format and the need for better supply chain collaboration with various suppliers.

All of these different initiatives start to roll up into the need for supply chain digitalization, not just as an IT efficiency but as a business imperative, and supply chains and visibility into supply chains in all industries.

Specifically, the healthcare and life sciences supply chains is maybe more critical

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than it has ever been. When we think about this, it's around being able to build a platform that we start to refer to as the Internet of supply chains that allow organizations to connect people, processes systems, multi-enterprises into a collective network.

That is what TraceLink is starting to move to. In order to do that, it's about being able to create digital networks that represent our business, whether it'd be connecting with our suppliers if their contract manufacturers, direct material suppliers or on the customer side.

If we look at our supply chain here in the US as it relates to DSCSA, being able to connect and interoperate with wholesale distributors starting for compliance purposes, but then moving into other business processes.

Being able to enable the exchange of information bi-directionally between manufacturers and wholesalers, manufacturers and health systems, manufacturers and retail pharmacies.

Enabling these shared processes across a network. I think if you move to the right-hand side here, it starts to focus in on if you're doing this in a way in which you're thinking about not just compliance but leveraging your ability to digitize your supply chain and glean benefits from that investment.

It's coming up with a common data model not just from my own organization that represents the supply chain but represents the network, a common data model for the network.

In doing so, when you create that common data model, you have the ability to start to not only gain full transparency but be able to adapt to changing market conditions and get better collective intelligence across the network.

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If we have a full network data model and not our own enterprise data model, a data model that represents the full supply chain, we start to get very clean and actionable, and timely data.

The message today is really about how can DSCSA help us move down this continuum of a fully digitalized supply chain experience in operating across that network. The reason we think we're well-positioned for this as a company is because what track and trace has done for us, is it has created this Global Case Study for deploying what we refer to as the Internet of supply chain.

Today, what we've worked with many of you on is the ability to exchange serialization information so that we can serialize products, to be able to manage serialized products within our operations, whether it be on the packaging line or within the distribution centers.

Then, today, from a lot-level perspective, but to be able to communicate that information out to our customers, and manage that shipment information, or receiving shipment information. Today, all been driven from compliance. An opportunity for us to lay the foundation for just better visibility into the overall supply chains.

Then, of course, we would be remiss if we didn't recognize the role that master data plays in our ability to create a common language of how we speak and how we interact with each other.

As TraceLink continues to evolve as an organization, our solution suite is increasingly growing to not just focus on serialization and traceability, but looking at the digital supply network, our capabilities to be able to manage that network and administer that network.

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To connect companies across that network in this integrate once interoperate with everyone model, create the catalogs, the map plugins, the data mapping, and then expand that into a low code application development environment. Starts to enable us to solve some pretty daunting supply chain challenges.

Today, we're focused as an industry on serialization and traceability, and regulatory compliance. Specifically, this large requirement in DSCSA that we have coming in November of next year.

Then, expanding that into better collaboration with our partners, moving into network applications like verification and digital recalls, collective intelligence, where we're able to look at the velocity of products moving through the supply chain, across the network, to make better decisions about product availability.

Ultimately, moving into full process orchestration of various supply chain processes. It's important that we layer this in as a backdrop, as you're starting to think about and evaluate your approach to DSCSA. How you're going to meet those requirements.

Do you look at this as a, how do I just check the box or how do I start to invest in a set of assets that are going to be able to provide additional business value to my organization over the next 5, 10, 15 years?

Let's dig into a topic where we want to start to unpack for you, that impacts all of us. It impacts whether you're a manufacturer or a wholesale distributor, a health system, or a retail pharmacy. That's this ability to be able to integrate our partners so that we can exchange information.

We feel it's important that we want to unpack this in such a way that we understand, what is an integration mean, what is a connection mean? This is

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somewhat of a heavy topic. We'll do our best to explain it in terms that we can all understand.

It's important to recognize, so that we don't oversimplify the challenge that we have in front of us, as it relates to DSCSA. The next three slides will take a perspective of each segment in the supply chain. First starting with manufacturers, then moving to wholesalers, and then looking at retail pharmacies and health systems from the point of view of what does it mean to integrate a partner.

If I start with pharmaceutical manufacturers represented on the left here, a very simplistic view of your supply chain is in this middle column. You're interacting with CMOs and 3PLs.

Obviously, you have wholesalers that are your primary customers, as well as retail pharmacies, and then the health systems that you sell into. Today, we are very focused on this first box here in green.

In 2017, we had the requirement to start to serialize all of the products. That involved integration with contract manufacturers. Being able to orchestrate the request and response of serial numbers commissioning, serial numbers that get destroyed in the packaging process.

We accomplish that. Many of you accomplish that. You did it with your CMOs. For those of you that have internal manufacturing capability, you executed on that for your US-based products, and for many of you that are shipping internationally for other global markets.

If we specifically look at DSCSA, now we have to prepare our organizations to be able to track and manage that information throughout our supply chain. We think about how do I get that information and incorporate if I use a 3PL, or in my

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distribution center?

I have to think about now am I transferring information about serialized products to that 3PL? I have to think about aggregation. What are the different aggregation levels that I'm tracking?

The 3PL is managing product that may get destroyed or decommissioned. They're introducing SSCC codes into distribution, obviously, shipment notifications. They may get involved in return products.

Then, exceptions. We know we're going to have exceptions that are happening. If you look at this bucket and for many of you, you have not started that process of integrating serialization with your 3PLs.

This is a sizeable chunk of work that we need to do. Because ultimately, when that 3PL ships out the physical product to the wholesaler, the manufacturer is required to be delivering the DSCSA compliance information. In order for that to be correct, you have to be managing that serialization information within the 3PL.

We look at the wholesale distributor. In terms of your relationship and the integration requirements between the MAH and the wholesale distributor, that integration, that connection when we talk about integrating with a partner, really involves, "How do I make sure they have the latest GTIN and pack-level master data so that they are prepared to handle my product?"

We have to move to this EPCIS shipment notification, which includes the serialization aggregation information. We still want to be sending them advanced ship notices. That's something that was a positive of the lot-level traceability requirements. Is we increased the availability of ASN to the wholesalers.

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Then we have these new requirements that are coming into effect in 2023 around verification for saleable returns, verification for investigations, this ability to do product tracing, and then obviously exceptions.

For many of you, you have direct relationships with some retail pharmacies, some health systems, you may be doing drop shipments out to them. You still have issues where you may get involved in verifications for investigations or product tracing.

I think that the point with this slide here is that as we start to unpack this perspective, and we're not trying to overcomplicate it but just unpack to say, what are the different scenarios that could evolve or that will evolve with my relationships with, traditionally, my direct partners, my wholesalers, but also retail pharmacies and health systems?

This move to item-level traceability is going to require the integration of distribution processes and the orchestration of sending information to both direct and indirect customers, wholesalers, as well as the dispensers. We want to, this misnomer of, "Hey, I just need to send an EPCIS transaction," DSCSA for 2023 is much larger than that.

When we look at this as a wholesaler, your challenges in some cases are larger because you have both sides. You receive product, and you're shipping product out. In your integration with a manufacturer, you have to be gathering that master data, that G10 and pack-level master data.

You're obviously going to be receiving in EPCIS transactions. Product identifier verification, so this might be for an investigation or if you're doing some sort of a salable return. Product tracing, exceptions, you still want to be receiving ASNs.

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For some of you, you may also purchase products from a secondary wholesaler, so you have this wholesaler-to-wholesaler relationship that you have to consider. You have many of the same requirements with that wholesaler.

Obviously, your direct customers are the retail pharmacies and hospitals. Your relationship with them in your integration requirements is more than just making that EPCIS information available to them but participating in investigation verifications or product tracing.

You'll have exceptions to manage. In many cases, you want to be continuing to send them advance ship notices. That concept of what is involved in that integration as it relates to DSCSA, your requirements are increasing as we move to 2023.

To date, wholesalers have only been required to receive and send serialized product. You haven't necessarily had a requirement to manage that serialized product and then receive electronic transactions and send those transactions downstream.

Now the capabilities that you will need as you move into 2023 is around master data, EPCIS exchange, managing aggregations, verifications, product tracing, resolving exceptions. There's a fair amount of work for us to start to embark upon here as we work towards 2023.

From that dispenser requirement, if you look at your supply chain, it may not be a direct commercial relationship in all cases, but you do have this relationship with manufacturers where you're handling their product. You will need master data, GTIN, and pack-level master data for situations where you do receive direct shipments receiving in that EPCIS notification.

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Being able to perform verifications in support of an investigation. Being able to manage product tracing. You absolutely receive drop shipments in from the manufacturer and then you'll have your exceptions as well.

Your direct relationships are largely with your wholesaler. You'll be receiving EPCIS shipment notifications. You will have verification requirements for investigations. Being able to support product tracing requirements typically for investigations. Managing those exceptions. Continuing to receive in ASNs.

In situations where you are operating in a loan borrow capacity, being able to perform some of those same functions. We're moving to this electronic process. I think today, for many dispensers, they're operating in an electronic manner for a number of their suppliers. For many of you, you're still receiving DSCSA information on a packing slip in this paper fashion.

We have to look at the requirements. Particularly for a dispenser, your requirements are increasing. If you think about it in how it's articulated in the law, requirements for secure electronic data exchange indicates that paper's no longer going to be acceptable. Needing to be able to manage DSCSA compliance in electronic way, leads to this need for additional capability.

In many cases, that's similar to the wholesaler requirements of being able to receive master data, receiving EPCIS shipment data, submitting verification requests, tracing products, resolving exceptions that will happen.

The point here isn't to scare everyone. It's to start to unpack this and increase our knowledge level and increase our education about what has to happen within each relationship that we have with each one of our customers or each one of our suppliers.

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Traditionally, we've often looked at integrations in this point-to-point manner. When we look at what would have to happen when we set up a relationship with a company, there's five high-level steps that we go through. There's B2B configuration that has to happen, we're aligning on data formats, and now we're doing this on a per-transaction level.

Before where it was just an ASN, now we're moving to EPCIS. We have verifications that we have to worry about, we want to be exchanging master data with companies, being able to test and validate those transactions, the going live, and then just the ongoing maintenance. We're maintaining these connections.

If you start to explode this out and provide you with a visual here, in a point-to-point architecture each step is performed between each trade partner over and over and over again. Each yellow line that's represented here is the equivalent of these five steps that we're going through.

You can start to see where the requirement to exchange this information electronically starts to explode into a significant amount of work that has to happen between organizations. If you just do some back-of-the-envelope calculations around this, and you start to multiply this out using some of those transactions that we went through on previous slides and then some industry benchmarks in terms of what it might take to integrate a partner.

You can see for a mid-size company that has a fairly small supply chain here, or a mid-size supply chain in terms of who they're interacting with directly for their US business, you start to create some pretty substantial integration costs that are in traditional point-to-point models, are costs and investments that you're either taking on directly or that you're paying to a solution provider in order to manage all of this.

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From a wholesaler perspective, as we mentioned, your world is in some cases more complicated because you're receiving and shipping.

Looking at the integration cost, and this isn't taking into account all of the work that you have to do to outfit your internal processes, just the integration cost alone in this point-to-point model can be pretty substantial.

We're applying what I think, are maybe fairly conservative estimates on per partner cost when you compare this to what you see out there from other models like an EDI model and other types of point-to-point integrations that companies are involved in.

Then for a health system, and again, we try to be conservative, our retail pharmacy, we try to be conservative. I know many of you and some folks on the line here today have networks that are two, three, four times the size of this.

It's pretty substantial as you look at primarily, how you connect and integrate with your upstream supply chain.

The underlying message here is that the typical approach of looking at this and saying, "OK, I need to receive information from a partner, whether it'd be a wholesaler or a manufacturer, I'm going to engage in this point-to-point integration project." When we look at a requirement like DSCSA, it's pretty substantial.

You start to get down this path where you're doing these tasks over and over again and it's right for optimized approach. With TraceLink, we've taken this network approach where companies integrate into this network and TraceLink's managing the work that needs to happen.

If you look at the benefit here, you look at taking those same five steps from a

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partner perspective, TraceLink is taking on the work associated with configuring the B2B and aligning on the data formats, and multiplying that across per transaction. You may have if you want.

Some of our customers rely on the testing that TraceLink does. You may do your own testing and validation, or you don't have to. You have control over when you flip the switch to go live, but TraceLink's also taking on the overall ongoing maintenance.

If you look through this network architecture, what we're enabling through this integrate once, interoperate with everyone.

In addition to TraceLink's network services team that is managing the onboarding and integration process on your behalf, TraceLink is performing the B2B configuration. We're doing that once per partner so we don't have to do it over and over and over again.

We are aligning with the trade partner on how they want to receive the data, the format that they want to receive that data in. Remember when we talk about EPCIS, there is a variety of different versions that are out there.

We've gone through multiple versions of verification at this point in terms of product verification. TraceLink is taking on the lion's share of the work in order to integrate these partners.

The reason we're able to do that, let's maybe flip back to this slide here, is we're doing that once with each company that's on the network. With the 290,000 companies that we have on our network, each representing one of these yellow lines here, we've gone through this step to be able to integrate them into the network.

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Now, some of them, they're receiving that information through a portal, particularly some of the smaller clinics and some of the smaller hospitals. There are a number of them that are going through this full B2B configuration. We're able to optimize our work.

In addition, we have a dedicated team, a network services team that's managing the integrity of the network. We're verifying companies before they're defined. In reality, the vast majority of the US supply chain already exists on the TraceLink network, either directly as a customer, but many of them as partners.

We configure their experience on the network on behalf of the trade partner so that they can receive the transactions. We have some, not customers, but there are customers' partners, that log into the TraceLink solution and are able to retrieve those transactions.

Some of them never log into the solution and they receive those transactions through a B2B connection that we enable them.

I think maybe, one of the key differentiators here is, as a TraceLink customer, our network services team is taking on the responsibility of providing support and being a point of contact to that trade partner so that the customer doesn't have to. I'll give you an example.

Something that happens all the time, is you may have an AS2 certificate expire. When that happens or it's leading up to expiration, TraceLink is managing the updating of that certificate with that particular company, so that you're not going out and having to manage that certificate update on your own.

It creates this air gap if you will, between yourself and the partners that you do business with, in order to be able to reduce the work that you're involved in. It's

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from both an architectural perspective, as well as the services that we're providing. We do it all as part of the license fee when you have a commercial relationship with TraceLink.

Just to try to quantify this in a single example, if you have 100 trade partners, and I'm not really assessing whether they're a supplier or a customer. The vast majority when we go through, and we do the network analysis, 95 percent of them are typically on our network already.

You're being able to enable those 100 trade partners go through all of the onboarding activities and to get them live for the exchange of EPCIS information. It's pretty straightforward, it's five weeks.

If you multiply that out times the cost, a typical cost, it's much less than what you were looking at on the previous slides, which is this model here on the right-hand side. Same 100 partners, you have a number of weeks to establish the point-to-point connection, you have a number of weeks to validate and test each of those connections.

You multiply that out, and you can see how pretty quickly this becomes unsustainable in terms of meeting the item-level traceability requirements.

We covered a lot. I know we went through this somewhat quickly, but the goal here was to unpack what we have in front of us in terms of partner integrations, understanding the work that's involved with that, and trying to distinguish.

For many of you who are looking at maybe building this capability on your own or using another solution provider that's maybe based on a point-to-point model, I know on the manufacturer side some of you may be evaluating 3PL relationships, which are typically a point-to-point model, recognizing the work that's required and

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do those other approaches.

The providers of those other approaches, do they really recognize what they're signing up for in being able to manage that? Are they outfitted to be able to manage that?

Now what I'd like to do is, I think on the benefits that we described in the previous 40 minutes or so, on DSCSA alone and meeting the DSCSA requirement, we now really want to start to look a little bit forward and look at how does this work that I'm doing today start to benefit me in terms of supply chain digitalization, in accelerating supply chain digitalization.

Virtually all of you, whether you're a manufacturer, a wholesaler, a retail pharmacy, or a health system, you're all looking at your supply chains with a more critical eye. Coming out of the pandemic, we recognize some of the challenges that are the structure of our existing supply chains have.

We're looking at the challenges in terms of the opaqueness of our supply chains and not having the visibility that we need in order to manage changing supply chain conditions. Virtually, every company I talk to, every VP of supply chain that I talk to, or CIO, supply chain digitalization, supply chain transformation is a boardroom level topic.

What we wanted to be able to do is, start to paint a picture of, based on your investments in DSCSA, and I'll refer back to this diagram that we explained earlier. What you're doing with your DSCSA investment through the TraceLink network is you're creating...what I call these assets.

You're creating these assets that can help you accelerate the work you're doing around supply chain digitalization.

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First and foremost, when you're operating on this network, what you're doing is, you're operating on a secure and integrated network in which your partners both direct and indirect on the supply side, on the customer side are operating on.

There's a network integrity aspect of this. If they're on the TraceLink network, there's a verification and a process that we've gone through to verify those partners.

You have an integrated network of your trade partners and of your supply chain. What you're also doing through DSCSA is, you have now a digital representation of both shipments and receipts, not just at the lot level, but at the item level as well.

I now have this ability...I'm moving away from packing, relying on packing slips for compliance, and moving to this secure electronic exchange of information that's required by DSCSA.

That represents the movement of product through the supply chain. It represents a digital representation of product velocity. Now, when I'm operating in a silo by myself, there's not a lot I can do with that information. It's great that it's in digital form, but I know what I received, I know what I shipped out. That's information that you largely have today may not be in a clean digital way.

Now, when we start to look at this, across a network, and what TraceLink's able to do in terms of looking at this information across a network and running through this network data model that we talked about earlier, what that does is it creates this very clean, timely and actionable data set, that can really start to provide valuable input into our decision making.

That's really a fundamental difference that of looking at DSCSA as these check-the-box compliance requirements. Certainly, that's very important for us to do, but

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you're also building out this asset by operating on this digital network platform.

The things that we're now able to start to create from this, are there are some new capabilities in terms of what we call supply chain work management. Being able to connect across the supply chain in the supply planning process, to be able to provide things around visibility, get the overall health and welfare of supply chain activities.

To be able to collaborate with my providers, creating this virtual team to be able to track issues that happened between whether it be a pharmaceutical manufacturer or a wholesaler, a retail pharmacy, a health system, and their supply chains. To be able to orchestrate that work management.

This particular solution will become very important as we look at the exceptions that are created from DSCSA. When I receive a shipment in and the physical products in that shipment are 20, but the electronic documentation that I received in tells me that there was only 15 products in there. How do I manage that exception?

Not just internally, but how do I manage it with the supplier that I received that product from? Supply chain work management, particularly for DSCSA exceptions really helps us in this area.

Digital recall. This is a capability that companies are facing across the supply chain. This is another benefit of two things. One, our ability to be able to digitalize the supply chain, which we'll get from DSCSA. Being able to now look across that supply chain and execute a digital recall.

Being able to digitize recall notices, being able to quickly assess what's the impact of this recall to the inventory that I have, in order to be able to identify have I

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received recalled product in the past.

From a manufacturer's perspective, being able to get visibility into where have these products gone and give your...not only your direct customers but particularly your indirect customers, the ability to be able to notify you very quickly on whether or not they have recalled product in their possession.

Then finally, what I think is probably one of the more exciting topics that we're pursuing is this concept of collective intelligence. With that, I'm going to pass it over to my colleague Bharath Sundararaman, who heads up our intelligence supply, network, and analytics solution area. Bharath?

Bharath Sundararaman: Thank you, Dan. Hello, everybody. I've been here at TraceLink focused on analytics, as Dan said, for the past three years. Before coming to TraceLink, I spent 10 long years at Merck based in Germany, as a large drug manufacturer leading digital supply chain, data, and analytics.

What pulled me to TraceLink is exactly what Dan has been talking about for the better part of the hour, which is the largest network in life sciences with 1,300 customers and all that data on the network.

When you look at your company and the data that's within your four walls and what you can do with it, and then you compare that to having a network-wide data set with clean, well-organized master data that's driven by compliance, it's a whole different ballgame. The impact you can make with that data is unbelievable.

That's really my reason to come to TraceLink. It's a dream come true to be able to work on initiatives. I think, Dan, you can move to the next slide. Initiatives under the umbrella of what Dan already described as collective intelligence.

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Meaning, applying sophisticated analytics and artificial intelligence on a network-wide data set of clean, well-organized master data that's available on a daily basis. To then extract insights that can digitize your supply chain. That umbrella is what we call collective intelligence, those set of initiatives.

Rather than us, TraceLink, coming up with what could be transformative for the industry, we actually went to our top customers and said, "What is it that you want us, TraceLink, to be working on that's going to be most impactful for the industry?"

You can see on the slide that we had representation from large manufacturers such as Pfizer, Merck, and Novartis. We have from the health system and pharmacy side the likes of Mayo Clinic, CVS, OPTiM, and Novant. We also had a couple of wholesalers and several CMOs in the mix.

What we did was, we took an industry-wide view, brought in VPC-level decision-makers. The collective output from this compelling group and the number one prioritized use case that they wanted us, TraceLink, to work on was to provide an early warning of drug shortages by applying collective intelligence on this compelling clean data set across our network.

That's what got us to this exciting use case of, for the first time, being able to provide folks like you on this webinar and other customers of TraceLink, an ability to see shortages up to 90 days before they happen. Next slide, Dan. That's really what we've done in the last couple of years.

We kicked off this forum that I just mentioned with all these big names back in 2020. The first thing that we did was to come out with an actual solution that leveraged our network-wide data set to predict shortages back in 2021. But that first solution was providing an early warning 10 days in advance, as you can see in the bottom step of the ladder, at nearly 90% accuracy.

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The feedback was, "Hey, that's great. We're happy that you're able to come out with a solution that works and that predicts shortages, but 10 days is too short. We can't react and get ahead of the shortage, is too little time to make impact and to prevent or avert the shortage."

What we did was to go back to the drawing board. Recently, we went live with a solution that can now predict shortages up to 90 days in advance. For a large number of drugs, we're able to do that at 80% accuracy or higher in the US. The enabler for the predictions is DSCSA and the data we get through DSCSA.

When you choose TraceLink, you're not choosing a provider that just checks the box on compliance. You're choosing a provider that got you covered with leadership and proven success in compliance. That has the network to enable multi-enterprise collaboration so that you can work better with your partners especially as you get to 2023.

In addition, bring highly value-added applications, such as supply chain work management, such as digital recalls, such as product availability intelligence to predict shortages before they happen. Our goal is really to leverage DSCSA as the foundation to digitize your supply chain with a variety of high-value applications that's going to help us transform the industry together.

Dan: Great. Thank you, Bharath. It's really exciting that we have this type of capability because of the drug shortages. I think we've seen this firsthand. I think virtually all of us have had situations where we needed medicine.

We've gone to a pharmacy and we haven't been able to get that because it's just not available because of a condition that may have happened 1,000 miles away in another geography.

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This is exciting for us, and I think another example of how we can start to advance the overall intelligence of our supply chains by taking these thoughtful approaches to solving problems that we have in the here and now around compliance in DSCSA. Thank you for that.

What I'd like to do now, we have received a couple of questions. I want to take a couple of these questions on. Then I have a couple of questions for the group as well. But a few of the questions were related to this network concept of what does it mean to be a TraceLink customer versus a TraceLink partner, and those types of things.

The analogy that I'll provide is when you have a company that is a partner on the network. Let's say you have a manufacturer and you have a wholesaler or a retail pharmacy or health system, and the wholesale or retail pharmacy is a partner on the network. They're not a TraceLink customer, unfortunately, but we'll use that as an example.

In that scenario, you can think about it in such a way in that the sender of that information, if they're a TraceLink customer, we are dropping that information, that EPCIS transaction, to the B2B front door of that partner.

We're saying here's an EPCIS transaction for this partner. This partner has told us that this is my B2B information. This is how I want to receive it, the format. I use EPCIS version 1.2. Deliver it to me in that way.

The service that we provide to our customers is we obviously assemble all the information to create that transaction. We manage the workflow with inside your internal operations. We send that information to the front door of that company, the digital representation of the front door.

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Now, that company through their own DSCSA solution has to then take that information, pick it up from the front door or the mailbox, if you will. Then they're going to process it internally based on whatever solution or approach that they desire.

You can kind of think of it as, if you're a partner, we're delivering that information to you on behalf of our customers because the commitment that we make to our customers is that we're getting them the compliance information in a way that they want to receive it so that they can ultimately consume it. I hope that clears up and maybe addresses those questions.

We had another question just on timing of the regulation between pharmaceutical manufacturers, wholesalers, distributors, pharmacies, specialty pharmacies, and the requirement for item level traceability and compliance is November 2023 for all segments.

This is the last of the last milestone in this 10-year, DSCSA journey that we've been on, and so the final Milestone is in November of 2023.

Manufacturers have some requirements, wholesalers have some requirements, and then dispensers whether you're health systems, specialty pharmacy clinic, retail pharmacy, and you have requirements on those dates. We can certainly speak with you directly to clear up any knowledge that you might need around those.

In the spirit of time here, I did want to jump forward to next week's webinar and the reason I wanted to bring this up is we're going to be joined by a couple of our customers. H-E-B Pharmacy, Leon Nevers, is the Director of Procurement and Business Development, and Kim Crabtree, and some others from Henry Schein as well, Director of Pharmaceuticals at Henry Schein, who is a large national

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wholesale distributor.

They are going to speak to you about their requirements as it relates to DSCSA. If you are a manufacturer or you're a wholesale distributor, you'll get a perspective of what their requirements are. Henry Schein may have some information about how they plan on providing information out to dispensers.

This gives you an opportunity to hear directly from two of your trade partners. Then we'll do a Q&A fireside chat with both of the organizations. It should be a really informative session for all of us.

Finally, I do have a couple of questions for you, and that is, first and foremost is, how would you rate the information that we've presented here? We're really trying to make sure that we are able to meet your requirements.

We want to make sure that the information is on point and it's useful for you. As we look to continue the series for the rest of this year and heading into next year, we'd also like to hear from you. Would you like us to contact you and more information about these particular topics?

Some of you have asked some specific questions. We'd certainly like to reach out to you directly. If you can take a few moments to fill this information out, be much appreciated.

Just to wind down and give it a few more seconds here. Three, two, one. Thank you for providing that information to us. For those of you that have asked us to contact, we will be in touch with you shortly. Finally, I'd like to, for those that are our existing customers, make you aware of, many of you already are, but our customer community group, specifically related to DSCSA 2023.

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We invite you to come in. We go much deeper into specific topics, whether it be around EPCIS exchange or verification. We try to summarize some of the happenings that are going on in the various industry groups, whether it be HDA or GS1.

This is your place. It's live questions. It's not this sort of traditional webinar format. We have a set of topics that we go through, but it's live questions discussions. We take things head-on and work through issues within this group that's open to our customers. We think it's a real benefit.

Then in general, for those of you certainly reach out to us and contact your account executive if you have questions about getting started with your DSCSA projects. If you don't have a relationship with TraceLink at this point, you can certainly reach out to us at marketing [at] tracelink.com.

With that, I appreciate your time. I hope to see you again next week at our next webinar with H-E-B and Henry Schein. Have a great rest of your week and weekend. Thank you, everyone.

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