# Preparing for Electronic, Interoperable Exchange of DSCSA Compliance Information



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Schedule a Free Consultation with a TraceLink DSCSA Expert

In this quick video clip from our DSCSA Webinar Series, Caitlin Czulada, Director of the Center of Excellence at TraceLink, looks at how the TraceLink network speeds integration compared to conventional point-to-point methods. Watch the clip now and then fill out the form to see the entire webinar!




The **U.S. Drug Supply Chain Security Act** (DSCSA) will require **drug manufacturers** and their trading partners to achieve the fully electronic, secure, and interoperable exchange of transaction information and transaction statements, including product identifiers at the package level, by November 27, 2023. What does that mean for your organization? What do you need to do today to achieve interoperability ahead of the looming deadline?

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Watch our on-demand webinar, "**Preparing for Electronic, Interoperable Exchange of DSCSA Compliance Information**," and you'll get the answers you need. Topics include:

- A complete overview of critical DSCSA mandates and definitions associated with interoperable exchange, transaction information, transaction statements, authorized trade partners, EPCIS, and more.

- A deep dive into the fastest and most effective ways to onboard and integrate all of your downstream trading partners on a fully interoperable traceability platform.

- Real-world examples of manufacturing organizations and trading partners that have already achieved electronic and fully interoperable EPCIS data exchange—and a look at their secrets to success.

Get a step-by-step guide to achieving electronic and fully interoperable exchange of DSCSA compliance data with trading partners. Fill out the form on this page to watch the webinar now.

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Transcript

Dan Walles: Good morning, everyone. Thank you for joining us again in the next session of our DSCSA 2023 webinar series. Today we're focusing on a topic that I believe is top of mind for many in the industry, and that's preparing for electronic interoperable exchange of DSCSA compliance information. This is really the exchange of information via EPCIS that so many of us are focused on.

I'm happy to introduce a couple of my colleagues that will be joining us today that many of you may be familiar with. Beth Bernick is our Global Standards and Traceability Analyst and spends a lot of her time working within industry, within the various Standards organizations and industry organizations, representing on your behalf what standards need to include and how standards need to operate in order for us to successfully meet DSCSA 2023.

In addition, I'm joined by Caitlin Czulada, who is our Director of Center of Excellence. Caitlin is responsible for really helping our customers deploy their solutions and get the best out of their solution as they're approaching the DSCSA requirements.

I'm Dan Walles. I'm the General Manager of the Track and Trace and Compliance business here at TraceLink. I will be playing host for some of the session.

Just as a reminder, this is the second in our series targeted towards manufacturers and wholesalers. As Melanie had mentioned earlier, each of these are being recorded. They're available in our Resource Center, not only the slide material but also the recordings of the discussion as well.

You can join us for the next session on December 8th, where we'll be joined by Henry Schein and HEB. That's a wholesale distributor and a retail grocery store pharmacy. You'll really hear from them about what their requirements are related

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to DSCSA.

It will be a real interesting topic to hear directly from your colleagues in the industry, who are trying to meet DSCSA from another industry segment.

A few things that I'll call your attention to as we're going through the material today. Some key takeaways that we hope you leave the session with. The first is, I think, we're all recognizing that DSCSA the secure interoperable electronic exchange requirements are a network challenge and you'll hear that theme a lot around how do we successfully onboard and integrate.

For some companies, there can be thousands of customers who are receiving their pharmaceuticals. Many of you have a wide range of customers that you ship products to and because of the large numbers, what we recognize is that architectures and solutions that are based on sort of point-to-point models are just not valuable at that scale as we as we look at DSCSA.

Whether you're integrating to 10, 20, 30, 100 will show a case study about one of our customers who has integration requirements since to over 1,500 customers in the US and in recognizing what a viable approach is to be able scale that.

What we'll also see is that onboarding and integrating trade partners, particularly customers is a multi-step process and it really requires a team of resources that are not only managing the technical aspects of verifying who the partner is the B2B configurations portal configurations but some of the partner outreach that is happening.

If you leave here with one notion today, this is at the heart of TraceLink's solution and offering our network services team and Caitlin will walk through how our architecture supports that but also the team of resources that our customers have

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available to them, that is provided as part of the solution to manage that onboarding and integration.

We'll also talk about the current thinking of drop shipments, certainly a complex topic that the industry is wrestling with today, and Beth will provide some commentary as to where the industry is in there in their current thinking.

The last point I'll leave you with is, when we talk about our network model, it should be recognized that for the vast majority of the US drug supply chain, they have already been onboarded and integrated to the TraceLink network. We're exchanging information with a number of customers today for both lot-level traceability as well as EPCIS information. We'll share some of those statistics.

Caitlin will walk you through, really how easy it is to configure an integration to your customers through TraceLink's network solution. We'll walk through that.

Just a little recap of where TraceLink is today, we are approaching 1,300 customers and we should surpass that by the end of the year. When you think about serialization experience, TraceLink has approaching 900 customers that are actively managing serialized product today, from manufacturers, wholesalers, retail pharmacies, and health systems.

We have deep experience in understanding how item-level traceability is impacting your operations and therefore we have taken that feedback and are building that into our solutions, and have built much of that capability into our solutions.

When we talk about connectivity with customers, that's represented by that number 339, these are active service links so you can think of this, these are the workspaces and integrations that DSCSA information is flowing through.

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Because of that network model, it's really led to savings in the industry over point-to-point integration approaches well in excess of 4.4 billion. When you look at an average integration, B2B integration taking anywhere between 10 and 15 thousand dollars of staff time and staff effort.

We continue to invest in our employee base and those investments are largely within our R&D and services organization. Again, looking at just the amount of DSCSA experience that we have. Almost a billion transaction histories processed through the TraceLink network. That gives us great momentum as we move into item-level traceability.

One of the key points that we want to make available to you today is that TraceLink, the functionality for exchanging EPCIS information exists. It's something that we have deployed for somewhere on the order of six or seven years. That exists today.

Really, what we are focused on is making sure our customers are able to effectively and efficiently onboard their customer connections. Caitlin will walk you through that, how we do that, and show a demo of how we do that today.

Let me just recap some of what we have been talking about in the past and that's...TraceLink, we're here focused on DSCSA, but DSCSA is a challenge that we're facing within the supply chain that is as large as some of the other challenges that we face as an industry whether it be better transparency, better visibility, needing more collaboration with suppliers, much of the sustainability efforts that are happening in Europe right now.

What this ultimately leads to is, digitalizing the supply chain through things like item-level traceability is a business imperative and this is something that TraceLink is focusing on is to not only help you meet your compliance requirements but to be

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able to deploy a supply chain platform that allows you to address some of these other supply chain challenges that you're facing.

What that is based on is developing this Internet of supply chains that allows our customers to create these digital networks that represent their supply chain share processes and applications across those networks.

DSCSA and item-level traceability is one of those processes and that ultimately drives cross-functional and cross-company execution and leads to a common data model not just within an organization but across the network. That's really what is uniquely differentiated by TraceLink's network approach, is having that common network data model.

That ultimately leads to our ability to bring collective intelligence and predictive analytics, not just at the enterprise level but at the network level, at the industry level, to help our customers solve challenges, whether it be drug shortage detection, being a faster response time to recalls, and other types of challenges that we face as an industry.

One of the reasons we feel so confident about our ability to do this is because, when we look at DSCSA and we look at some of the other requirements that are happening around the globe, we have built out this Internet of supply chains around traceability.

If you look at our network, whether it be on the healthcare and pharmacy side, working all the way upstream to many of your direct material suppliers, we've built this network, this thriving network that is actively exchanging information, traceability information between each other.

This has led to our Internet of supply chain suite of products that certainly

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encompasses things like DSCSA and regulatory compliance, obviously serialization and traceability, but extends into better supply chain collaboration, network applications, things like verification, master data sharing.

Then we talked about collective intelligence and leading into our ability to better orchestrate processes, not just within our four walls, but across our partners and across the supply chain that we operate in.

As you think about what we can do around DSCSA, it's important to recognize the opportunity here to not just meet a compliance requirement but to be building a platform, to be building an Internet of supply chains that's really going to allow you to solve more advanced supply chain challenges.

At this point, I'd like to pass it over to my colleague, Beth, who will walk us through more specifically the regulatory requirements for secure interoperable electronic exchange. Beth.

Beth Bernick: Thanks, Dan. Just to do a little recap of what is DSCSA and what does it require in the law today, and what changes are coming for 2023. Let's dig into that a little bit. Today's exchange of information, hopefully, a lot of you are familiar with it. What do we need to exchange today?

Well, right now there's the transaction information, the transaction history, and the transaction statement. It can be transferred in a couple of different ways, paper or electronic. Right now, the focus is on lot-level data, but this is all going to change in 2023 when the DSCSA shifts into what's called the enhanced drug distribution security.

When we get to this point, the transaction history fades away. Instead of that, just the transaction information, we now have more enhanced transaction information,

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which has a little bit more information in it.

In addition to that, the option of paper goes away. It has to be transferred in electronic format, and also, it has to be package-level data. Instead of tracking just a lot, we now need to be accountable for every single bottle, every single package, every single unit that's going into the market today.

Instead of the transaction history, we still need to have the ability to pull in that thread of ownership should the FDA have any questions about it. Instead of providing that information upfront on all transactions, you need to have a system that's available to you and processes so that you can properly gather and respond with the transaction information and transaction statement information.

If the FDA has some questions for a recall suspect or illegitimate product investigation. How do we do that? Instead of lot-level traceability where you had far smaller amounts of data to transfer, we now have thousands of serial numbers that need to be accounted for across all production lines.

You need to store that information for many years, and the information needs to flow quickly and electronically through the system. In June of 2022, the FDA recommended in a draft guidance that we use EPCIS as the standard for communicating this information.

EPCIS was designed to account for transaction events such as commissioning, aggregation, and shipment. It will flow freely with the information that we need to track for DSCSA, but there are different versions of EPCIS.

How as a business are you going to communicate with all of your connections and all of your partners if one requires EPCIS 1.0, one says 1.2, maybe one has custom fields, maybe another one isn't ready for EPCIS and they want to use a portal for

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communication.

These are all things that you need to think about from a business perspective when it comes to communicating in this new 2023 world where we have the product-level information, thousands of details, and it all needs to move electronically.

[pause]

Beth: The next slide. [laughs]

OK, so what are some of the changes that's happening? From transaction information today, we're enhancing that a little bit to be the serialized transaction information. This we now need to include in addition to the drug's name, the strength, the dosage, all the fields that we have today.

We also need to add the serial number and the expiration date to this transaction information. There's now more information that needs to be transferred for all the products in the market.

In addition, we also have the transaction statement. Now, there's a lot of fields in the transaction statement, many of which we're familiar with today, but let's take a look at what they actually say.

A couple of the first two points here that are very specific is the concept of authorization. The first two fields reference, are you as a company authorized to act in the DSCSA market? Are you sending the product to a company that is also authorized? It goes on to ask questions about the product itself.

Is it suspect or legitimate? Do you have any reason to believe that it is? Making sure that the information you're providing, to the best of your knowledge, is still

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accurate and valid and complies with DSCSA. Another factor of this is that the transaction information and transaction statement is getting processed along with the product.

That information flows along with the goods, but in a world where we can't use paper, how do we do that? As we go into 2023, we're going to have to shift from the notion of using paper to strictly using electronic.

Again, if you're ready for EPCIS, great, that can make things a little bit more streamlined, but there's other options available, including a portal, if you need to transfer that information.

When the DSCSA talks about authorization and being an authorized partner, what exactly does that mean? The DSCSA does get into that a little bit. On the next slide, we'll see this. It talks about [laughs] whether or not you're licensed. The question of licensing, it's very important today.

The questions remain of, how do you confirm licenses? What processes do you have in place to verify that your licenses are accurate today? You probably have some system in place to make sure that your license is up to date. What do you have in place for your trade partners? Then as 2023 progresses, maybe you're going to hear from indirect trade partners.

In those situations, what processes do you have in place to ensure that the people who are communicating with you are in fact authorized to do so? How can you be sure that the licenses that they say that they have are accurate, they're up to date, they're not expired or revoked, or any other situation that could come into play for licensing?

These are all important business questions which you're going to have to address

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as we move on into 2023 and as we go into this more electronic world, where you may not have such a paper transaction to communicate back and forth.

In addition, you may have more indirect partners that you're working with. You may not have direct business connections like we see a lot of today. Even in today's market, there are several conversations that happen with indirect partners.

[pause]

Beth: Going after this, another really big topic that's coming up in the industry today is not just are your licenses up to date? Are they accurate? Are they still valid? Also, in the digital world, how can you be sure that the partner you're talking to is in fact the one that they say that they are?

I'm sure we've all gone onto some online situation, and you have to click the box that says, no, I'm not a robot. You have to click the boxes that say, [laughs] this has a stoplight or this has a bus in it.

The same thing applies to DSCSA. When you get a message from someone and they say it's the FDA, are you sure it's the FDA? I'm sure you want to confirm that information before you reply with sensitive details about serialized product.

Similarly, if someone in the market says that they're coming from another company, you want to confirm that they're authorized to ask that question. Do they have the right licenses to do so, to act in the role in which they're acting, and also to confirm that they are who they say they are?

How, as an industry, do we face all these? Especially in the notion where indirect business partners are going to come into play. One of the really common situations that we see today which address indirect and direct partnerships is with the

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concept of dropship.

For those of you who are not familiar with what dropship is, dropship is when product takes one path, but ownership takes another one. From a DSCSA perspective, ownership is really what matters.

In this scenario, it could be where a dispenser is trying to order a product from a wholesale distributor, but the wholesale distributor doesn't have it in stock.

They in turn place an order with a manufacturer, but instead of having the product shipped to the wholesale distributor, they ask the manufacturer to shift the product directly to the dispenser. That case, the product goes directly from the manufacturer to the dispenser, and they now have an indirect partnership.

Whereas, from a DSCSA perspective, the product ownership goes from the manufacturer to the wholesale distributor. We can no longer send paper packing slips that send to the transaction information and transaction statement details. How do we electronically get that information from point A to point B, as well as the product?

There's a few ways to handle that in the industry today. One of them is with sending the EPCIS message. Then, from a manufacturer's perspective, you can send it directly to the wholesale distributor, and then you can also send it directly to the dispenser yourself.

This means that you have to enhance your partner network. You have to have more connections, more master data, and that's a lot of work that you can have to maintain.

You could post the message simply to the wholesale distributor, and then post a

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link to it to a portal online, which a distributor could then, or dispenser could then access to download that information directly. That information could be transferred through a link that's transported somehow.

In addition, there could just be a portal that everyone accesses to download this information. There's lots of different ways electronically that you can gather these details. It really comes down to your partnerships and your business partners, and what method works best for you.

[pause]

Beth: As we go into 2023, how is TraceLink going to support you with these options? Well, TraceLink will be supporting all three of these scenarios, whether it be a dropship portal that's accessed through a portal login, or whether the EPCIS information is handled directly from one partner to another.

There will be several different ways to do that, and Caitlin will show you how easy it is to connect from one partner to another, so that this information can be easily accessed and easily disseminated throughout the industry, so that we can continue to supply products safely, effectively, and quickly.

Dan: Thank you, Beth. I appreciate. We appreciate the information and the updates. I think I will echo the challenges around drop shipments and really, when you're a drop shipment by its nature is, you're sending the product to somebody that you may not have a direct commercial relationship with. However, being obligated to provide that compliance in information.

Again, it really speaks to when you look at not just your customers, but when you're assessing your requirements and potentially the need to integrate or make information available to anyone that you ship product to.

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You're looking more at your ship-to customers. It starts to grow the number of potential integrations that you might have to do depending on the approach that the industry aligns on. If the industry aligns on a single approach, what we expect to happen is that there may be a variety of approaches that are acceptable and as your solution provider, we're committed to supporting you in each of those scenarios.

One area that I'll talk about is just again, trying to reinforce where TraceLink is today as it relates to item-level traceability and DSCSA. The reason we're bringing this up and maybe repeating some information we've provided in the past is making sure that our customers and our prospects recognize that we're already off and running.

We have almost to the day about a year left to go before this requirement goes into effect. Today, we have almost 800 DSCSA customers spread across manufacturers, wholesalers, and dispensers. We have 135 companies that are exchanging DSCSA EPCIS transactions with TraceLink.

These are transactions that are compliant with the 2023 requirements for item-level traceability that we're exchanging in production capacity. What that means is that, things around understanding formats and issues around scalability as we move to item-level traceability. We've largely encountered those challenges because we've been deploying and working within EPCIS for a number of years.

Earlier, we talked about service links, and these are the integrations and connections between companies on our network where information is exchanged. When you look at what we have in place today, at 318,000 service links, these are connections.

These are the representation of integrations and connections between companies,

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manufacturers and wholesalers, manufacturers and dispensers, wholesalers and dispensers. The connections are already in place across the network because these are the same connections that we'll use for item-level traceability that we're already using today for lot-level traceability.

The message here is if you are an existing TraceLink customer, you're largely already underway in terms of configuring your network. Maybe you're using an alternative solution provider's approach that was more focused on lot-level, you will get a running head start by partnering with TraceLink on your item-level traceability requirements.

Some more information on our T3 information's process. I'll call your attention to this 713,000. That is DSCSA T2 Information Exchange through TraceLink. These are the item-level EPCIS transactions. We are already today exchanged hundreds of thousands of EPCIS transactions that will be required in November of 2023. Tremendous amount of experience that we already have in place.

With that, come to our first, and I believe this is our only poll question for today. Melanie, you can load the poll question for the audience. Today's poll question or survey question is when considering the network challenge for DSCSA, which of the following is most important?

Is it the efficient and cost-effective onboarding with trade partners to meet DSCSA deadlines? Is it supporting ongoing changes of trade partner integration? These are situations where, let's say one of your wholesalers or one of your dispenser customers has a new requirement.

Maybe the addition of a new data field that they want included in the transaction. Maybe moving to a new version of the standard, because we know that that doesn't always happen all at once.

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Adding new trade partners. We all go through mergers, acquisitions, divestitures. Our supply chain particularly our downstream networks are organic. They're growing, not shrinking, but growing on a regular basis, our customer base that we will be required to send information to.

Is it related to the staffing support of trade partners? Your ability to not only establish the integrations but when we have situations where things may go wrong, you need a staff in place that's allowing you to be able to manage those exceptions and understand what impact that might have on the delivery. Or is it all of the above?

It looks like we have pretty good response at this point. Give it a couple more seconds. Three, two, one, we'll end the poll. It looks like we have a lot of spread. The all of the above is obviously, we're concerned about many of the things that are happening in the environment as it relates to onboarding those trade partners.

Many of you are looking at what's staring us right in the face. How do I make sure that all of my trade partners are onboarded efficiently and cost-effectively? This leads to our next section here that Caitlin will lead us through the discussion on how to manage that onboarding process with your trade partners.

Caitlin Czulada: Thanks, Dan. I am going to take over presentation. Now that you've heard about the requirements, we're going to talk about how TraceLink might be able to help you meet those requirements. Specifically, we want to talk about the secure, interoperable, and electronic data exchange with your partners.

How will you manage the onboarding of those trade partners? We just saw the poll. It sounds like 30 percent of you, if not more, are really concerned about that.

In the traditional model, which you may be used to, in the point-to-point, these are

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the steps that you had to go through to create one connection. To set up that B2B connection, whether that's AS2 or SFTP or another B2B, then you have to align on data formats.

How does this partner want to receive format best talked about changing standards? Those will continue to change, but you need to align on that upfront. Then you need to test everything, make sure that it's working, align with that, and then you can go live.

After a live, everyone knows though that it's not over. There's always ongoing maintenance. There are changes to standards, there are changes to business requirements.

You work through all of that to create one connection. Then you had to do it for every connection. You had to do it over and over and over and over again. It's a ton of work to set up your entire trade partner.

As we're about a year out, like Dan said, how are you going to meet the requirement to do all of this work for every one of your trade partners? That's where TraceLink can come in and help.

In the TraceLink model, you have to do those steps, but you only have to do them once. You're going to connect to TraceLink. You'll set up your connection directly with TraceLink. You'll work with us, we'll align on how you want to send or receive data format. We'll work with you to test that and then go live. Then, we'll work with you on ongoing maintenance.

That's your one connection and the one work that you have to do to connect to TraceLink. As you onboard each one of your partners, it's TraceLink who's responsible to build those partner connections. The good thing is that each

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customer gets to take advantage of that shared network connection.

What does that look like? For each one of those partner connections, you are responsible for only testing as you need and we will certify the partners, we'll provide that certification to you up to your level of risk of what level of testing you want to do, and then go live.

TraceLink is responsible for all of that other work. We will set up that B2B. We'll work with that partner to align the data format. We're making sure that the ongoing maintenance of that partner if they change formats, we do that.

What's nice is that, because we have a network model, we only have to do this once. TraceLink lets companies interoperable, integrate once, and then we're integrate, interoperable with everybody.

This is possible because TraceLink network has one shared connection for each company that is managed and maintained by TraceLink. For example, those large wholesalers in the industry, we have one connection to them, and then all of our customers get to take advantage of that one connection.

That's how we're able to scale, that's how we're able to move the industry forward, and that's how we're able to get you connected quickly and efficiently is because we share those connections with all of our customers. We take that burden of that point-to-point and we manage it from a network perspective.

[pause]

Caitlin: What does that look like? What does that really mean? As a TraceLink customer, the first thing that you'll want to do is you'll build your connection with TraceLink. As I mentioned, we'll go through all of those steps, and you will be able

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to transact with us in your format.

Then, TraceLink will build and manage the connection to all of the companies on the network. As you heard from Dan and his statistics, we have 290,000 entities already on the network, and hundreds, if not thousands of them already exchanging data with an hour.

We will weld those connections, and then what you do is that you will link to those specific companies on the network that you do business for.

Obviously, you don't transact with 290,000 companies, but you certainly do transact with a subset of those companies. I'll show you in a moment how you will be able to search the TraceLink network and make those connections within a matter of minutes to start exchanging data with those businesses.

Then the partners, as I mentioned, they get to transact in their own format. TraceLink has already done the work to figure out how they want to exchange the data. We've done that. We've exchanged those information and we've set them up to exchange data and how they want to.

Obviously, there's going to be portal companies. As we all know, a lot of the downstream isn't capable of receiving data but you still have to provide it in a secure, interoperable, and electronic data. The FDA has already said that a portal is in electronic format, so we would provide that portal for them.

The nice thing is that it's one portal for all the TraceLink customers. Those entities aren't having to log on to a million different systems, remember different passwords, URLs, they can just come to TraceLink and they can see all of the data for the companies that are using TraceLink. It makes their lives a lot easier as well.

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Once you've made those links, then you're able to start exchanging data with all of those companies.

Beth: Now what we are going to do is we're going to do a quick demo of how you will connect on the TraceLink network in the application. Let me stop sharing and really quickly we'll go into the application to show you how you'll do that.

The very first thing that you're going to want to do is you're going to want to add all of your partner master data's. These are any of the companies downstream and upstream that you have to send the serialized data exchange to.

Once you've add them to your master data, what you're going to want to do is we're going to want to link them to the entities on the TraceLink network. That's the 290,000 entities that we've been talked about that TraceLink has added and verified are authorized trade partners in the US supply chain.

After you add them to master data, you're going to come here to this screen and we're going to create those links. We're going to choose product track and then we're going to enter the identifier for the company that we are linking to.

You can add an additional email. You can certainly do that. It's a secondary step after you make the link. What you're going to do is you're going to create that service link. What that does is it takes that identifier and it goes out to the TraceLink network and tries to match up an entity that we have already added to the network.

It tries to say, "OK, you are trying to link to Rask Enterprise with GLN123. Does that match to a company that we have already created on the network?" It goes out there, and then, in a matter of minutes, it's going to see and make the connection.

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Obviously, in the real world when you're doing this, you will want to do a lot all at one time. We do have the ability for bulk linking, so you can upload all of your partners at once. It'll go through the network, and it will try and find those partners and make those service links for you.

You can see down here that somebody's been in the system. They've been linking, so they have two connections to other companies. Here, we just made a connection to this third company here. This is Rask Enterprises that we have connected to. It's as simple as that. The onboarding has been done.

Now you can start sending them serialized data through the Product Track portal immediately. There are no other onboarding steps that you have to do to start sending them data in the portal and to be compliant with the serialized, secure, interoperable electronic data exchange.

Obviously, if the partner wants to receive an outbound EPCIS file, we would want to work with that partner to get that set up, like we've talked about, but you linking to them is an important first step, and it only takes a matter of minutes, as I've showed.

Let's get back into this. We will look at an example here.

Caitlin: OK. What does this mean, and how can TraceLink help versus a traditional point-to-point? I went through all of the steps. What does that look like? If we take just 100 trade partners...

Just to be clear, Dan. Are you seeing the slides?

Dan: Yes, we are.

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Caitlin: OK, thanks. [laughs] If we take 100 trade partners...On average we have between 95 and 98 percent already on the network. If we assume 95 percent of these companies are already on the network, it would take about five weeks of effort to complete all of the onboarding activities, and be live for DSCSA, because if you remember TraceLink is already doing a lot of the work.

Because we have to do it once for the TraceLink network, you get to really take advantage of all of the work TraceLink has done and then you just need to make that connection as I...Sorry, I didn't show you in real-time, but I showed you after the fact, and then decide what level of testing meets your company.

On average you could probably do that in about five weeks, give or take. Now let's take a point-to-point provider. Again, we have 100 partners. Typically, they say that it would take two to six weeks, estimated to create each connection and then about eight weeks in addition to that, to validate the trade partner connection.

All in all, that would be about 1,000 to 1,400 weeks. That's about 26 years. That's not reality, partners can be onboarded in parallel. Still, the amount of work is tremendous if you're doing point-to-point connections. As we all know, we only have one year to get this all done.

Point-to-point is not going to scale and is not going to meet the deadlines for the upcoming DSCSA requirements.

Dan: I think just to comment on that, Caitlin, with lot-level many of you in the industry elected to continue to use your EDI systems. You had to send the ASN, create some modifications within the ASN that was being sent out to your customers for the lot-level traceability requirements.

That was a good solution because you had a lot of existing infrastructure in place

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and knowledge in place around EDI, specifically ASNs.

What we're looking at here is, not only are we moving to item-level traceability, which has its own challenges in terms of communicating the amount of data we're communicating, add into that the business requirements of many of the wholesalers for aggregation. Then the knowledge associated with that.

We're not going to be able to send EPCIS transactions through an EDI system. We're starting from ground zero in many cases, as an industry, and I think this is where TraceLink's approach has a lot of advantages because we're not starting from ground zero.

We have much of this work already in place. The amount of work that's described on the right-hand side here wouldn't be something that you would encounter. Your scenario, through TraceLink, is looking more like the left-hand side of this diagram.

We can't underestimate the importance of that. I know many of you are focused right now on, "I got to send a transaction to my primary wholesaler or my top wholesalers," but we shouldn't underestimate the amount of time in that long tail. Being able to get that process stood up if you're starting from zero.

With TraceLink, you're not. You're already, will have a head start to get that going.

Caitlin: That's exactly right, Dan. As you were saying, we do tend to focus on the large wholesalers. They tend to come first, but DSCSA is agnostic to how big you are.

You as a manufacturer are required to provide data to 100 percent of your downstream partners. It's always that long tail that takes the longest and is the hardest. As Dan said, we likely already have the majority of them, if not all of them

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on the TraceLink network.

Even if they aren't getting EPCIS, you'll be easily able to link to them, like I showed, and then immediately send them data in a portal. That may be perfectly acceptable for them to receive. You know that you would be meeting your requirement for them.

OK. Now we talked about how you might do the initial connection. As we all know, that doesn't end there. How do you think you'll be able to manage the maintenance of your trade partners for DSCSA? How that might work in TraceLink? We expect there to be a new version of the US Healthcare Guideline or EPCIS, but today the current version is 1.2.

For this sake, let's assume that you're using 1.2 to exchange data and you're happy. 1.2 is compliant with the regulation. It has all the required information so you're happy with 1.2. Maybe your partner decides that they want to upgrade to 1.3. On a traditional point-to-point, you would be required to make that change. You would be required to manage that.

In the TraceLink model, each partner can upgrade on their own time and there is no impact to you. You can continue to stay on 1.2 and there's no impact, so your partner gets to upgrade on their time with no impact to you.

Maybe the other partner wants to use custom 1.2. Maybe they have custom data that they want to send into the system. Again, in a traditional model, you would be required to manage that upgrade with them, but for TraceLink we will manage that on your behalf.

We'll make sure that they get the correct format that they need to transact with. Then maybe other partners will want to continue use 1.2.

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You can see from this model that you'll be able to transact with a variety of different partners in a variety of different ways, all at the same time. One of the biggest challenges that we've heard in the industry is, how are we going to manage the upgrades from 1.2 to 1.3 and then 1.4. We know things don't always stay the same.

With TraceLink, you don't have to worry about that. We are backwards and forwards compatible because of the way that we do our data modeling. We can manage all of that and you won't have to worry about different partners wanting to exchange data in different ways.

Now, what did you say? I said we have about 95 percent on average, 95 between 98 percent of partners on the network. What are we going to do if the partner's not on the TraceLink network? Well, we have solutions for that as well. We have entire teams who we dedicated to do this work on your behalf.

We only have to do this once. That's a really important point. If the company is already on the network, we never have to do this activity again.

If it's adding it for the first time, we're going to receive that company information, we'll research them and verify the identifiers that's talked about, making sure that these are authorized trade partners. We don't add any company to the network, we need to verify them and verify that those identifiers are valid, those licenses are valid.

Once we do that, we'll add the company to the network. Once they're on the network, you can connect to them. I apologize for the demo error, but essentially you would key in their information and you would make the link as soon as they are added to the network.

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We also need users. A company may not be good enough if nobody is getting the data, so we also verify users on the partners as well. We'll receive the email information, we'll verify that that's a valid email for that company. Once verified, we do add them to the network. That way that user can have access to the information.

As I mentioned before, once they have access to the TraceLink network, they get to take advantage of seeing all of the TraceLink customers. They don't have to log in to seven different portals with different URLs and passwords. They have a single place that they can go to view all of the information.

Then finally, if they are exchanging data, we will set up that B2B. It's a shared B2B so once they're set up, we don't have to do that. We'll set up their B2B of choice, AS2, SFTP, we'll exchange the credentials required for that and then we'll add that B2B to the company network and they'll be off exchanging data from there.

Then finally, how are you planning to staff your company to support each trade partner connection? We know that DSCSA is going to bring an additional level to your company that needs to support these connections. They need to make sure that the data's flowing.

We haven't talked anything about exceptions but we all know that the exceptions are coming. How are you planning on supporting that? TraceLink can help with that as well.

As we mentioned several times before, we have two teams who are dedicated to managing all the partner connections. These are come as part of your subscription so there are no additional cost to you and there are no additional cost to your trade partners. They don't have to worry about those as well.

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We have a network operations team that's there to create and verify all network companies and set up those users. All those steps that I talked about, their job is to maintain and curate and make sure that we have a secure network that you can ensure you're exchanging data with authorized entities.

We have an additional team, the network success team that's your technical integration. For all of those companies that want to exchange data and not just get data in the portal, we have a single point of contact for that trade partner.

That's important because the trade partner doesn't want to have to know who to work with for TraceLink. By having that single point of contact, they can go to them and say, "OK, I need to manage my connection, I need to change this," or whatever it might be. It streamlines things significantly.

Your trade partner gets the support that they need. They get online learning and they have no charge of them to being on the network and to getting that additional support. The way that we can scale the support of the network is by offering these teams.

This is a huge augmentation to your staff that you would otherwise have to staff yourself. You would need people on hand to manage those connections, to work on any issues that occur. Going with TraceLink, we have that staff that's all built in as part of the subscription so it's really is an augmentation to your staff.

Dan: Great. Caitlin, maybe you can continue to drive the slides and I'll speak to them. If you can go back to that previous slide, I do want to call out a couple of additional points here and reinforce some of what you stated.

Often times what we're seeing right now is, as companies are looking to deploy their DSCSA 2023 solution and they're engaging with their existing solution

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provider that may not be TraceLink, they are getting quotes from that solution provider to go off and onboard, and integrate the trade partners one by one.

We've seen estimates, the consistent estimate that we hear is about $15,000 to onboard a partner. If you look at that and if you go to the next slide, we've taken that and this is the exact analysis that one of our customers had gone through.

They're a new customer that had not been using TraceLink for DSCSA. They recognized the challenge that they had was being to able ensure DSCSA compliance and being able to exchange EPCIS transactions.

This particular company had selected an alternative provider for level four which is the repository for serial number management. They were not using TraceLink's capability here. However, they approached us around being the level five provider for them. Managing the integration and taking over the information exchange, the verification requirements for that provider.

This is a scenario that we support out of the box, if you will, we integrate. We have a number of customers that use an alternative solution provider for serial number manager in Canada, the EPCIS repository. We essentially layer on top of that system and manage the integrations and outbound communication with their partners, whether it be CMOs or customers.

In this example, this company has about 1,500 customers in the United States, representing just over 10 billion in revenue. Their US presence...It's a global pharmaceutical company, but their US business is fairly significant, as you can imagine.

When we did the analysis against those 1,500 customers, 93 percent of them were already on the TraceLink network. If you look at what that savings is, if you were to

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go and approach this through a point-to-point model, that cost is in the tens of millions.

Maybe more importantly, as Caitlin pointed out, is the time to do that is just not viable. You would need an army of internal resources to be able to go off and onboard them. For TraceLink, the services effort to integrate to their level four, the TraceLink services effort of that is about 37 days.

When you start to compare that to alternative solution approaches that are charging you one by one to onboard and integrate to your partners, the cost and time is pretty significant.

From the IT lead or the head of IT that's managing it, they recognize right away their current provider's ability to be able to onboard their 1,500 customers in time for the regulation.

They weren't in a situation where they wanted to rip and replace their current level four. We're able to address that concern based on already having this large percentage of their customer base already onboarded and integrated into the network.

Certainly, a value and a real example of the capability that we're able to provide. I know we only have a couple more minutes here. I just want to tee up our next webinar. This is a webinar that's really targeted primarily at the dispenser community but certainly, something that we invite all of our customers, prospects, members of industry to attend.

Next week, it's being held on Tuesday because of the US Thanksgiving holiday. On the 22nd we'll really be looking at, from a dispenser perspective, transitioning from lot-level to item-level traceability under DSCSA in the need for an experienced

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partner. We bring that up because there are multiple approaches that a dispenser can take.

The operational impact to a dispenser is fairly sizable. There's different approaches that we recommend that our customers have taken that we want really walk you through. We also want to talk about a service that is available to our dispenser customers.

That's our host service, our healthcare operational support team, which really becomes an extension of your staff to help you manage the day-to-day care and feeding of a DSCSA compliance system. Then we'll also talk about what an audit might look like under DSCSA 2023 and how your solution can support that audit. Hopefully, we'll see you there.

Just in summary, a couple things that I hope you take away or were able to take away from this is we harped a lot on the network challenge of DSCSA. We hope that you recognize the point-to-point approach is just not being viable when we talk about the numbers of companies that you may have to onboard and integrate to for compliance.

Failure to do so or any disruption in that has a meaningful impact to the patients that you serve as well as your business objectives. We hope that we were able to describe and provide some visuals to the multi-step process that happens when you're onboarding and integrating to a trade partner.

Then the advantages that a solution like TraceLink, not just from the software that we're providing, but also through the services that are available to you at no cost, like our network services organization. Hopefully, the update around drop shipments was informative and helpful for you.

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Then maybe last, and put an exclamation point on this topic, hopefully, we demonstrated the head start that we already have in the industry, with over 290,000 entities already onboarded, many of them integrated into the TraceLink network, the vast majority of those are representative entities in the US drug supply chain.

Our ability to be able to get you compliant in time for November 2023, we believe that we can meet your requirements there and get you compliant well in advance of the deadline, and really reduce that risk for you as you work through 2023. With that, I do see we have a number of questions, unfortunately, we're over our time.

What I'd like to do is we'll collect those questions, we will have our account executives reach back out to you to provide responses to those questions. Certainly, if you are not an existing of TraceLink, reach out to us at marketing [at] tracelink.com, we'd love to spend some time with you and work through your requirements for a DSCSA.

With that, that completes our webinar. Beth, Caitlin, thank you for joining us today and driving some really informative and useful information for us. Have a good day, everyone.

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