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DSCSA 2023: Requirements, Necessary Capabilities, and Preventing Drug Shortages for Manufacturers





The U.S. Drug Supply Chain Security Act (DSCSA) will require **manufacturers** and **wholesale distributors** to configure thousands of individual connections between trading partners and establish an interoperable system for tracking pharmaceuticals across the end-to-end supply chain by November 27, 2023. Will your organization be ready?

Watch this on-demand webinar to **learn the most effective ways for manufacturers and wholesale distributors to meet DSCSA 2023 compliance mandates** while leveraging compliance investments to create new business value, ensure drug supply, and improve patient outcomes. Topics include:

- A complete overview of item-level traceability and other critical **DSCSA 2023 requirements** for manufacturers and wholesale distributors, and the capabilities needed for achieving fully interoperable, EPCIS data exchange and electronic tracing of pharmaceutical products at the package level.

- How a digital network platform-based approach to compliance ensures that

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transaction data, including product identifiers, are formatted into EPCIS files that conform to GS1 standards and can seamlessly be shared with supply chain trading partners.

- Timelines and step-by-step strategies for achieving DSCSA 2023 compliance before the FDA's deadline.

- Why existing TraceLink customers are much closer to achieving DSCSA compliance than you may think.

This webinar is the introductory session in the TraceLink DSCSA 2023 Webinar Series. Watch the whole series to learn how TraceLink can help you turn compliance efforts into real business value—just fill out the form on this page to get started.

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Transcript

Dan Walles: Hello, everyone. Welcome to the DSCSA 2023 Webinar Series for manufacturers and distributors.

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This morning is our first webinar for the manufacturer and distributor segment. It is the first in a series that will be running through 2023, where we take a specific topic and go through it in detail and talk about some of the challenges of DSCSA in that area.

Joining me today is my colleague, Allan Bowyer. Many of you know Allan. He's a Senior Director of Industry and Community. Bharath Sundararaman, who's our General Manager for Intelligent Supply Network, and I'm Dan Walles, the General Manager of TraceLink's track and trace, and compliance business.

Just to level set, this is a series that we're kicking off for the manufacturer and distributor segments.

This is our first session where we'll go take a look at the requirements as a whole, the necessary capabilities to meet those requirements as you are evaluating various solutions and approaches. Then really talking a bit on some of the value that we believe can be achieved and realized from your implementation around 2023.

Then as you see in the coming weeks, we will be diving deep into topics like electronic information exchange, preparing for verification. We'll do some case studies where we talk about wholesaler and retail pharmacy requirements, exceptions, and then the ever-elusive topic of product tracing that I know the industry is working diligently to figure out.

First, let me talk about TraceLink and where we are today. For many of you, we started our relationship with you back in 2013, '14 as we were gearing up for the initial requirements and milestones of DSCSA. We certainly appreciate the partnership we've had with many of you.

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We've been quite busy over the past seven or eight years or so. Our business is approaching 1,300 customers. We have close to 900 customers that are actively using TraceLink for serialization capability.

Then, I'll call your attention over to the right, particularly around the activity that's happening on the network today in terms of close to 40 billion serialized units being tracked across the TraceLink network.

When you look at the T3 information or transaction histories, close to a billion transaction histories have been processed through the TraceLink network. As we move towards serialization and we move towards item-level traceability, today, the network is managing what we call in-network product GTINs over 47,000.

That means our manufacturing customers are relying on TraceLink for over 47,000 unique item GTINs. Certainly, a lot has happened. We are pretty excited about what we've accomplished, but obviously, we have a lot of work to do as we move towards the deadline in November.

This is an important milestone for the industry, not just from a compliance perspective, but really from the overall supply chain challenges that the industry is going through.

Obviously, we're talking a lot about traceability from a compliance perspective, but it is starting to combine challenges that we have as an industry in the area of better transparency in the supply chain. We see a lot of activity around sustainability initiatives within the supply chain.

Things like digital leaflets outside of pharma when you look in Europe, things like the digital product passport initiatives that are happening. Then we all know things that have been happening in the area of material shortages.

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My colleague, Bharath, will talk about medicine shortages specifically. All this leads to a need for better collaboration with our suppliers. The supply chain, the world that we've lived in with you, over the past 15, 20 years, digitizing that supply chain and moving to a digital world has become a top priority business imperative for our industry.

When we look at what is required to be able to address that initiative, it all comes down to this concept of the Internet of Supply Chains which is really linking people, processes, systems, and enterprises together to be able to have an intelligent information network.

Approaching DSCSA is one of those first challenges that we have been working on that is truly an Internet of Supply Chains application. When you look at what we've done around track and trace and what we need to do as we look at digitizing the supply chain and creating this Internet of Supply Chains, is being able to create digital networks.

To be able to share those processes and applications across that network. Enabling cross-functional collaboration, not just within my organization, but externally as well with my partners, whether they be customers or suppliers.

I think what's unique is doing this, recognizing the need for a common data model across the network, which drives the value of creating incredibly clean data sets that become very actionable for things like collective intelligence and analysis.

Providing full transparency and traceability to reduce risk, real-time information, adaptability to be able to change to various market dynamics. Obviously, that enables us to be more responsive to change in market demand.

Ultimately, when we look at this, this sounds an awful lot like what we have been

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doing for the past 10 years. We have essentially created, through serialization and track and trace, that many of you have been going through, this global case study for deploying what I believe is the first Internet of Supply Chain applications.

You look at whether it be through the creation of serial numbers, through operationalizing serialization, through distribution channels, continuing with compliance, and the analytics around that, across all of the segments.

You can see some of the success that we've had here, in our business, in the healthcare space, in distribution and logistics, with pharmaceutical manufacturers and contract manufacturers.

We are living and breathing today along with you, particularly those that are operating on the TraceLink network as customers, the first Internet of Supply Chains application. We've learned a lot about that that has ultimately led to how we are building out our Internet of Supply Chains solutions suite.

The foundation for this is the digital supply network. Being able to provide those network administration tools, many of you are familiar with our network services organization, responsible for managing the integrity of the network with onboarding partners.

Our Integrate Once, Interoperate with Everyone model, catalogs of plugins and maps, which are now being expanded to include additional applications that are being developed in this low-code environment of OPUS that we are bringing to market.

When you look at what we have to accomplish for DSCSA, it covers the full spectrum of these solution and application areas that you see at the top.

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Serialization and traceability, regulatory compliance, supply chain collaboration, operating on a network, and having network applications. Verification is a great example of a pure network application. Collective intelligence. We'll talk about our product availability solution.

Moving into areas that are more process orchestration, you look at things like cell and gene therapy that really require tight orchestration across not only our supply chain partners, but obviously the patients that are involved in that process.

We want to set the stage for you in terms of how TraceLink is building its business, and how DSCSA fits into that in our approach for DSCSA. What I'd like to do now is in this next section, we'll be looking at the challenges and capabilities in the value that can be gleaned from a DSCSA implementation.

To kick this off, I'd like to pass it over to my colleague Alan Bowyer, who's going to walk through what are the FDA's intentions around DSCSA. Alan.

Allan Bowyer: Great. Thank you, Dan. I noticed in the participant list, I already know some of you from TraceLink community. I host many of the groups here at TraceLink. I also analyze track and trace requirements globally.

The whole purpose of community is to help members help one another implement requirements, and we already have a couple of groups dedicated to DSCSA 2023. I do invite our customers to join those. A little bit of background about the DSCSA or Drug Supply Chain Security Act that was signed into law in 2013 on the day before Thanksgiving in that year.

The whole purpose was to make the prescription medicine supply more secure. Unfortunately, this happened on the tail of some fatal incidents and some near misses in the industry. The DSCSA laid out a roadmap for industry for the next 10

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years.

The eventual goal is that when it's fully implemented, prescription drugs can be traced from the manufacturer through wholesale distribution and down to the dispenser. We see a variety of ways that occurs, as Dan was referring to earlier in this Internet of Supply Chains.

We'll look at that timeline in more detail shortly, but what I want to concentrate on in this slide is about product tracing and how the FDA sees product tracing as relating to its goals for 2023. You can think of product tracing as requirements for each trade partner to either provide or to receive information on a product transaction.

The FDA has a couple of high-level goals for this 2023 DSCSA phase. The first, as you can see there at the top there with the number one, is to implement this secure interoperable exchange of product tracing information at the package level. Big difference, and to do so electronically. Specifically, what it means, and I'm going from left to right in those four white boxes.

Today, trade partners exchange transaction information at the lot level. In 2023, this information exchange will be fully electronic and include not just a lot number, but all of the product identifier elements at the package level. That means each and every serial number.

Then in the second box, this package level information, which is imprinted on the pack through the identifier, is then used to verify physical product through electronic means. There's where the FDA in 2023 has identified additional scenarios under which verification tools may be used. We have one in place today for saleable returns, but this is being expanded.

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Then in the third white box if through this series of processes and verifications someone finds suspect, or illegitimate product, then this pack-level tracing information is used to locate that product, perhaps quarantine that product, dispose of that product. There are many uses of both verification and tracing that work hand in hand to make these goals realizable.

Finally, the last box, the applications of DSCSA, don't stop with suspect, or illegitimate product, but in scope for DSCSA is for a trade partner to provide to the FDA or perhaps a state regulatory authority tracing information in the event of a recall. I have a little bit bored you with the term tracing, but this is the watchword along with interoperability for 2023.

Alongside this, the DSCSA imposes strict time limits for providing that tracing information. To sum things up, essentially in 2023, we have your physical supply chain of products flowing through from manufactured to patients, but alongside that, and the part that must match that physical supply chain is what's called the virtual or electronic supply chain.

That's where Dan will address later how we rectify any differences between those.

The bottom box is about establishing National Standards for licensure of wholesale distributors and third-party logistics providers. That is a work in progress with a proposed rule, but it certainly is an ambition of the FDA to make sure that everyone is singing from the same songbook, so to speak, in 2023.

We know that these requirements are several, they're intertwined. Let's hear from you, our audience on which of those keep you up at night. Let's go to our survey. You can see that popping up on the screen. We'd like to know -- this is anonymous -- which of the following requirements do you feel are the hardest for your organization to meet in 2023?

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Is it exchanging this serialized TI and the TS? In 2023, it's all electronic, even between wholesaler-distributors and dispensers. Electronic exchange for everyone. Perhaps it's verification. As I mentioned, we have additional scenarios besides saleable returns, more data, more processing, more responses to those queries.

Perhaps it's the third product tracing. It's not only managing the interoperability, but you have all this data that you need to manage, store, retrieve very quickly. Maybe it's figuring out the exceptions when the electronic supply chain doesn't match the physical one. What do you do then? Or perhaps it's about authorized trade partner credentialing.

This is using a third-party service to ensure a trade partner is who they say they are and has the right to perform certain actions. All of these have certainly significant challenges. Let's hear from you and we'll give you just a few more seconds to weigh in on what's keeping you up at night.

[pause]

Allan: Select one answer. I know there may be multiple, but we'll give you eight more seconds to finish that one up. Then we'll display the results. Eight, seven, six, five, four, three, two, and one. Let's display the results there.

It looks as though we have a clear front-runner in managing exceptions. I'm pleased to say, we will have a webinar dedicated to that. That is indeed managing exceptions can be across many different processes in DSCSA. It's not so surprising it came up as the front.

Not far behind was actually exchanging the serialized TI and TS. Yes, there will be much more data and it will all need to be done electronically and in a way that is interoperable.

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I won't go over the others, but we will cover them as well in our webinar, so thank you for your input. That's very helpful. I'm just going to run you through the timeline for DSCSA. On this next slide, I want to illustrate how the 2023 requirements relate to the earlier ones. There is a method here. [laughs]

Let's start over on the left-hand side in 2015. The law which again was passed in 2013 dictated that trading partners needed to be licensed or registered to perform their given role. In essence, thus was born this idea of an authorized trade partner and you can only do business with other authorized trade partners.

2015 is also when a major requirement went into place and that was at lot-level tracing through this T3 -- TI, TH, and TS. Then we also saw the beginning of verification processes or even systems to identify and quarantine product that was suspect or illegitimate.

Now, as we move forward in the timeline, you're going to see how these capabilities and these requirements got enriched. In 2017, we saw a step change. It went from lot identification now, to this identification at the saleable unit level and homogenous case.

In other words, we got serialization, and you saw that manufacturers had to apply these elements within a barcode. This was a hugely important step because then that individual identifier enables product tracing, product verification, and the rest that we see later. Let's jump to 2019. Here is where industry furthered the verification requirement.

Sometimes industry will refer to this as saleable returns verification, and that meant that a wholesale distributor could accept product it intends to resell from a dispenser, but it can only do so let's say, reintroduce that product into the supply chain if they're able, the wholesaler to verify that individual product identifier with

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the manufacturer.

That's where we got a new network verification router service, and we'll talk about that more in further webinars. That was an additional network that spawned off of DSCSA. There was enforcement discretion for that until 2023, for wholesalers, not for manufacturers.

Even today, if a manufacturer does receive a request for verification of a saleable return, they must respond within 24 hours so that enforcement discretion was not across the supply chain.

Now we're up at 2023, where it all comes together. The FDA refers to this phase as Enhanced Drug Distribution Security, sometimes called EDDS. The tracing information is TI and TS no longer TH. Looks like we got rid of that requirement, or did we? We'll redress that in a second.

The second major change is the expansion of verification requirements, not just saleable returns, but suspect or illegitimate products. We talked a bit about tracing and I mentioned a second ago that the transaction history sunsets in 2023. Well, the reason for that is maintaining that would have meant an avalanche of data.

With product tracing requirements in effect in 2023, that TH will now need to be reconstructed upon request, say by the FDA piecing together the serialized TI, is now much more fully enriched TI in a one-up/one-down manner to find out the history of the product. In a sense, maybe that TH disappeared, but now you need to reconstruct it from a TI. New challenge.

Back in 2015, we mentioned there was that concept of authorized trade partners. 2023 takes things a step further, having third-party credential issuers vet trade partners and provide these credentials electronically.

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The reason for that is with these new product tracing requirements, you may be dealing with a trade partner you haven't done business with directly before. You're going to need some way to find out that they are a bona fide trade partner. That's DSCSA in a nutshell.

I've tried to give you a sense of what DSCSA says and what the FDA says you must do, but getting that done is another story. Dan's going to show you next how to do that with confidence. Back over to you, Dan.

Dan: Great. Thank you, Allan. I appreciate the depth of information that you provided. It's quite interesting to see as we've moved from 2015 into 2023, we've accomplished so much. I think you used this term, and I think it's a good one. When you break that down into capabilities, the remaining capabilities that we have to implement as an industry are yet another step change.

I certainly don't want to minimize the work that we've done as an industry in 2015. Then, obviously, with serialization in 2018, many of us were also working in other markets like Europe and Russia, who were pursuing serialization requirements and reporting requirements as well.

When we look at 2023, the requirement now is not just serializing, but we have to now incorporate that serialization and that data into our operational processes. In order to be able to send those transactions, we have to be thinking about whether it be integrating with our WMS or if we're in a virtual model with our 3PLs.

What impact does this have on our edge systems, our mobile scanning? Things as simple as taking a sample out of a case now starts to disrupt any of the predefined aggregation that may have been captured earlier as part of the packaging process.

Then as we touched upon these through the poll, things like exchanging, hiding

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that serialized TI and TS, exchanging that information, new use cases around verification. I think the audience is spot on in terms of the challenges around exception management and how do we collaborate as an industry to resolve exceptions.

It's no longer just fixing something inside my four walls. As a wholesaler, I may have to collaborate with a manufacturer, who may have to collaborate with a CMO. You have this multi-enterprise party sets of organizations that are involved in resolving an exception.

Then continuing to move up and authorize trade partner. There's some more work that we need to do there in terms of understanding those requirements and the implementation of those requirements. Similarly, with product tracing.

Then let's not forget the FDA's intentions of using these capabilities created through DSCSA really as a tool to get better at identifying recalled products in the market and pulling them out of the market, doing that with more efficiency to ensure that those products don't end up in patients' hands.

The key message from this slide, and we'll touch upon some of these areas individually, is we really have a lot to do. Now, the piece that I want to impress upon you is TraceLink as we've been building out our capabilities, taking a very methodical, piecewise approach to its solution.

First starting with what we refer to as the core serialization capabilities that many of you are using today throughout your packaging operations. Assembling and defining those GTINs and creating serial number pools, and allocating that information out across your packaging lines and CMOs.

Now, we start to move into the compliance aspects of whether it'd be exchanging

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information, product verification, product tracing. Then we get into what I refer to more as the how do we operationalize DSCSA.

This gets into the troubleshooting around exception management. Troubleshooting through the production and operational and compliance events that are happening. When there is an exception that's identified say at a wholesaler, manufacturers can be going through and have the tools available to do the investigation of what might have happened.

Then through supply chain work management, being able to collaborate with the wholesaler on resolving that particular exception and bringing a digital collaboration environment to exception management.

Then, we can't forget that we're operating under GMP processes. We're operating in an environment where we need to remain validated, knowing that requirements are going to continue to change and evolve.

Many of you are subscribers to both our automated validation manager solution, as well as TraceLink universally to help. You can ensure that your users and operators and administrators of our systems have the training and certification that they need. Then finally, how do we get some business value out of this?

Looking at the information flow not just inside my four walls, but across the network, this network, this digital supply chain that we've created, this Internet of Supply Chains that we've created from CMO to manufacturer, to wholesaler, the 3PL out to the dispensers, and being able to drive real business decisions, actionable decisions from this digital information that we've created.

We'll bar off. We'll talk about being able to receive early warning signals around drug shortages. In an upcoming webinar, we'll talk about the ability to drive some

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efficiencies around the recall process in digitizing the recall process.

The other piece to call out here is, this is something that TraceLink has been doing for some time now. When I looked at the poll, 29 percent of the audience had concerns around exchanging the interoperable transaction information.

Just to bring some context to that. Today TraceLink has over 760 companies that rely on TraceLink for DSCSA. Over 100 of our customers and their partners are exchanging EPCIS transactions in production today.

We talked earlier about exchanging the T3 information, the ASNs. To date, TraceLink has facilitated the exchange of 683,000 EPCIS transactions already. We are working with the big three. We have customers that are sending EPCIS transactions in production capacity to the big three today.

You can see the GTINs that are ready for verification, and the number of serial numbers that have been commissioned through TraceLink. We have a lot to do as an industry and I don't want to oversimplify the work and the concerns around exchanging information, around verification.

TraceLink feels pretty confident that we have a great head start. We have a lot of momentum built for our customers in terms of getting them ready for November 2023. Part of that is driven in looking at the problem and what we have to do, and characterizing it into a couple of areas.

When we simplify what we have to do as an industry and particularly TraceLink as a company, what we're looking to do, we break it down into four areas. That first area is DSCSA is a network challenge.

We have to communicate information with companies that we have direct

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commercial relationships with us, with you, as well as indirect. You can start to think about, there may be situations where a secondary wholesaler or a dispenser may be issuing verification requests against a manufacturer.

Scalability, we're going to be introducing more data and more events that have to be processed at real-time than we've ever seen before. This operational scalability. Compliance, we know things are going to continue to evolve.

We believe that if we do these three things very well, that there is opportunities for us to not only ensure supply from a compliance perspective, but drive advances in the area of drug shortage predictions and optimized recalls.

Let's spend a little bit of time drilling into these, and talk about what we mean when we say DSCSA is a network challenge. If you look at these boxes on the left-hand side here, it's obviously about exchanging EPCIS data, very straightforward.

If you look at verification, now we're talking about, I may receive verification requests from direct partners, I may have to issue it to a manufacturer. A dispenser may have to issue a verification to a manufacturer that it has no direct commercial relationship with.

Many of you today are exchanging GTIN across the supply chain, and that's currently being done through spreadsheets and emails and those types of things. Product tracing, we've talked about.

Then obviously, recall. When you look at what we mean by needing a network in order for this to run smoothly and run efficiently, these are the types of use cases that we're talking about.

Looking specifically at the network, TraceLink's, the KPIs that we're tracking that

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we believe accelerate your readiness in the area of DSCSA is close to 300,000 participants.

Network entities, almost 800 DSCSA customers. 103 companies exchanging EPCIS data, production-ready with the Big Three, 680,000 EPCIS transactions exchanged, and almost 50,000 GTINs ready for verification. Certainly, a lot to build on.

From a scalability perspective, let's look at where we are today and where we're going to be. When you compare a lot of 10,000 units and you look at the processes that are happening today, I really have to capture a transaction to create the batch. I'm picking things in quantities. I'm picking a pallet that may have 10,000 items on it.

I'm shipping that whole pallet, and then I'm creating and sending that ASN. The activity that's happening is minimal. It's very minimal in terms of operational processing and scale that's required.

Now, you look at what we have to do when we introduce serialization, we're looking at a 10,000x increase in processing capacity and scalability. This isn't necessarily about storage as much as it is about that operational scale. We can't underestimate that.

If any of you that are on the call have been working within other markets, and you wonder why they have requirements for you to split files and sequence files.

It is exactly because of this reason that many traditional architectures, relational database architectures that many solution providers use just can't scale to meet the demands that serialization and traceability will introduce. That will result in delays in getting product to patients.

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From a compliance perspective, this is a slide that may be familiar to many of you. We call it our infinity loop slide, and it's really meant to communicate that we are over the next...certainly up to November, but even beyond, we are going to be in this evolving require period.

I think we're on EPCIS version or moving to 1.3. In terms of the standards, we've updated the lightweight messaging standard around verification. Obviously, there's changes within your supply network, mergers, acquisitions, along with the normal product enhancements and infrastructure upgrades.

The challenge around this is not only how do I deploy this capability efficiently, not just to myself, but ensure that all of my network connectivity remains intact and do that in a way that keeps me validated, really requires a specific architecture to work within.

Then we'll add to that compliance exceptions and again, calling out what you defined earlier on today in that area of being able to manage exceptions, that being able to quickly create that exception following the industry guidelines using user interfaces, common user interfaces, or APIs.

Ultimately, we're driving this through an API model. Being able to triage that exception, understand the assessment, the impact assessment alerts, deadlines associated with it in collaborating across your partners in order to resolve that exception.

This is something that we'll go into deeply. My colleague Amanda Bettman will take a deep dive into this topic as part of Webinar 5 coming up in a few weeks.

Finally, if we do this thoughtfully, we have an opportunity, and you have an opportunity as manufacturers and distributors, to really create a strategic asset

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that will help you manage your supply chain with more efficiency.

Where we are focused on immediately is in the area of drug shortage detection and recalls. What I'd like to do now is get your thoughts on some of these things. With our next survey question, when you're considering your organization's objectives for DSCSA, which of the following is most important? It's not that others are not important.

What do you believe in your approach? Are you looking at just meeting compliance, your concerns around being able to not only integrate with customers and suppliers but doing that in an efficient and cost-effective way?

Do you have concerns about scalability? Being able to process all of this data at operational scale. Being able to remain compliant knowing that standards requirements are going to continue to evolve over time.

There certainly isn't something that we're going to be set it and forget it. This is something that we will need to operationalize into our business. Are you thinking about making investments in compliance "How do I start to drive business value from these investments that I'm making in terms of understanding what is the velocity of my product through the supply chain?"

"Can I through network approaches be able to execute recalls more effectively?" We'll just provide a few more seconds here to let you record your responses. We see some trends here that are evolving. Maybe count down from eight, seven, six, five, four, three, two, one.

Let's look at these results and I think what we are seeing is not too surprising. There's certainly a clear winner here in terms of where the focus is as an industry, where the main share is.

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First and foremost, we have to make sure that we are able to get compliant and remain compliant. We are operating in a new model. It's no longer simply about getting the physical product to the customer.

It is about not only getting that physical product to the customer but also getting this digital information, this compliance information to that customer at the same time because if that is missing they are not able to receive or sell that product. That product essentially has no value at that point.

Other areas here, many of you're echoing the concerns in the first poll around being cost-effective in those integrations with customers. I know I've worked with some of you who have downstream networks in the US in the thousands. That's a formidable task really to take on here in 13 months.

That really speaks to the need for efficiency in cost-effectiveness, and think about this concept of an Integrate Once, Interoperate with Everyone.

Those that are thinking about the scalability challenges, I hear you. Many of you have started to touch upon this now as you're moving serialization into your operational processes, your warehouse management processes. Then certainly looking ahead. A handful of you are thinking about "How do I start to glean value from the investments that you're making and that we are making as an industry?"

This is really a great time to transition to the next part of the presentation here. I'm going to hand it over to my colleague Bharath who heads up our intelligent supply network area to talk to you about the work that we're doing in the area of drug shortages. Bharath?

Bharath Sundararaman: Thank you, Dan. Really excited to talk about product availability intelligence today, which is a newly launched predictive analytics

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application to provide an early warning of drug shortages.

How did this application come about? To give you some context, my role at TraceLink is I'm the general manager of the analytics division. The number one question I get from customers is, "What can we do to drive more business value from the compliance investments that we made? What can we drive through this valuable data generated through DSCSA compliance?"

Rather than us, TraceLink, coming out with great ideas, we thought, why not pull together an industry-wide forum with top brands and decision-makers, leaders from these brands? Get them together.

That's what we call the collective intelligence executive forum, which we kicked off sometime in 2020 and asked them, "What are the kind of things that would be high value for them that they would like tasting to drive value beyond compliance?"

The number one unanimously voted need, the most pressing need was an early warning of drug shortages. That's what set us off on this journey. You can see on the slide there was strong representation from drug manufacturers, where most of you come from on this webinar. You can see health systems, hospitals, pharmacies, several wholesalers.

It was important for us to get an industry-wide point of view before we got into this initiative, and we're happy to have taken that feedback and now come out with a product, which I'll talk about in the next slide.

What have we done is we've launched this predictive analytics application that predicts and even helps prevent drug shortages before they happen. Why is that important? It's important because it's all about the patient.

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TraceLink's slogan motto is "Network for Greater Good." There is no greater good that we can see than getting ahead of drug shortages, which impacts all of us when those things occur.

The number one goal is to help you manufacturers improve service levels, which is your experience of your patients, making sure that they get the drugs on time and in full. Also, help you lower the fines you incur when you're not able to get ahead of the shortages and help you improve your sales performance.

What we've done is, after launching this forum that we spoke about in 2020, we took a good year to come up with the first solution that could predict drug shortages 10 days in advance at high accuracy in the US market.

Most of our manufacturing drug leaders said, "Hey, that's great, but 10 days is too short. I can't do much within a 10-day window, to actually get ahead of a shortage and prevent it to help the patients in need. I need more heads up."

We went back to the drawing board, spent another solid year, and came out with an enhanced solution, which is the middle step on this ladder, which allows us to predict shortages up to 90 days in advance, still at high accuracy.

Our goal moving forward is to go even ahead up to 180 days and go beyond US to other geographies. We strongly believe that this is going to be a game-changer. One last thing I'll say here is that before coming to TraceLink, I spent 10 years at Merck KGaA based in Germany focusing on digital supply chain data and analytics.

One of the things that the Merck team always said with DSCSA or with compliance is "No comply, no supply." This is really an extension of that, is "Yeah, you want to comply to make sure you're able to supply your drugs, and you also want to stay ahead of the curve in getting ahead of supply issues." We really hope to make

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impact in this arena.

Thank you, Dan. Back to you.

Dan: Great. Thank you, Bharath. Certainly, some exciting things that we're working on, and I know you've been out working with a number of customers in terms of building out the capability.

There's two steps that you've been going through and maybe you can just touch upon this briefly. One is the algorithms in the models. I know the team has been working heavily on that.

One of the other things that you've talked about is, what is the user experience around this? Maybe you can talk about, just briefly, some of the work that you're doing, and maybe how some companies can get involved in providing their input and insights into how this might ultimately be used.

Bharath: For sure, Dan. I strongly believe that customers, people on this webinar, they're way smarter than us, way smarter than I am. They're on the front lines getting patients, the medicines that they need.

Our approach is to work with what we call pioneers, customers that want to get on this journey with us and collaborate with us to truly get ahead of shortages because this is too big of a problem.

It's an industry-wide problem. We're not going to just solve it in a silo, we truly need to collaborate. That's the call for action here, is if in your organization you see an opportunity to improve and ensure reliable supply, and you want to collaborate with us in getting a solution that changes that situation, then we encourage you to reach out to us and be a pioneer, get on this journey with us.

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We'll go after this big problem and definitely improve patient experience together.

Dan: Great. Thank you, Bharath. What I'd like to do now, many of you can see an area for you to enter in questions. I'm popping this up now. It looks like we have a number of questions that have been entered already.

I don't know if we'll be able to get to all of them here. We'll gather all of these and reach out to you directly about this, but if you could capture your questions in there.

One, Allan, I will direct to you is in the area of EPCIS standard. I'm going to summarize here. There's a question around version of the standard and the current status of the EPCIS standard from 1.2 to 1.3 and some additional status update on where that is.

Allan: We do expect the 1.3 to be implemented. GS1, of course, has formulates those standards and we will be as TraceLink implementing them. I would encourage if you have a project manager at TraceLink, to talk with them about what that transition entails.

Dan: Thank you, Allan. Another question that I'll take. This is a good one. This is one that we get fairly frequently. It's in the context of...It's great if everybody is a TraceLink customer, and it's TraceLink customers talking just to TraceLink customers. What happens if there are non-TraceLink customers?

The way I'll describe that is if you look at our network, so we have 290,000 business entities on our network today and those are manufacturers, wholesale distributors, health systems, pharmacies, contract manufacturers, so a number across the entire segment. Not all of those 290,000 are TraceLink customers. We have about 1,300 customers that are obviously also on the network.

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Part of the value that TraceLink provides to you is when we're working with you, so say in the context of DSCSA, if we're fortunate enough to be your solution provider, we, as part of the service that we provide, will proactively onboard and integrate to your partners.

The value of operating on a network is if you are, say, shipping product in the US, typically when we do this network analysis, it frequently exceeds 90, 95 percent of a company's downstream network already existing on the TraceLink network.

What that means is a couple of things. We know who they are. We know how they want to receive information. What I mean by that is for those that are receiving things through a B2B connection, like an AS2, we have all of that configuration set up.

If there are data translations where they want to receive the data in a specific format, specific extensions that they want to use, we have those maps already pre-configured in the system.

That's really this concept of Integrate Once, Interoperate with Everyone. As, say a manufacturer, you integrate to TraceLink and say, this is a shipment. Then we look at that shipment file through our solution and we say, where is it going? How do they want to receive that information? What's the format that they want to receive it in?

As many of you know, EPCIS allows you to extend and add custom fields in there. Same thing for a wholesaler. We look at your suppliers and many of them are already on the network, and we go through that. If we come across a company that is not on the network, part of what our network services organization does, is they go off, they define that company on the TraceLink network.

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They go through a verification process. They verify things like their state license information, HIN information, DEA information, and they define them on the TraceLink network. Then if a B2B connection needs to be stood up for them, they go through and they create that B2B connection.

Within the TraceLink model, what you're looking at is focusing on how do I integrate myself into the TraceLink network? Then TraceLink is through its solutions and services is managing the exchange of that information elsewhere. Great question.

That's something that we'd love to talk to you more about in more detail and step you through not only the process but also the cost advantages around doing that. This is where we already have integrations established with the big three. Obviously, the big three are many of your primary customers on the manufacturing side.

We also have a number of large wholesalers that are our direct customers as well, so it's a straightforward process. Just seeing and we have maybe one more minute to answer questions here. Can we get the deck? Absolutely. A couple of things. This session was recorded and it will be distributed, so you'll be able to share that with your colleagues.

They can go through and register and view this on demand. You can register for the entire series. I will spend a bit of time. That next series that we are covering is diving deep into electronic and interoperable exchange. That is November 17th.

This is the M&D series. I will say next week there is a dispenser-focused webinar on Thursday. The week after that, we're doing a deep dive into standards. Then on the 17th, we're going into electronic interoperable exchange. For the foreseeable future, you can join us on Thursdays at 11:00 AM, and we'll be talking about

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specific topics related to DSCSA.

Finally, I'll leave you with this call to action. If you are an existing TraceLink customer, many of you have already licensed our DSCSA capability, there are some steps you need to go through to configure it to get ready for EPCIS exchange and verifications. Reach out to your account executive. We can get that process started.

If you're a new company, let's say you're launching your first product into the market and you are looking to get educated, looking for a solution, reach out to us at marketing [at] tracelink.com. We'll spend as much time as we need with you, either remotely or on-site, to educate you on serialization, DSCSA, the whole process.

Finally, if you're using an alternative approach to DSCSA at this point, or maybe you built your own solution around sending ASNs, certainly reach out to you.

I understand your concerns. I echo your concerns around exchanging information at scale through EPCIS. We have to now be thinking about more fine-grain exception management, so certainly reach out.

We hope we've impressed upon you our readiness for DSCSA and the scope and comprehensive solution that we're bringing to market. Certainly, looking forward to speaking with each of you. I thank you for your time, I know 60 minutes is a long time.

I appreciate all of the questions. We'll get back to each of you individually and looking forward to seeing you on the next webinar. Have a great day, everyone.

Allan: Bye, everybody.

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