WHY AN OPEN, STANDARDS-BASED APPROACH IS ESSENTIAL FOR THE PHARMACEUTICAL SUPPLY CHAIN

5 Questions to Ask Before Selecting Your Long-Term Partner

tracelink

NETWORK FOR GREATER GOOD

In November 2019, the next phase of DSCSA track-and-trace requirements go into effect, requiring wholesalers to verify all saleable returns before returning those products to the shelves. There is much at stake. With an estimated 60 million returns a year industry wide, saleable returns pose a significant challenge to the industry, requiring companies to exchange verification data in near real-time with direct and indirect trading partners to ensure that products reach their intended destination without being delayed, quarantined, or worse, destroyed.

But product verification is just a small piece of a much larger picture, requiring you to answer a number of questions that will have broader, long-lasting implications for your business. How will you connect to your trade partners, both direct and indirect? How will you exchange data—potentially enormous amounts of data—at scale and in real time? And, are you partnered with a proven entity that supports your long-term vision?

Your investment in serialization should set you on a path to create transformational value for your business by creating a global repository of serialization data across your supply chain. With the right partner, that data can help you achieve greater visibility, deploy analytics, and create intelligence to solve new challenges.

Very few solution partners can deliver that value. And in fact, this is nearly impossible for vendors that use closed, proprietary networks, which inherently limit, if not prevent, your ability to use your own investment to see more, share more, and do more with your serialization data. This is not to mention the very real risk that the vendor of a closed solution just goes away due to internal or external reasons, maybe having difficulty raising money or deciding that the complexities of managing a serialization and compliance business is more difficult than they had originally planned.

Here are a few critical questions you should consider when deciding whether you want a partner or just a vendor.

Why are standards essential to the industry's success?

A fundamental principle of DSCSA is to create a digital, interoperable system to identify and trace certain pharmaceutical products as they are distributed across the supply chain to protect patients from counterfeit, stolen, contaminated, or otherwise harmful drugs. Importantly, while the law has laid out specific requirements that companies must meet, it does not prescribe a specific solution.

Because of this, stakeholders in the industry quickly recognized and acted upon the need for a standards-based approach to ensure interoperability and to prevent any one proprietary solution from creating and profiting from gated bottlenecks and jeopardizing the scalable, rapid exchange of data between stakeholders.

TraceLink partnered with the industry and took an early leadership role in this standards-based approach. TraceLink's Elizabeth Waldorf was one of three chairpersons that led to the ratification of the GS1 Messaging Standard for Product Identifier Verification, the standard which governs saleable returns verification. More than 55 individuals representing stakeholders from across the supply chain—from the Big 3 wholesalers to manufacturers to solution providers—contributed to this standard.

Notably, not every solution provider in the industry participated in this effort, nor do all solutions truly support a standards-based approach. In particular, vendors with private, proprietary solutions cause considerable risk to the industry by undermining the ability for all stakeholders in the supply chain to exchange data quickly and at scale based upon these industry-supported standards.

Critical question to ask your partner: How do you support standards that promote interoperability and transparency?

What is the difference between an open and closed network?

An open network allows all participants to connect freely, so that all trading partners across the supply chain can rapidly exchange critical product data without gating that information exchange behind a proprietary paywall.

TraceLink's global digital network is open. TraceLink's customers subscribe to our services, but TraceLink charges no fees to our customer's trade partners to participate and exchange data on our network. While TraceLink is the leading solution provider for DSCSA compliance in the industry with more than 1,200 unique customers, TraceLink supports a vastly larger ecosystem of 275,000 trading partners.

Vendors using a closed, proprietary network require everyone to pay, inherently limiting their network. A blockchain-enabled verification router service provider, for example, charges other solution providers to purchase nodes on its network, undermining the ability for trade partners to freely exchange data and creating potential paywalls between trading partners and their chosen solution providers.

Critical question to ask your partner: Do participants and trade partners need to purchase access to your network in order to exchange data?

Why is interoperability important?

While open networks facilitate communication between trading partners, industry standards support interoperability so that all stakeholders in the supply chain can select and deploy technology and solutions that best fit their needs. TraceLink's solutions are based on industry-endorsed standards and undergo extensive interoperability testing with other providers to ensure that data can be exchanged quickly and seamlessly, and to ensure success for TraceLink customers whose trading partner might use a different solution.

By definition, vendors who create closed networks have not demonstrated the same level of commitment to interoperability. By creating closed, proprietary networks, they create significant challenges and, in the case of saleable returns, significant delays in end-to-end testing in the industry, requiring bolt-on solutions and creating potential risk not only for their customers, but for everyone in the supply chain.

Critical question to ask your partner: How does your solution support industry standards and interoperability with other entities in the supply chain?

Does this technology offer proven performance and scalability?

The advent of DSCSA has spurred significant technology investment for the Life Sciences supply chain and stakeholders, TraceLink chief among them, are constantly innovating on new approaches to solve problems digitally. One of the core technological challenges is the ability to exchange huge volumes of data at unprecedented speed and scale.

Consider saleable returns verification, where manufacturers may be faced with a sudden influx of verification requests that require sub-second response times. TraceLink's proven technology solution has simulated receiving ~10,000 simultaneous requests per second with an average response time of 300ms, or less than half a second.

But not all solution providers can operate at this speed and scale, hamstrung by technology choices that were not designed for the task at hand. For example, one blockchain solution has yet to demonstrate more than 15 transactions per second, calling into question its viability as a scalable solution for track and trace requirements.

While blockchain is not a proven technology for high-volume operations like product verification, it has exciting potential when deployed appropriately. TraceLink's FDA pilot, Trace Histories, for example, leverages distributed ledger technology to help stakeholders securely exchange information to satisfy the 2023 DSCSA requirement.

Critical question to ask your partner: Is your solution based on proven, scalable technology?

Who has control of your data, and its value?

As DSCSA matures toward full implementation in 2023, every stakeholder in the supply chain will be generating and exchanging huge volumes of serialization data. That data provides nearly unlimited new ways for companies to reap value from their serialization investment, giving them unprecedented intelligence on things like product disposition, excursion tracking, and stockouts.

TraceLink's focus is on creating solutions and applications that allow companies to orchestrate critical business processes across the supply chain using open, interoperable standards that can lead to exponential new value for its customers. TraceLink puts the access and control of data in the hands of its customers, with no bias toward any stakeholder or set of stakeholders in the supply chain. Moreover, TraceLink is heavily invested in our customers' access to data to enable them to solve both existing and future challenges for their businesses.

Do you want to be partnered with an entity whose priorities may significantly differ, or even run counter, to your own? If your vendor uses a proprietary, private technology, you will miss out on full visibility and access to your serialization data. And, it will considerably limit, if not prevent, your ability to build new value for your business, cede control of your own data, and give a competitive advantage to other stakeholders who may not have your best interests in mind.

Will you choose a partner or just a vendor?

From the early days of DSCSA, industry stakeholders from across the supply chain—including TraceLink—have led the initiative to establish open, interoperable industry standards that support a variety of different technological approaches designed to enable maximum flexibility, transparency, and interoperability for all stakeholders.

There is a clear reason for this. Vendors who create proprietary solutions based on unproven technology and closed fee-based networks directly undermine the shared goal of an open, interoperable supply chain. Such solutions only serve to exacerbate the imbalance in the pharmaceutical supply chain, enabling a small number of stakeholders to unfairly influence the many at the expense of the wider goals of the industry. And, while these vendors may feed off of the buzz around technology solutions like blockchain, they have limited networks, a small number of customers, and are unproven to deliver in both scope and scale.

In contrast, TraceLink's proven network approach to DSCSA compliance is built on the industry's shared desire and respect for open standards, transparency, and interoperability. For more than ten years, TraceLink's global digital network has partnered with more than 1,200 customers and their 275,000 trading partners to seamlessly exchange data on more than 5 billion serial numbers already in circulation.

Importantly, TraceLink's customers range from manufacturers to distributors to logistics providers to dispensers, and every entity in between—meaning that no one link in TraceLink's digital network is more important than any other. For saleable returns alone, TraceLink has more than 125 customers, including manufacturers, wholesalers, and one of the largest US pharmacy retail chains.

And, unlike small vendors with proprietary solutions who may be waning in their commitment to their network or their technology, TraceLink continues to invest. In addition to a global compliance solution, companies who partner with TraceLink are realizing a whole new level of value from their serialization investment to solve new and long-standing challenges for their business.

Whether you are trying to implement a saleable returns solution or working toward a larger vision that takes advantage of your investment in serialization to create new value, how you approach these challenges—and who you choose as your partner—will make a difference. For more than a decade, TraceLink has led the industry in its commitment to an open, interoperable, standards-based approach. The reason is simple: the success of our customers, and the success of the industry, depends on it.