Preparing for Electronic, Interoperable Exchange and Verification Requirements of DSCSA

Achieving secure, interoperable, and electronic exchange of EPCIS data and managing verification requirements with supply chain partners before the November 27, 2023 DSCSA deadline requires a digital network platform-based strategy. Why? Because establishing point-to-point connections with supply chain partners is prohibitively expensive and will not scale. But with TraceLink, it's as simple as "Integrate Once, Interoperate with Everyone."

Watch our on-demand webinar, "**Preparing for Electronic, Interoperable Exchange and Verification Requirements of DSCSA,**" to learn more about verification requirements and see how the **TraceLink Opus Digital Network Platform** delivers DSCSA 2023 compliance. Three reasons to watch now:

1. Get a complete overview of DSCSA verification requirements and key DSCSA terms and concepts like Transaction Information, Transaction Statements, EPCIS, and more.

2. Learn how the DSCSA Authorized Trade Partner concept impacts verification

processes and find out what your company must do to acquire Authorized Trade Partner credentials.

3. See a live demonstration of the TraceLink Verification Router Service (VRS) capability, which supports new use cases and Authorized Trade Partner requirements, including support for receiving requests with Authorized Trade Partner credentials.

You'll also see real-world examples of organizations that have already achieved electronic and fully interoperable EPCIS data exchange—and discover their secrets to success. Fill out the form on this page to watch the webinar now!

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Transcript

Dan Walles: Good morning everyone and Happy New Year. Thank you for joining us today. We want to continue our webinar series into the year 2023. Today, we're going to be talking about the end-to-end requirements for DSCSA 2023.

I think over the past six weeks or so, we've covered a variety of different topics and our plans heading into 2023 is to start to stitch these together to give you a

full picture of what your requirements are for DSCSA and how TraceLink can partner with you to help support you in your compliance needs.

I'm pleased to be joined by a couple of my coworkers. Caitlin Czulada, who many of you are familiar with and presented with us in the past. Caitlin is our director of Center of Excellence and has been focusing on DSCSA 2023.

Rachel Hummrich, many of you probably have worked with Rachel. Rachel is our network principal and our network success group and has been responsible for helping to build out our network. As many of you know, our network success team is a liaison to your suppliers, customers, and trade partners.

My name is Dan Walles. I'm the general manager of TraceLink's Track & Trace and Compliance business.

Just a quick disclaimer, we will be showing some product today. Caitlin will take us through a demonstration. We want to provide our disclaimer in terms of the information that is being presented here today.

In addition, we want to recap the various webinars that we've had running over the past six weeks or so to reorient folks. We have a couple of different tracks. We have a track that's focused on the requirements and challenges being faced by pharmaceutical manufacturers, distributors, as well as a second track focused specifically on the dispenser segment and dispenser community.

In addition to that, we have a series of Deep Dive sessions that go into a deeper view of topics. You can access all of these webinars through our website. Ones that have happened in the past are available on demand. You can see here some of the ones that we have coming up in the future as it relates to the dispenser community.

Let's jump right into today's webinar. As I had mentioned before, we're going to combine a few of the key topics that are part of DSCSA 2023. The first one that we want to look at is interoperable exchange and understand what those requirements are as defined by the regulation.

Also, PDG. PDG is a group that many of you may be familiar with. It's the partnership for DSCSA governance. This is an industry organization that is working alongside GS1 and some of the other industry organizations to define the industry blueprint for meeting the DSCSA requirements. We want to expose you to their interpretations and their requirements.

We want to talk about where the industry is currently at in terms of drop shipments, as well as TraceLink's perspective on this important topic. We'll take a similar view of industry requirements and regulatory requirements around verification. As part of that, start to provide some definitions around this concept of Authorized Trading Partner and credentialing.

This is a topic that I think is warranted further discussion. It's created a little bit of confusion in the industry in terms of what exactly those requirements are and what members of the industry have to do.

Then we'll provide some data to you about our leadership in the industry as it relates to DSCSA. We're underway with a number of projects, a number of customers that are starting to implement their 2023 solution, and want to provide you some visibility into that.

First, let's take a quick look at where TraceLink is today. This is more of a full view of the TraceLink organization across our entire business, which is focused on not just regulations in the U.S., but regulations globally. We have about 1,300 customers as of the end of 2022 across 50 countries.

One of the key points on this slide is that almost 900 of those customers are related to serialization. Whether they be pharmaceutical manufacturers, or wholesale distributors, or even dispensers, we have a number of customers that are actively implementing their serialization projects and working towards the 2023 requirement.

A big part of our value prop is our network, which we've gone through in a fair amount of detail. What we want to do is look at supply chain digitalization and the value of a network. Some of the challenges that you're facing today across that network are in the area of traceability. Obviously, DSCSA is a traceability requirement.

In other parts of the supply chain, one of the things that we've learned from, whether it be the COVID pandemic or some of the other challenges that we've seen in the medicine supply chain, is in the area of material shortages and shipment delays, so getting better visibility into our supply chain.

Having a more transparent supply chain so that when we do have issues around material shortages, we can not only be better at detecting them but also executing on getting bad product out of the supply chain in the area of recalls.

We're also, from our customers who are starting to talk to us a lot about sustainability initiatives, moving to things like digital leaflets. We see activity in Europe as well as Brazil in that area. It all just leads to being able to collaborate better with our suppliers, whether they be finished-goods suppliers, or even working further up the supply chain in terms of API.

When we talk to our customers, supply chain digitalization is really becoming a business imperative, and companies are looking at, "How do I address all of these different challenges through a more harmonized approach?"

If you move to the next slide, when we think about this, we start to think about it in this context of an Internet of Supply Chains, which is linking people, processes, systems, and enterprises across a network to help us execute supply chain processes better.

Although we're here today to talk about a fairly specific process in terms of meeting the requirements of DSCSA, we want to talk about what this enables us to do to solve some of these business imperatives. The need to be able to create digital networks for supply chain processes, to be able to share and execute those processes not just internally across my own enterprise, but with my partners.

If we do this in a way across the network, we can start to create a common data model that is managing and maintaining the information flowing across that network. This allows us to start to do more things around what we will refer to as collective intelligence—how can we analyze the information flowing across that network to solve more advanced challenges, things like drug shortages or product recalls. Being able to build out this platform in order to solve these challenges.

One of the reasons why we believe we're well-positioned to do so is because, over the past 20 years, when it started with the state-level pedigree requirements and then expanded into federal legislation in 2013, along with the various global requirements that have gone into effect and are underway.

We have really created this foundation for creating a digital supply chain, whether it be our healthcare customers and pharmacy customers, wholesale distributors, pharmaceutical manufacturers, contract packagers, even moving up to direct materials suppliers.

We have created this Internet of Supply Chains rooted in serialization and compliance. It's become that global case study for supply chain digitalization.

When we think about what that platform looks like in terms of the Internet of Supply Chains in our applications and solution suite, the foundation of that is in this digital supply network.

Those tools we talked about on the previous slide, for when you're operating on a network, it requires the network administration tools and ability to quickly connect to your suppliers and your customers. We refer to this model as “Integrate Once, Interoperate with Everyone”, which marks a departure from the constraining point-to-point model that we have today in areas like EDI.

Catalogs that are driving the solution and applications, a low-code application development environment and then various plugins to be able to extend our UIs. Now, today we're talking about serialization and traceability and regulatory compliance as it relates to DSCSA.

We also want to make sure that our customers recognize the value and assets that they're building, that they'll then be able to leverage for more supply chain collaboration, network applications such as digital recalls being able to share master data.

Collective intelligence solutions then being able to detect drug shortages and then ultimately, process orchestration in the area of targeting towards things like cell and gene therapy.

When you look at TraceLink, it's really about driving a more holistic platform approach for how you're addressing your supply chain initiatives and digital transformation initiatives.

Specifically, let's talk about the Drug Supply Chain Security Act around the area of electronic and interoperable exchange. What we want to do is compare and

contrast where we are today in terms of the lot-level traceability requirements that went into effect in 2015 and compare that to item-level traceability and what will be required in 2023.

You can see, in the yellow here, there's some of those key differences. Just to level set what we have in place today as an industry and as a requirement is this exchange of Transaction Information, Transaction History, and Transaction Statements.

We're doing this at the lot-level, and we can exchange this information via paper or electronic. There are a couple of things that are significant in terms of our requirements in 2023. We still have this concept of transaction information, but this transaction information now includes the product identifier, the serialization information.

The transaction statement still exists, but I'll call your attention to this third bullet here, the requirement for this to be secure, interoperable, and electronic. For many, particularly on the dispenser side who are really taking your packing slips and putting those into file cabinets or working with an organization like TraceLink to manage that on your behalf.

There is a movement where this now has to be an interoperable electronic exchange. We really have to understand how that is going to impact our pharmacy operations and how you're going to get that information from your primary wholesalers as well as the long tail of other suppliers that you receive product from.

There's also now the requirement for systems and processes for verification at the product and package level and then processes to respond to requests for TI and TS. Upon request, whether that be as part of a recall suspect or illegitimate

product investigation.

A fairly sizable jump in terms of requirements that we have to be ready for as an industry as we move from lot-level traceability to item-level traceability. This comment here on the right is about what the industry has done—they've harmonized on at least the standard that is going to govern the exchange of that information, and it is EPCIS.

This notion of “will EDI continue along as a compliance vehicle” will shift to this EPCIS format because it's better designed to handle the increase of information when you start to include serialization and item-level traceability.

ASNs will still continue on in a business optimization capacity, but your compliance vehicle will shift to EPCIS. Drilling in this a little bit more deeper, when we look at the serialized Transaction Information and Transaction Statement. The Transaction Information is a lot of the information that's included in there today and I apologize, it's cut off at the bottom there.

The additional information that we have included is now the serial number. Rather than just including the lot information, it's now including that GTIN and serial number, expiration date, as well as the information that was listed above here in that Transaction Information.

There's some requirements around the Transaction Statement. This concept of introducing Authorized Trading Partners and the definitions around what is authorized, and we'll go through that as a set of additional slides in a few moments.

What I'll call out here is one of the things that you do not see on this screen—Transaction Histories. In the current model, what is being communicated

is this Transaction Information, Transaction Statement, as well as the Transaction History, which is essentially that chain of custody of where the product has been when it was shipped to you.

That requirement for the Transaction History is sunsetted in 2023. It goes away, which introduces another set of requirements for the industry to determine “how do I assemble that Transaction History as part of a suspect product investigation, a recall, or other requirements?”

This is where product tracing is introduced as a new capability that the industry will need. We'll have a webinar focused on the industry's current thinking around product tracing in… I think that's coming up in a few weeks.

We also wanted to talk about drop shipments because we recognize that drop shipments are an important and needed mechanism of sending product to dispensers directly when there is some sort of a shortage or a dire need for that product. There is no exemption for drop shipments under DSCSA. We still have to meet the regulatory requirements.

There's really a few options that are being discussed within the industry. One of those options is that the pharmaceutical manufacturer, when they send that physical shipment to the dispenser, they send the Transaction Information and Transaction Statement to the wholesaler that you ordered the product from.

In that, the manufacturer may establish a direct connection with the wholesaler and send that information via EPCIS. Then the wholesaler puts it in a porta. That wholesaler may send the information to you via EPCIS in and directly into your system or the manufacturer may put it into their own portal. There's one option that the industry is talking about if you just go back to that previous slide, Caitlin.

The other is that the manufacturer sends this information to both the wholesaler and the dispenser, and that would be delivered via an EPCIS transaction. Then finally the manufacturer just makes that information available in a manufacturer portal exclusively. Lots of different options, the industry is trying to figure out what is the right approach.

Our experience has been in these situations that we may not harmonize on a single approach. There may be multiple approaches that dispensers have to contend with, based on the manufacturers and wholesalers that they are working with. We expect that all three of these scenarios may exist.

We have capability to support the different scenarios that you see outlined here. There's a lot to learn in terms of drop shipments.

What it speaks to is that, as a dispenser, as a health system, or a retail pharmacy, you will continue to have a need to identify and connect or integrate quickly and easily to find information from what you might consider an indirect supplier. You may not typically have a direct commercial relationship with a manufacturer because you receive most of your products from your primary wholesaler and other wholesalers.

There are situations, drop ships being one of them, verification being another, that can lead to your needing to be able to identify and find pharmaceutical manufacturers across a network to retrieve information from them. It really speaks to this network approach and the value of this network approach that's unique to TraceLink in terms of meeting some of these nontraditional but important use cases.

At this point, I'd like to pass it over to my colleague Caitlin, who's going to walk through some of the requirements related to verification.

Caitlin Czulada: OK, great. The next section here we want to talk about, as Dan mentioned, interoperable verification requirements. This is another part of the DSCSA regulation. What is interoperable verification?

In the requirement, it says that the term verification, or verify, means determining whether the product identifier affixed to or imprinted upon a package or homogenous case corresponds to the standard numeric identifier or lot, and expiration date assigned to the product by the manufacturer.

Essentially, that's a lot of words to say that you're confirming what was printed on the product was printed by the manufacturer and is valid. PDG notes that there are two different ways that companies can provide this verification.

The first is direct to source. Asking the source, "Is this valid?", asking the manufacturer or packager, "Is the product identifier, is the serial number, lot number, and expiration valid?"

The second is direct to replicate verification. What does that mean? That means that you're verifying against the data that you have in your own system, essentially, a copy of the data. That copy comes from the EPCIS message that Dan just mentioned and was discussing.

Those are the two different options that PDG mentions for how you verify that data on the box is valid. The industry came together to figure out how the first option would be managed.

How are we going to communicate to all of these different parties in the network to ask the question, "Are you valid?" What they did was they came up with what we call the VRS—verification router service. It's a method of direct to source verification.

It follows two different components. It has a lookup directory that maintains a list of GTIN records that are synchronized between all of the different parties that are participating, and it follows a standard.

GS1 created a new lightweight verification message standard, different from the EPCIS standard. It's the way that the different solution providers communicate with each other because we need to be interoperable in order to be able to pass these verifications back and forth between different parties.

What does that lightweight messaging support? In 2017, the lightweight message was originally designed for the saleable return product verification.

There was a requirement in 2019 that was postponed to 2023 that said, "If you take a saleable return back, before you restock that return and resell it, you must first verify that the information is correct." Everything was designed around that specific requirement.

However, as the industry started to look closer to 2023, they realized that they could extend the use of this verification to support things, like suspect an illegitimate investigation, recall investigations, and other things that come into play in DSCSA 2023.

Last year, in 2022, they released a new version, version 1.3, of the lightweight messaging that included some additional information and some additional functionality.

First, it was extended to support extended expiration dates. We see some products that have extended expiration dates given by the FDA. Those expiration dates differ from what's on the actual product. We needed a way to support those extended expiration dates and not say that they were invalid.

The next was, "Do you actually have physical possession or control of that actual product you're doing?" This was added as an additional attestation to prove, "Yes, I have this box that I'm verifying," and it is supposed to just fishing for the information.

They added some fields for emails and phone numbers. This is to aid in correspondence between the requester and responder. In the original version, if you got a failed verification, you could see the party but if it was an indirect party, you may not know how to contact them.

You don't have a direct business relationship with all the parties in the industry. You had no way to reach out to them and say, "Oh, you have a falsified product that we need to investigate?" They added additional information so that you can have direct correspondence with the providers.

Then it added a reason code and that reason code—I'll show you in a minute when I do the demo—supports suspect and illegitimate investigation. When you do a verification, you need to provide the context for which you are doing that verification or you're doing a sale overturn verification, or you're doing something like a suspect or illegitimate investigation.

These were all the changes that were made LVMS in the new release. I will say that the industry right now is doing interoperability testing, because one of the big things in DSCSA is being interoperable. Rachel can discuss that when she goes through her slides, but the industry is trying to come together to make sure that we can have this in place for this November 2023.

What is a verification router service? It contains three main things.

The first is a requester system. A requester creates and submits that verification

request to receive the response. Requestors could be people like hotel distributors, dispensers, maybe government agencies. Anybody who's saying, "I have a physical product, and I want to verify this."

The next is the responder. Those are the manufacturers or re-packagers, who have a fixed product identifier to the box. You need to ask the source, information, to verify it and only the source of information.

Then, thirdly, we have the look up directory. The look up directory acts as a phonebook of GTINs, and it links all of the responding systems where a GTIN can be verified.

Each solution provider has a copy of this look up directory and they are synced between solution providers, so that when somebody gets a request, the systems know how to route that request, and who should be the correct responder of that request.

Those are the three components that make up a verification router system service. Let's look at how it works.

The first use case I talked about is the saleable returns use case. You can see here that we have a manufacturer, they're acting as the responder. They have their own VRS system and their own look up directory.

We have a distributor who's acting as the requestor, and they also have their own VRS and their own lookup directory. The very first thing that's going to happen here is that we're going to issue the master data, which is then going to sync the two lookup directories, with all of their GTIN information. That has to happen before any verifications can take place.

Subsequently, product is going to move through the supply chain. We're going to have serialized product moving to the distributor and then all the way to the dispenser. In this case, we're doing a saleable return. The distributor takes back product and they want to resell that product. In order to resell the product, they have to do a verification of those four elements imprinted on the box.

What they're going to do is they're going to issue a verification request to their VRS. Because they have a lookup directory, the GTIN is going to act as a key to tell that system who they should point that request to.

In this case the request is going to go back to the manufacturer, they're going to look it up, they're going to say “yes, these data elements are valid or invalid,” and then they are going to return that verification response back to the distributor. If everything comes back valid, they return the inventory and the product back into inventory.

What about the second scenario here? The suspect product investigation. In this case, we still have the manufacturer with their VRS. But in this case, we also have a dispenser who is doing the suspect product investigation.

In that case, they will also have their VRS and their look up directory, and the same thing is going to happen, that they will also need to sync that information to know how to route the product. Product will move through the supply chain, the dispenser will get it.

For whatever reason the dispenser feels that this product needs a verification, maybe it looks funny, maybe they weren't sure where they got it. What they're going to do is they're going to issue that verification request to their VRS because they have a lookup directory. They'll use the GTIN, they'll send that to the manufacturer, who will respond back with that verification.

Again, if everything comes back valid, you can put the product away. If it comes back invalid, they will need to continue with their investigation to determine why it came back invalid. That's how the whole VRS system works.

In addition to the VRS, one of the things that the industry started to discuss was additional credentialing. As part of the DSCSA law, there is a requirement that you are providing valid credentials and registration and only responding and communicating with people who have valid registrations.

In addition to that, you also have trade partners. A trade partner is a direct partner of yours that you are transferring ownership to. In that case, you are more likely to have a valid registration for them, because they have a direct relationship with you.

I just showed you on the other screen, verifications can come from anybody in the industry, you don't have to have a direct relationship with them to receive the verification. The industry talked about how you will know that the party on the other side is actually a valid, authorized party in the industry.

What they came up with is this additional Authorized Trading Partner credentialing or ATP. It's a tool, an actual tool, that allows people to meet an additional set of requirements to ensure that the party on the other side is a valid trade partner.

How does this work within the broader VRS? Let's look at it without the additional credentialing. As you just saw, the dispenser or any other requester is going to issue that request. That request is going to come to the responder's VRS.

However, over here, the manufacturer requires that additional credential and sees that it's not valid. In that case, because they want to verify the party on the other side, they're going to have to pick up the phone, they're going to have to call

them, or email them or talk to them. There is this manual process in between to say, "Are you valid? Are you authorized to provide this verification?"

Once they have that worked out, they can issue the response through the VRS and then back to the dispenser, so all that can take time. What does it look like if you actually have credentialing in place for a verification?

In this case, the dispenser is going to issue that request. That request will then go out to their digital wallet. The digital wallet is what contains those additional credentials. That can then be passed forward on to the new VRS. In addition to the four data elements, you're actually going to have an additional piece of information, that's your credential, passed forward to the manufacturer and repackager.

That then gets forwarded to their own walleting system for verification. If it comes back valid, then it responds back and then forwards that verification all the way back to the dispenser. All of this is happening within a system. As you can see, there's no human in the mix here, right?

Everything is happening, and it actually happens within sub seconds. It's actually very quick. While there's a lot of things happening, it happens very quick. Where as opposed to not having the additional credential, you're required to have humans in the mix and pick up the phone and verify that other.

The industry came together to talk about how we can add this additional credentialing as part of the verification. Again, that was part of the new lightweight message.

The industry is doing interoperable testing right now to make sure that TraceLink as well as the other providers are able to pass and verify all of these different

credentials that you see here. That's where the verification router service stands in the industry today as we prepare for the upcoming 2023 requirement.

The question I have to everyone here is how are you planning to manage those verifications for those indirect trade partners for DSCSA. If you remember, verifications can come from anybody in the supply chain.

There are two different approaches here. TraceLink as a verification router service means that there are no human interactions. The only thing you have to take action on is a failed verification, and you'll get notified anytime there's a failure. In that case, you will have to take subsequent steps to determine why this was failed as there's falsified product in the industry, something like that.

Everything happens automatically. As I showed you before, there's no human in the mix. All of the systems are communicating directly with each other.

The industry has over 84,000 GTINs already on that network. That's the number of products that you're able to use that verification system for. It continues to grow each week as more and more companies are onboarding to the verification router service. It's instant, right? It provides sub-second responses.

One of the biggest complaints we get about the DSCSA is added steps for my employees. It's disruptive to my business processes. We want to make it as least disruptive as possible.

By using a verification router service to meet this requirement, you get instant verification. Your wholesalers can restock your product. You can be sure that they can resell it. Because if they can't resell it, they're probably going to ship it back to you and ask you for a refund, which you probably don't want.

The other option is manual verification via email or phone. If you don't have a verification router service to meet this requirement, you're going to need staff to manage those requests.

Someone's going to have to answer those phone calls. Someone's going to have to respond to those emails. You're going to need to augment your staff possibly to do that. Because you're doing everything via phone or email, someone's going to need to know how to access the system, need to check the data.

They're going to have to manually key in the serial number. We know those are 14 to 20 digits long. That could always cause human error as well. That takes more time. Anywhere from one to six hours per verification, maybe longer if you're running into issues.

That could cause disruptions in your daily operations. When you're thinking about the manual approach, really think about it, holistically, and do you really want to go down that road versus more of an automated solution for this requirement for November?

The next question I have for all of you is, how are you going to prepare for different serial number statuses and responses to those status? We're talking about all the systems and how they're going to communicate to each other.

We all know that product is in different states at different times. We have recalled product. Is that product valid or invalid? Technically, the identifiers match the box, but are you going to say that it's valid or invalid?

The manufacturer gets to choose whether or not they clarify that or classify that as valid or invalid. As a dispenser, what are you going to do if you have different responses coming back from different manufacturers? How are you going to

respond to that? Expired product.

Again, manufacturers can determine whether or not that is valid or invalid. The ones receiving those responses are going to have to deal with the differing responses coming back and then destroyed or decommissioned. Is that valid or invalid? Determining what those rules are.

I'll show in a just a second here, in the demo, how you can configure these within the TraceLink system, as a responder, to respond to these different types of statuses.

Lastly here, the question I have for you is how are you planning to manage the exchange of master data for your DSCSA requirement? We all know that DSCSA introduced a brand new element, which was the GTIN, and that verification and serialized data exchange require access to that product GTIN.

Everything we do, whether its the EPCIS messages or the VRSes, everything is built around those GTINs. All of that needs to be communicated throughout the entire industry so that you're all talking a common language.

In addition they must be accurate. If they're inaccurate, you're not going to be able to be interoperable as an industry. Those missing or incorrect GTINs could result in supply chain delays, which we all really don't want, or returned product, which is also not a great thing.

One of the additions that TraceLink's VRS system provides, is the ability to share out that master data. We recognize that this is a huge challenge for the industry, and so we built it as part of the VRS.

When you sign up for TraceLink's VRS system, in addition to doing that verification,

you also get the ability to share out your GTINs or your master data to the downstream parties.

Then, corresponding, if you are a requester or wholesaler or dispenser, you get access to all of those GTINs. You can be ensured that they're accurate because they're coming directly from the manufacturer.

Master data is a big challenge in the industry and one that TraceLink's working really hard to help the industry be interoperable and move forward on that.

Now, I'm going to go into the product and we'll do a really quick demo of the TraceLink VRS system for how that works. Hopefully, you guys can all see my screen here. As I mentioned, the VRS has three components. The product directory, that's that list of GTINs, that's that lookup directory of GTINs. That exists in there.

Verification history, so I'll show you that in a second. The ability to download reports for your verification history. If you are a responder and you want to see who's doing requests, you can provide that history, or do further investigation on failed verifications, you can use that history. Finally, the verification of that product itself.

Here, we have the different reasons. We mentioned that it was extended to support the 2023 requirement. Now when you do a verification, you have to provide a reason for that verification. Illegitimate product suspicion, salable returns, just a status check, or verify the expiration.

We'll just do salable returns for now. I'm going to manually enter the information. I'm going to confirm that I have possession of this product. I'm going to put in my GTIN number here, I'm going to put in my lot number here, my serial number, and

my expiration date.

You can see that, within one second, it came back and said that this was valid product. Now, if I'm in my operations, I know this is valid product, I can just continue on with what I was doing and I don't have to worry about anything further. I don't have to pick up the phone, I don't have to do anything else.

Let's see what it looks like if I put invalid information. Really quickly, I'm just going to change the lot number here, I'm going to put the serial number here, and I'm going to put the expiration date.

It's going to come back and say that it's invalid. In this case, you can see I put in an invalid lot number, it's showing me that that lot number is invalid.

One of the things that the TraceLink system provides here is that ability to set those rules. The fact that I'm knowing that it's an invalid lot number is because the manufacturer set that rule, to say that they should provide that additional information.

As part of the TraceLink solution, we have the ability for those responders to set all of those different rules. Some of the rules include expiration dates.

Sending that failure reason, that's saying, "I want to tell them that the lot number was invalid," versus just saying, "Nope, it's invalid. I'm not going to tell you why it was invalid."

We have the expired, the recall, suspect status, and illegitimate status, destroy, decommission, under investigation. These are all the custom rules that you, as both the responder and the requester, are going to have to be able to manage as part of all of these verification requests.

Really quickly, I'll just show you here, the verification history here. You can come in here and you can request verification history. I have downloaded them here. You can see here, you can see all of the verifications that were done, you can see the product information, the serial number, lot number, expiration date, and then the errors associated with that.

Both the requestors and the responders have access to all of the verification histories. That is just a really quick demo of the TraceLink verification system that we have up and running today. What I want to do now is turn this over to Rachel. She'll talk about some of the things that we are doing.

Rachel Hummrich: Thanks, Caitlin. Caitlin initiated and discussed a lot of the things that...within talking about interoperability with other service and solution providers for VRS, which I have been heavily involved in.

TraceLink has been a really integral part with the other solution providers to drive the industry. The different test cases and all of the different scenarios and all of the different abilities within the standard.

What I want to do is just talk about where TraceLink is and where we currently stand. This is the lookup directory and where it is now. You heard Caitlin refer to the lookup directory as the phone book of GTINs, that is really what this is.

This shows you, over the course of about two-and-a-half years, when we originally started this back in early 2020, how many GTINs are synced in production overall. Not just from TraceLink but with the other solution providers that we are live with.

As you can see, TraceLink is one of the six solution providers that are live in the industry right now. For these solution providers, each of these, what TraceLink did is we completed very extensive interoperability testing with them to ensure that

the lookup directory's sync was working properly. That when TraceLink pushed records out to the other providers, that they were able to pull them onto their lookup directory and vice versa. When the other providers pushed records out to us, that we were able to pull them. All of that works automatically and occurs on a cadence on a daily basis.

This really shows where TraceLink stands, as you can see we are that orange bar, in comparison to the other five solution providers that we are currently live with.

This represents, for those responders, how many GTINs each of the VRS providers, what their customers are responsible for. This shows you that, as of right now, there's just under 85,000 GTINs that have been synced to the lookup directory overall. You can see TraceLink customers own over half of those.

If you are a TraceLink customer as a requester, a lot of your requests are likely going to be within the TraceLink network and won't even leave the network. There's less connectivity between providers. There are other providers that there's multiple hops within their own system because they may not be a full service provider.

TraceLink is a full service provider, which means that we not only control the connectivity and the lookup directory sync, but we also control the requests and the responses. Other providers may only handle the lookup directory sync and connect to other service providers for the request and response. Within that one customer, you have multiple hops that occur.

With TraceLink, that doesn't happen because we are a full service provider. We do control everything. When you're in-network it works a lot faster and there's a lot less room for any connectivity issues that providers may have.

That is something that, again, with interoperability, TraceLink has been a very big part of those discussions and that have been going on for the past three years about, to make sure that we're in line with what is expected within the industry for that connectivity.

To make sure that our customers are really prepared and that we are prepared for them for the regulation in 2023.

In line with that, this gives you an idea, for DSCSA, where TraceLink is. The fact that what the depth of knowledge, our understanding and involvement has been for DSCSA.

We have over 760 customers specifically for DSCSA. Of those, 135 of them are already exchanging EPCIS transactions. That is the serialized transaction requirement between our manufacturer, wholesaler distributer, and dispenser customers.

There's also, you can see, between those customers and of those customers, there's over 317,000 service links. That is each individual link between our customer and their supplier or their customer, between the manufacturers, wholesalers, and dispensers.

The number of serial numbers that have been commissioned by TraceLink customers, you can see, is well over 40 billion. That's a pretty impressive number of the data that we already have within our network.

Along with DSCSA, so you can see the number of T3s that have been exchanged through TraceLink. That is the lot level ASN requirement, with the transaction history, information, and statement. You can see that number is pretty staggering for what we have within our network.

Then, for T2s, which again, is that EPCIS serialization data, the number we already have is already at over 700,000. Those are the actual serialized data T2 requirement that is required in November. A lot of our customers are already down the pike and already live with a lot of those transactions.

Just to talk about our network itself, we always talk about the value of the network. The reason is, look at what we have on our network. There is over 290,000 companies that we have already vetted by our verification team and added on our network. Those are companies that we already have and that are already vetted on our network.

Then that last number, it just goes to the slide that I showed you previously. There's almost 85,000 GTINs that are synced for VRS in that shared lookup directory. Of that number, over 50,000 are owned by TraceLink manufacturer or customers. Those are the GTINs. Those customers are ready for verification now and have been supporting it for some time.

That just gives you an overview of essentially where TraceLink stands and so you can see the value of the network that TraceLink brings. With that, I'll just hand it back over to Dan for a wrap-up.

Dan: Thank you, Caitlin. Thank you, Rachel. Very informative sessions. I know we're short on time here. A couple things that I'd like to do is...I think we have a brief survey that will pop up here.

One of the things that we would like to do, as it relates to this webinar series, is to continue to gauge if the information's useful, the accuracy, is it informative to you. If you could take a moment here to respond to this survey, just click one of those circles there.

If you have questions about the information, you'd like more information about this topic, DSCSA in general, or any of the specific topics here, certainly just let us know by clicking Yes. We'll be sure to contact you and set up some subsequent time. You could just take a couple of moments to respond to that.

Then what I'd like to do is tee up the next webinar series. Today we walked through the narrative of end to end, and Caitlin provided a view into what verification looks like.

For our next webinar, we're going to continue with this theme of demonstrating capability. We're at the point where we're less than 11 months away here from a deadline, and we really need to drive interoperable exchange.

We want to show you our capability through a product demonstration around EPCIS exchange, verification, and exception management. We want to be able to understand how we're going to collaborate in an optimized way around exceptions.

If we go to the next slide and maybe review some other resources that are available to you, for our existing customers, we have our community group. For many of you that are on the call today that currently have a commercial relationship with TraceLink, please register for this community group.

This is your place to ask additional questions, share insights, collaborate. We'd love to have your participation in this group as well.

Then finally, in terms of key takeaways to review a bit of what we went through here. Hopefully, we drove some clarity around interoperable exchange and what that is as well as drop shipments.

Hopefully, the nuts and bolts of what verification is and the definition of it, as well

as some insights into TraceLink's role in verification and our leadership position in verification was helpful to you and then providing some education in terms of what authorized trade partner in the role of credentialing is.

We did have a number of good questions that have come in. I don't believe we're going to be able to get to all of them. One of the things that I would like to maybe there's a few that are related here. It's in the context of lot numbers.

One of the things that is happens today is with lot level traceability, ironically, many of the wholesalers have the option under certain conditions to not pass the lot information to the dispensers. There's an exemption there. If they purchase directly from the manufacturers, there's an exemption in that they do not have to provide that information downstream.

There was a lot of questions around, is there a requirement to provide that lot information as part of 2023? In December of last year, the FDA went through this and did highlight the need to provide lot level information in that EPCIS transaction.

This relates to some other questions that we received today around, are there opportunities for dispensers to use and access that information to drive other processes in the health system or retail pharmacy?

The obvious use case is recalls. You receive a recall notification, you want to understand do I have that product, and then certainly make that information available to your EHR systems to optimize your recall processes.

This is the exact challenge that FDA is hoping that industry grabs hold of to say, "Look, we can digitize things like lot information, make that available in systems like a traceability system like TraceLink." Then, what TraceLink is doing is we do

have a set of integration or APIs that things like EHRs can query to grab that lot level information about specific products.

I think these questions all related here are you're grasping and asking questions on the spirit of what the FDA is trying to prompt industry to start to drive. How can we, through digitalization, optimize critical processes in the area of recall? We'd love to talk to you more about our plans in that area in how we can help you there.

There was one additional question that I'll call out -- I know we're overtime here -- is in the area of ASNs. A key point, the vehicle for sending the compliance information in 2023 will shift from an ASN to the EPCIS transaction. What will be included in that EPCIS transaction is the product-level product identifier.

Although not a regulatory requirement, but quickly turning into a business requirement that in addition to the product identifier information is the inclusion of aggregation information as well. That provides some benefits to, obviously, wholesalers and dispensers to help to manage the receiving process.

It won't be through the ASN. The ASN is not a great format to include that item-level information. EDI systems are not architected to handle that type of scale. Through standards like EPCIS and systems like TraceLink, we're able to create those EPCIS transactions and then on the wholesaler and dispenser side manage the receipt of those EPCIS transactions to optimize some of your processes.

If we haven't gotten to your question today, we will certainly be reaching out to you to provide some information and some answers back to you. If you are interested in learning more about DSCSA, your requirements, some challenges that you're facing, certainly reach out to us through these vehicles here, marketing [at] tracelink.com.

Certainly, join us next week as part of the demonstration around EPCIS exchange, product verification, and exception management. Have a great rest of your week. Caitlin and Rachel, thank you for joining us today. I look forward to seeing you next week. Thanks, everyone.

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