FDA Pilot Project Program

DSCSA 2023 Traceability with Blockchain / Distributed Ledgers and Digital Recalls Network Pilots

Industry pilot projects undertaken to create a deep foundational understanding of the end-to-end traceability, operational, and technological requirements to meet Drug Supply Chain Security Act (DSCSA) 2023 regulations, and to develop and describe a model for building a highly efficient and responsive digital recalls network that leverages many DSCSA investments

February 2020

Executive Summary

A cross-industry, cross-functional team of industry leaders from each segment of the United States pharmaceutical supply chain collaborated for six months in 2019 under the FDA Pilot Project Program to study, analyze, and prepare recommendations on two key challenges facing all stakeholders.

1. To analyze how pharmaceutical recalls are executed today and to examine how a digital recalls network could be realized to improve the rapid and precise communication, management, execution, and closure of product recalls across the supply chain.
2. To analyze how the industry will be impacted by the upcoming DSCSA 2023 regulations, to research the critical capabilities and requirements for a network solution to meet these requirements, and to study the potential role of blockchain/distributed ledger technology combined with serialization, traceability, and other existing technology solutions.

Given the growing complexity of pharmaceutical supply chain and the exploding diversity of patient therapies and medicine portfolios being developed, the industry is at a tipping point in being able to manage its response to adverse events related to those medicines. Specifically, the industry ability to orchestrate a precise and timely response to identify and remove affected product under a pharmaceutical recall. Due to a combination of manual communications methods, poor ability to identify stakeholders with affected product, delays in being able to locate and quarantine affected product in inventory and on shelves, and complexities in accounting for quarantined and returned product against expected results, execution and closure of product recalls today takes longer and requires more work than necessary, thereby increasing risk to patients and cost to organizations.

During its analysis, the pilot team found significant opportunities to speed and improve the precision of recall notifications and responses between supply chain stakeholders, to more quickly and precisely identify and quarantine affected product in the supply chain, to increase coordination and confidence among team members responsible for the recalls process, and to enhance the ability to remove such product from the supply network and close the recall event. Initial steps could be taken today to implement parts of such a digital recalls network, providing immediate incremental benefits for stakeholders in managing recalls while supporting shared learnings on this transformational initiative.

DSCSA 2023 compliance also creates significant challenges for all supply chain stakeholders. The industry will be faced with new information needs, operational process changes, supply chain data exchange, and network orchestration requirements to enable secure, efficient end-to-end traceability of medicines identified at the unique saleable unit level in an on-demand, or “gather upon request” environment.

It is clear that the biggest challenges lie in developing an orchestration, based on common standards, harmonized approaches, and shared understanding of data, between those people, processes, and systems across the supply chain. The industry and its stakeholders must embrace the complexity, the scale, the diversity, and the continual change of the pharmaceutical supply chain and support the myriad of heterogeneous systems and technologies that will be used to meet 2023 requirements. There is no single technology, such as blockchain, that provides a “silver bullet” to manage the totality of these challenges. Rather, we expect that there will be a heterogeneous mix of technologies, systems, and standards in play, each one playing a critical piece of the puzzle. The key will be to create alignment, clear direction, and incremental development of the building blocks to build a confident roadmap to 2023 compliance. The industry should use all the time available to test and develop these elements.

Pilot Project Overview

Introduction and Approach

This pilot project brought together a diverse set of participants from across the pharmaceutical supply chain to examine ways to enhance patient safety, improve pharmaceutical security, increase operational efficiency, and decrease business risk related to the end-to-end supply chain processes involved in pharmaceutical traceability under DSCSA and pharmaceutical product recalls. The pilot project was separated into two pilot workstreams. One workstream studied the opportunities to provide increased public health and business benefits by enhancing the process for initiation, communication and reconciliation of pharmaceutical recalls in the supply chain through a digital recalls network. The other team studied the underlying requirements of supply chain members to meet DSCSA 2023 regulations which include, but are not limited to, systems and processes for stakeholders to build upon request a unit-level trace history of all serialized transaction information going back to the manufacturer. This included analyzing how companies comply with DSCSA today and the future system attributes and process changes that may be necessary for the diverse members of the supply chain for 2023.

Both pilot projects established a deep foundational knowledge of the information and processes involved, using early stage technology solutions to support investigation and analysis of potential industry solutions to these challenging problems. Both pilot projects were also deeply informed by previous FDA and industry activities, including FDA public meetings and guidance documents. The intent for both pilot projects was not to build a case for a specific technology or solution. Instead, our focus was to develop a holistic view of how pharmaceutical traceability and product recalls occur today, and to create a vision and blueprint for the data, operational processes, business systems, and network connections required to realize DSCSA 2023 compliance and to digitalize pharmaceutical recalls. This report is a comprehensive subset of the significant ideas and insights developed during the pilot.

Pilot Team

The pilot team embodied a diversity of roles, responsibilities, and viewpoints to ensure that our insights were informed by a wide variety of insights and experiences and that we could test our theories and ideas for applicability and impact across the diverse supply chain. Members included:

Contract Manufacturer	Pharmaceutical Manufacturer/MAH	Wholesale Distributor	Retail Pharmacy / Healthcare Org.	Logistics Provider and Returns Proc.
Thermo Fisher / Patheon Sharp Packaging	Agios A-S Medication Solutions Bristol-Myers Squibb Flexion Johnson & Johnson Merck Par Pharmaceuticals Pfizer Sagent Sandoz Novartis	McKesson Value Drug Company	CVS Health Novant Health Wegmens Yale New Haven	DHL PharmaLink Woodfield Distribution

Pilot Workstream 1: Digital Recalls

Introduction

Our pilot has been focused on analyzing the pharmaceutical product recall process as it stands today, with the hopes of understanding how the digitalization of the processes, the information, and the network connections leveraged across that recall process may lead to faster, more precise, and lower risk closure of recall events across the supply chain. The goal of this pilot was not to prove out a specific technology or system, but rather to develop a blueprint to help the industry realize a digital recalls network which could be used initially for pharmaceutical recalls but could also well extend across multiple other product types.

Our discussions included a wide range of viewpoints from a diverse set of stakeholders at every point in the pharmaceutical distribution supply chain. We sought harmonized viewpoints and consensus where possible, but more importantly the group agreed it was important to facilitate open conversation about the opportunities, the challenges, and the approaches for achieving a digital recalls environment.

Digital Recalls - Pilot Goals, Approach, and Methodology

Goals

The goal of this pilot workstream was to evaluate, given how pharmaceutical recalls are executed across the supply chain today, the potential patient safety and business benefits available through the establishment of a digital recalls network leveraging serialization data, traceability information, and interoperable electronic systems. The analysis was also to include detailed discussion regarding how such a recalls network could evolve from todays as-is process for managing pharmaceutical recalls.

Objectives

The current pharmaceutical recall process can be characterized as manual, time-consuming, and error-prone in its approach, often resulting in uncertainty of the status of a recall in progress, and in significant volumes of impacted product remaining in the supply chain. It often takes a tremendous amount of time and effort for businesses across the supply chain to execute recalls, and perform effectiveness checks, with variable and unpredictable results. The diverse and multi-tier design of the U.S. pharma supply chain contributes to these challenges as a significant number of participants in this supply chain are hard to effectively reach with traditional methods of communication. Patient safety is at risk if there are delays in execution and closure of a recall due to manual communication or inefficient coordination with supply chain partners to stop the recalled product from being dispensed to patients. We believe that significant opportunity exists for the stakeholders in the pharmaceutical supply chain to leverage better and more precise information about products and participants, and leverage today's digital networking technologies, to improve current recall verification, notification, and closure processes.

Methodology

Processes

The pilot team undertook to evaluate the complete end-to-end recalls process, including recall communication, coordination, and compliance processes that are executed today to deeply inform our discussions. This analysis was then used to help test the potential benefits and requirements of a digital recalls network in the following areas:

- Communication electronically of a recall by manufacturers and re-packagers to downstream trade partners
- Communication electronically of a recall by distributors to their direct dispenser customers or other trade partners
- Provision of targeted recall alerts based on shipment data for previously received product
- Detection of recalled product in new product receipts and in pending customer shipments
- Detection of recalled product at point of use in a healthcare environment or at point of dispensation to patients
- Enablement of affected supply chain entities throughout the supply chain to respond to recall notifications and to manage ongoing recall events electronically
- Maintenance of documentation and audit trail of recall actions to meet regulatory compliance

Technology

This pilot workstream leveraged several existing communication methodologies and systems used to manage today's recalls process, while adding current serialization and traceability tools, and new design approaches and capabilities being developed for an emerging digital recalls network solution, to inform the analysis across each stage of the process. These tools and solutions helped the participants to analyze the data, processes, and network interactions across multiple supply stakeholders and multiple participant personas within each stakeholder as we simulated real processes and transactions for each use case.

Analysis and Evaluation Methods

The pilot participant group of members representing all segments of the supply chain undertook a comprehensive study of the pharmaceutical recalls ecosystem. Methods undertaken during the analysis included:

- Mapping of the "As-Is" recall processes across manufacturing, distribution, pharmacy, healthcare organization, and returns processing points in the supply chain to analyze gaps, challenges, and opportunities for improvement in the current processes

- Study and analysis of enhanced "To-Be" recall methodologies enabled on a digitalized recalls network, assessing the business/operational impact of such modified processes for each supply chain stakeholder
- Identification and analysis of immediate and long term benefits that can be achieved with end-to-end digital recalls processes, the potential barriers to adoption which may exist, and the change management requirements to facilitate a smooth step-wise transition
- Review of efficiency and effectiveness metrics such as "improvement in percentage volume of recalled product returned" and "reduction in time to close the recall" to test the benefits of specific capabilities within a digital recalls network
- Evaluation of different methods of exchanging information, the systems used, and the stakeholders involved within organizations, to ensure interoperability of digital recalls
- Identification and development of standardized messaging and data models to support digital recall processes
- Evaluation of the uses and benefits of today's lot-level DSCSA TI/TH electronic data and DSCSA serialized product identifier data, and the serialized TI data available after DSCSA 2023 requirements go into effect, in enhancing the targeting and execution of recalls in the supply chain
- Identification of potential tools and technology infrastructures that may be further developed by the industry leading up to DSCSA 2023 compliance which may be layered on top of an end-to-end digital recalls network
- Review of existing FDA recalls management regulations and industry business practices which guide today's recalls processes, identifying areas that are candidates for review in light of newly emerging systems and technologies being adopted across the pharma supply chain due to DSCSA implementation and digital supply chain initiatives

Digital Recalls – Analysis and Results

The Pharmaceutical Recalls Environment of Today: Processes and Challenges

The pilot team started with a fundamental look at how recalls are initiated and executed today across the pharmaceutical supply chain. This grounding of "What is the lifecycle of a recall event?" was key in (1) establishing a solid baseline of the people, processes, and information accessed or impacted due to a pharmaceutical recalls; and (2) establishing a shared understanding of these principles by the diverse members of the pilot team. This understanding was critical in helping describe a different future model.

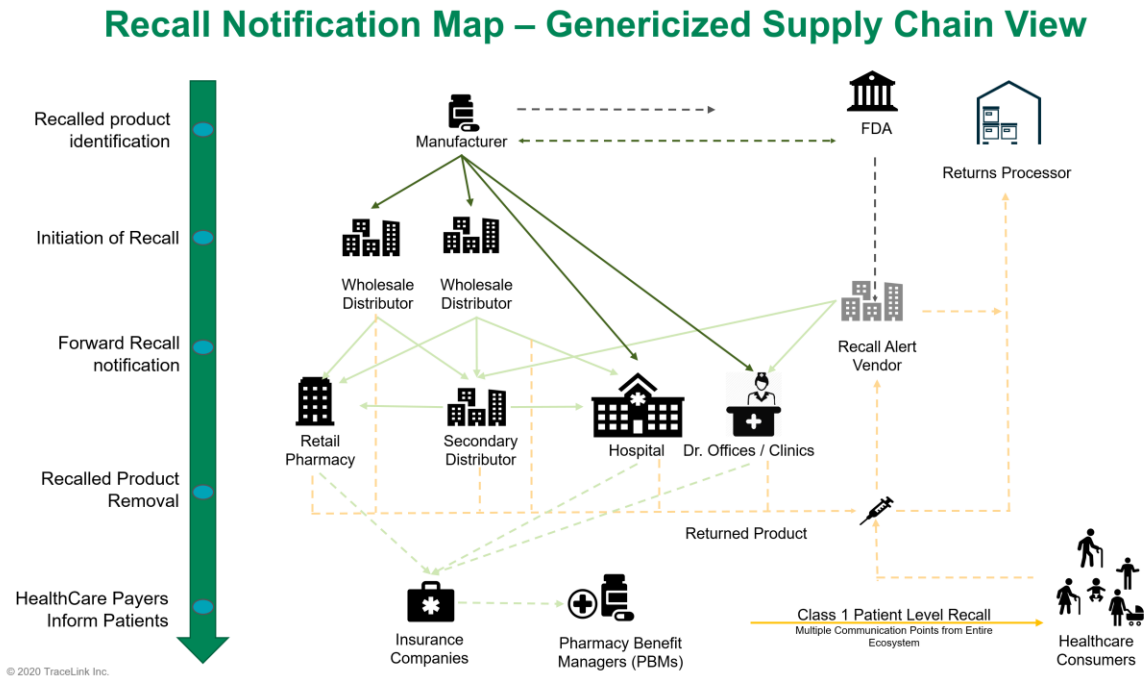
Recall Process Maps

The team looked at the recalls process from different perspectives, examining the various stakeholders involved and the activities that are undertaken today during a recall event. A key result of this analysis

was the development of numerous detailed process maps involving various recall scenarios and different stakeholders. These process maps were used to help understand certain key questions such as:

- How are recalls initiated today in the supply chain and what entities are involved?
- What is the entire lifecycle of a recall event and how does that lifecycle vary depending on the class of recall or the processes used to initiate the recall?
- How do the notification and execution processes work among each stakeholder?
- What information is leveraged and exchanged and what issues are involved in this exchange?

The process maps helped drive a critical shared understanding among pilot participants representing diverse companies including pharma manufacturers, CMOs, returns processors, wholesale distributors, healthcare organizations, and retail pharmacies on the procedures in place at each company and to gain a greater overall understanding of the touchpoints between companies during a recall event. This foundational analysis helped put into perspective the myriad of systemic impacts and issues that may be created depending on how an entity choses to initiate, respond to, or execute a recall event.

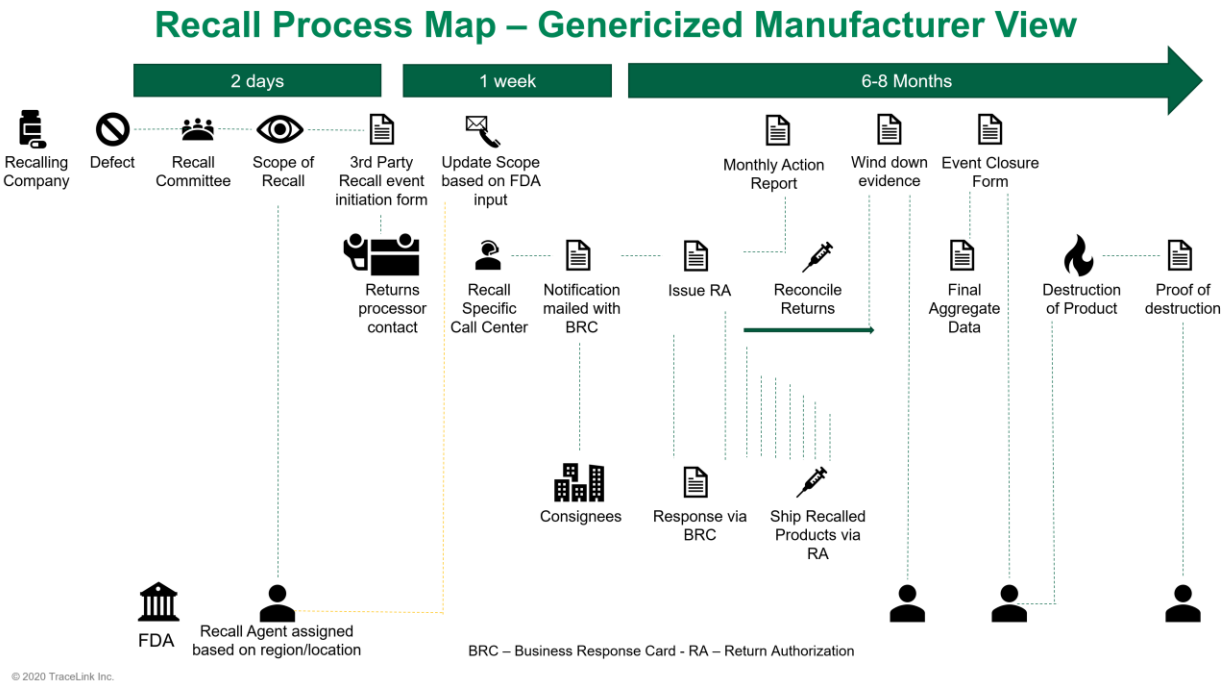


The pilot team sought to gain a deep, shared understanding across several product recall scenarios of:

- Who is involved and at what steps are these entities involved?
- With access to and leveraging what information?
- In collaboration with what individuals within their organization?
- In conjunction with what entities and individuals across the supply chain?
- To achieve what milestones and measured by what metrics?

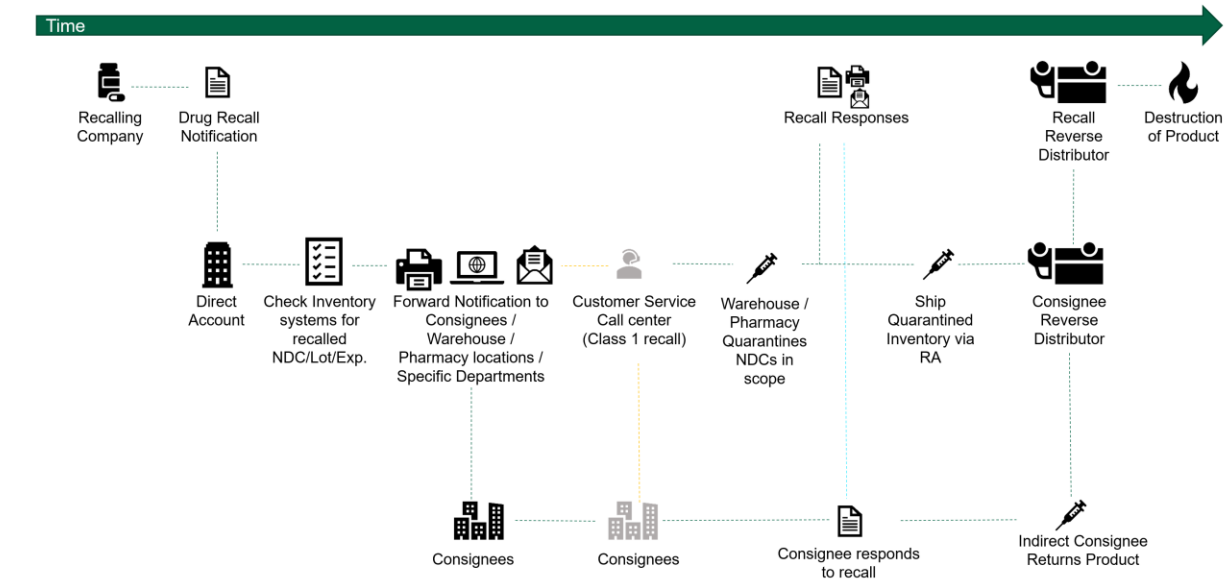
The team also mapped the organizational and network information flows to understand how information moves to other stakeholders. For example, how information flows from a manufacturer to the FDA when recall strategy is decided, or to direct accounts in the supply chain as soon as the recall is formally initiated. Other information flows included a look at how information is shared from FDA and wholesalers to doctors' offices, health care organizations, retail pharmacies, and patients. In particular, the key role that recall alert vendors play in recall management for hospitals and healthcare organizations. We also discussed the roles that insurance companies and PBMs have in class 1 recall process specific to patient level communication.

The team then developed process maps to look at the recalls process from the perspective of different stakeholders in the supply chain. For example, in the generic process map for pharmaceutical manufacturers and consignees, the team analyzed how the information is exchanged from the time recall committee at a pharmaceutical company is ready to initiate notification.



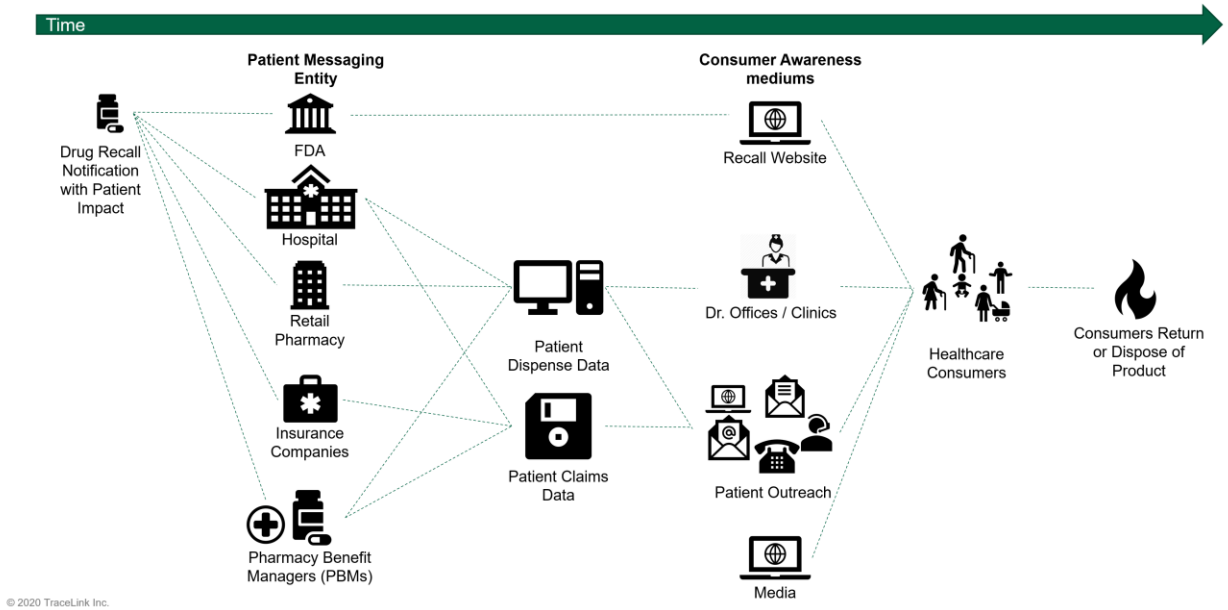
Process maps were then used to identify, downstream in the supply chain, the numerous ways that information is responded to and acted upon by various stakeholders. The group found that timelines were highly variable for recall notification and related responses in the downstream supply chain, in particular in hospitals/healthcare systems. It may be a few days or a couple of weeks for a notification to work its way through a given pharmacy organization or healthcare system while the reverse distribution processes for managing the returned product could last three to six months.

Recall Process Map – Genericized Wholesaler and Pharmacy View



While the pilot wasn't specifically focused on the patient-level process and responses, the team did look at patient-level interactions, the communication mechanisms used, and the information exchanged. There are many sources of information for the patient, including that provided by the general media. Specific approaches taken by entities to notify patients will vary depending up on the class of the recall.

Recall Process Map – Genericized Consumer Notification View



Following the initial broad survey and analysis of the overall product recalls process across the pharmaceutical supply chain, several key scenarios were selected and workshopped to develop a deep understanding of the gaps and challenges of the recalls process today, evaluation of the digital recalls network vision, and determination of the key elements of a blueprint for a digital recalls process and supporting network infrastructure. The scope of this detailed analysis was limited to the span from the point in time that a recall determination was made to the point at which a recall event was closed. The selected scenarios were:

- Initiation of a Recall Event
- Communication of the Initial Recall Notice
- Communication of a Sub-Recall or Forward Notification
- Receipt of a Recall Notice and Initial Execution Response
- Identification and Removal of a Recalled Product in the Supply Chain
- The Patient Connection and Communication of a Recall Notice to Consumers
- Monitoring of the Recalls Process and its Effectiveness

Each of these scenarios are in turn described in detail below to highlight the key recall activities, complexities, and challenges from our study to help illuminate the potential of a digital recalls network.

Initiation of a Recall Event

The initiation of a recall event is a critically important operation, but one which follows processes and SOPs which may vary significantly from pharmaceutical company to pharmaceutical company.

- The organization in a pharmaceutical company charged with Quality management typically facilitates the recall event strategy decision based on inputs from numerous sources including other internal stakeholders, consumers, and the FDA.
- The Quality management team typically determines the triggering and initiation of a recall.
    - A Recall committee is formed, often chaired by Quality, after recall is determined. A Recall committee is usually set up for each recall event at the company level.
    - The Recall committee may include members from Pharmacovigilance, Legal, Supply Chain, Communications/Public Relations, and others, highlighting the diverse nature of the internal stakeholders involved in the overall recalls process. The exact stakeholders may vary slightly from recall event to recall event.
    - The Quality organization is the underlying responsible party for the recall event and usually manages all FDA communications concerning it.
- During discussions, the pilot team found numerous variations in recalls SOPs depending on how the pharmaceutical company is organized and how it manages its supply chain. Some pharmaceutical companies may use a returns processor to manage the bulk of the overall recalls process. Others may use a returns processor primarily to manage all of day to day logistics

activities while keeping primary communications and decision-making in-house. The service agreements between the pharmaceutical companies and their hired returns processors can vary quite a bit across these situations, with implications for the rest of the supply chain. Still other pharmaceutical companies decide to manage everything in-house. During our analysis, we found initial indications that pharmaceutical companies who managed the recalls process in-house tended to use and rely upon some basic electronic or digital capabilities for recall notification and response more frequently than those who outsourced this capability.

- Some of the typical events and processes that are involved in initiating a recall event from a pharmaceutical company in conjunction with a returns processor include:
    - Creation of a recall packet containing a recall letter, a Business Response Card (BRC), and a shipping label and envelope in which to return the completed BRC. This is typically sent via FedEx or other carrier to all ship to locations identified by the pharma company.
        - The Quality team at the pharma company creates the official recall letter.
        - The returns processor creates the BRC.
        - The Quality team approves the entire recall packet before it is officially sent.
        - The returns processor then executes and distributes the recall notice.
    - Instructions for the direct trade accounts of a pharmaceutical company (for example, their authorized wholesale distributors) are created to define how to manage further communications in the supply chain, which may include the use of a copy of the initial recall letter plus an additional letter of instructions to be sent by the trade account to their own customers who may have received the recalled product.
    - Launch of the recall management process by the returns processor for this specific recall event, which may include organization and staffing of call centers, typically within 1-2 days of the decision to initiate the recall.
    - Some direct account customers and consignees may ask for a “corporate” notification in addition to notification for the specific ‘ship to’ locations. Regardless, a discrete notice to all ‘ship to’ locations is required by FDA for compliance. A large pharmacy chain may request that the notification also be sent to corporate (in addition DCs and stores) so that it can be manually transcribed and submitted into their internal recall messaging system.
    - Internal locations within the pharmaceutical company are also typically sent the notification package. These would include corporate headquarters, internal company warehouses, and the locations of third-party logistics (3PL) partners used by the pharmaceutical companies.
- Communication and coordination between the internal Quality team and larger Recall committee members, and the external returns process, occurs over email and relies on information which lives across disparate systems in the two organizations. Pilot members highlighted the significant time and effort faced by the recall manager on the Quality team to

identify customers potentially affected by recall event and to aggregate the list of ship-to location addresses that need to be notified for each specific event.

Communication of the Initial Recall Notice

Following the initiation of the recall event, the initial recall notice is communicated based on the recall execution strategy.

- For product distributions direct from the manufacturer, the pharmaceutical company alerts their direct trade accounts which, depending on the specific product type, may include a varied mix of wholesale distributors, retail pharmacies, and healthcare / hospital organizations. These notifications today are typically comprised of a mix of email and fax notifications to go along with the notification package and instructions provided via FedEx or other carrier. The notifications include severity of the recall, the NDC/lot(s) affected, and instructions on how to respond.
- Pharma companies face several challenges while sending recall notices and alerts, particularly those sent via mail.
    - Notifications may get sent to a specific location, such as a regional distribution site or a central warehouse for a pharmacy chain, but not to the current location where the product may be located following internal transfers of product.
    - Notifications may get sent to the right company and location, but may not get to the right person who is responsible for coordinating recall execution.
    - Notifications received may get lost in the daily shuffle of a busy organization and the informed location may not be able to locate the recall notice.
    - Notifications may remain unopened or may be refused due to a data entry or labeling error.
    - Notifications are typically sent to all potential recipients of their product, though the recipient in the supply chain may no longer have any recalled product remaining in their possession or control.
- Pharmaceutical companies typically do not have direct trade relationships nor visibility with all points in the supply chain that may sell, dispense, or use their product. Since the predominant communication method today is point-to-point via email and manual methods, most pharmaceutical companies depend on wholesale distributors to help notify entities throughout the supply chain of a recall event.
    - Based on a variety of factors, the ability of wholesale distributors to quickly and accurately execute a sub-recall or forward notification varies widely from organization to organization. Depending on the specific trade relationship involved, some distributors may not offer such services at all.
    - Returns processors or other third parties may be leveraged to provide additional coverage for and access to supply chain entities outside of direct trade relationships, but this not only generates extra cost but increases the potential for confusion when

pharmaceutical company, returns processor, and wholesale distributors are all sending out notifications for the same recall event.

- Due to the manual nature of most communications, and variability in how the recipient processes the notification received, the pharmaceutical company cannot rely upon having a clear picture of the success of the recall notification.
    - A pharmaceutical company may not receive a recall notification receipt confirmation from entities who either do not respond if they do not believe that they possess the affected product or who do not respond until they have taken action based on the notification.
    - Because recall notification receipt confirmations may also be received via a variety of manual or electronic methods, it takes time and introduces errors in collecting and collating all of the responses. In the meantime, the risk grows that a second round of notifications may go out to perceived "non-respondents" further introducing work and complexity into the process.

Communication of a Sub-Recall or Forward Notification

Sub-recall or Forward-recall notifications are typically executed by wholesale distributors in the supply chain, on behalf of a pharmaceutical company, to secondary distributors, retail pharmacies, healthcare organizations, or other direct trade partners of the distributor.

- If the affected product was distributed by a wholesale distributor, the distributor may take the alert notification received by the pharmaceutical company, augment its information with additional distribution dates data and handling instructions, and send further notifications to the distributor's trade partners. Alerts are not always targeted to pharmacies that actually received recalled product.
- There is a significant variance in the information made available to a distributor to execute a sub-recall, particularly for recalls of entire batches of product which may extend across multiple lots numbers. At least today, the information in the recall notification is not tightly linked to additional tracking data made available through DSCSA compliance processes.
    - Forwarded notifications may not be targeted precisely to only the distributor's trade partners who received the recalled product. Recall coordinators at wholesale distributors may not have the ability to determine locations of affected lots of product within the distribution environment and often do not have the ability to determine to whom affected lots of product may have been sold.
- Compared to the initial recall notification from there pharmaceutical company, there is even less standardization of the information and instructions provided in a sub-recall.
    - Two sub-recalls for the same affected product generated from two different wholesale distributors may include unique and differing execution and handling instructions, generating confusion in a retail pharmacy or healthcare organization that may be served by both organizations.

- Occasionally, the risk also arises whereby the instructions provided in the sub-recall by the wholesale distributor may be unclear or may partially conflict with the instructions provided in the original recall notice generated by the pharmaceutical company.

Receipt of a Recall Notice and Initial Execution Response

The existing process to manage pharmaceutical recalls in the retail pharmacy and healthcare setting is a complex mix of diverse information, disjointed or conflicting communications, and manual processes.

- The result is that hospitals and pharmacies spend a considerable amount of time and apply an excess overhead of resources in responding to and handling recalls.
  - This is compounded due to the multi-stage notification process identified above. Between pharmaceutical companies and other members of the supply chain sending notifications, any one location or entity at the end of the supply chain may receive several overlapping notifications for the same recall event.
  - Given the lack of specificity in either instructions, or in their ability to readily locate exact product to be quarantined and returned, dispensers will often cast a very wide net during recalls, informing more customers, and removing more medicine from their supply, than is necessary just to ensure patient safety.
- Virtually any dispenser, be it a retail pharmacy, a single hospital, or a healthcare organization, has a broad range of medicines in stock and in use at any given time. So while an individual pharmaceutical company may have very infrequent experience with executing a recall, the daily life of a dispenser is the exact opposite with any one location or organization often juggling a new recall notification while simultaneously managing many currently in-process recalls.
  - During our study, we saw an average of 20 to 30 ongoing drug recall events being managed at any given time by a dispensing organization.
  - Further complicating the issue were the overlaps of recall notifications due to multiple communication channels and execution of sub-recalls for the same affected product.
  - Additionally, organizations or locations may receive notifications for product that they may not have actually received or managed given the lack of ability to specifically target notifications to specific organizations or locations.
  - The management of multiple recall events is further exacerbated by delays introduced when notifications provided in paper form are not sent to responsible person (i.e. the recall coordinators in the company) or when email notifications are received and forwarded.
  - Finally, oftentimes additional time and effort is required at the outset of a received notification in clarifying exactly what is required based on the notification letter received. Individuals in dispensing organizations spend considerable time contacting call center listed in the recall letter for clarifications, or waiting for callbacks as often the individual on the call center doesn't have all of the information needed by the pharmacy or healthcare organization.

  - As a result, significant alert fatigue was identified as a continually recurring issue across both retail pharmacies and healthcare organizations as recalls stack up and the time to execute a recalls grows.

- To help manage these issues and the related operational challenges they create, some organizations are creating dedicated recall teams within their company.
  - The designated recall coordinator for a healthcare organization as a whole, or for a business unit within a retail pharmacy chain, is responsible for monitoring all ongoing recalls in the market and evaluate them for potential impact against the organization under a detailed set of SOPs.
  - These SOPs, somewhat similar to those of a pharmaceutical company, will typically identify the level of the recall, determine the organizational approach to this event, and develop a location, facility, and patient scope for notification.
  - Based on company risk and safety policy in the SOP, numerous organizations and staff may be informed by the recall coordinator or may be part of the organizational recall response developed by the coordinator including pharmacy operations, legal, safety, regulatory, compliance, marketing/communications, and call center operations.
  - For these organizations, they have started to develop internal systems to help manage the recall events, enabling the coordinator to capture internal responses to the notification and share a coordinated response back to the upstream suppliers and other entities that supplied an initial recall notification to the pharmacy or healthcare organization.
  - While promising, this formal and coordinated approach is still hampered by the highly manual underpinnings of today's recalls process and most organizations today do not have the time or resources to put such a structured approach into place.
- Many pharmacies and healthcare organizations do have sophisticated information systems which could be leveraged to assist in the initial recall impact evaluation process, but such systems cannot be effectively leveraged today given manual information sharing, the lack of standardization of the information that does happen to be shared electronically, and the lack of specificity in the information provided vs. the actual products affected by the recall.

Identification and Removal of a Recalled Product in the Supply Chain

There is a wide variation in the process of how recalled product is identified in the supply chain, particularly at the hospital, healthcare and retail pharmacy organization level, what data is used to help inform such processes, and how the potentially affected product is thus removed from the supply chain.

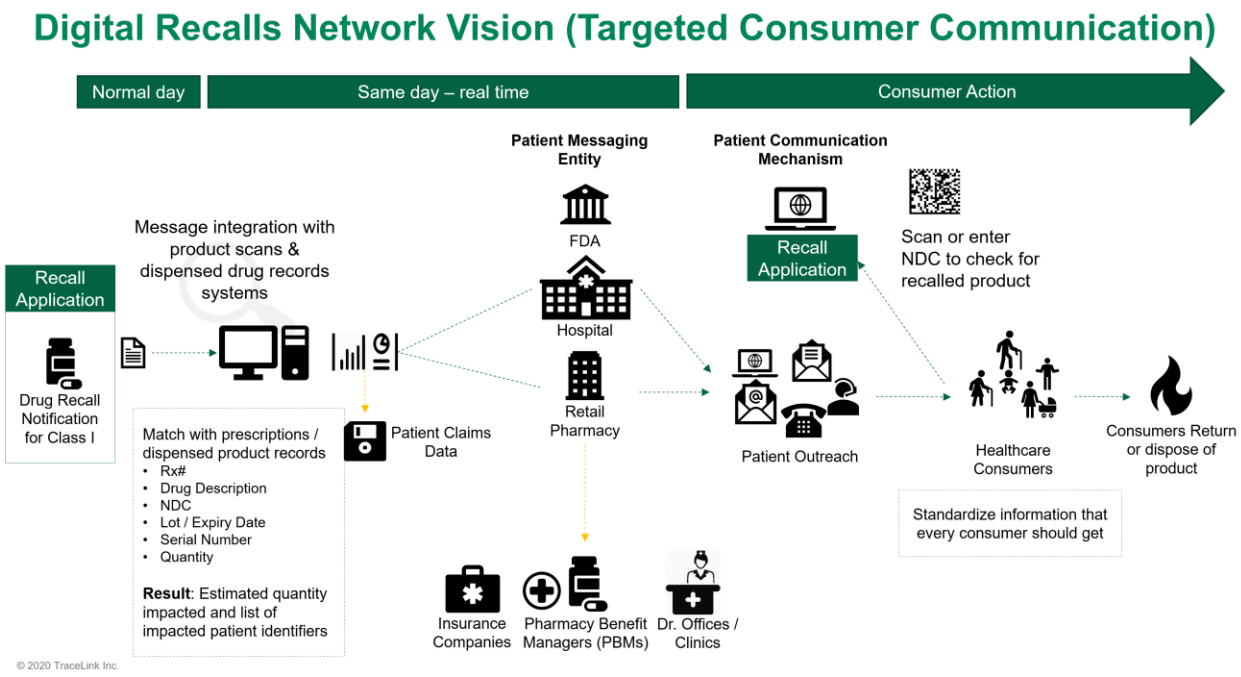
- Some companies manage the process in-house with existing staff while other organizations leverage third parties, using reverse logistics companies and other firms to check and sweep shelves and inventory locations of affected product.
- In general, due to lack of specific data on the affected product or ability to tie the data that is available to current inventory status or location information, it is typical that all pharmacies or

locations within an organization are searched manually to identify and remove recalled products. Pharmacy oversight responsibilities for managing recalls puts a significant burden on operations, and may even require dedicated staff.

  - In hospitals and healthcare organizations, this complexity is magnified given the wide variety of locations where affected product may reside, including surgical rooms, procedure carts, and other temporary staging areas. So, each department in which an affected medicine may be located may have its own unique parameters for executing the product check.

- One key factor in reducing the ability to target and focus the search for affected product is the challenge in determining if the exact NDC or lot was purchased by company or is stocked by a specific location. Oftentimes, information such as the lot number is missing in inventory records due to trade agreements, isn't provided as part of compliance documentation received, or isn't tied to specific locations or internal product movements.
  - Most companies have specific procedures in place to follow for searching and culling recalled product, but a significant amount of time is spent manually checking specific products in inventory and on shelves to determine if they fit the specific recall criteria.
  - Many pharmacies and healthcare organizations will remove all lots under a given NDC in the recall notice, even lots that may not be part of the actual recall event. This leads to excess wasted product and is a contributing factor to drug shortages, particularly when large scale removal of product at point of dispense is executed in a similar fashion.
- The specific actions undertaken during this identification, quarantining, and removal process are typically covered under specific compliance actions audit by the FDA.
  - The internal responsible party, or an internal Recall Committee if one exists, documents and reports upon actions taken. During this process, further follow-up activities may be identified or potential complications for the organization may be highlighted.
- Finally, a lack of clarity on reimbursement policies for recalled product returned and related administrative fees further colors the recall execution process at the dispensing point.
  - A dispensing company may use their own returns processor, separate from the returns processor used by the pharmaceutical company, to sweep the shelf, return the recalled product, fill in the business response card, and follow-up with supplier to receive credit for any recalled product returned. These processes may differ than those specified in the instructions received in the original recall notification from the pharmaceutical company. Conflicts can arise whereby the pharmaceutical company would like the recalled product returned directly to them or to their designated returns processor while the dispenser or healthcare organization may use their own organization, thus potentially slowing down the final resolution of the process.

The Patient Connection and Communication of a Recall Notice to Consumers



While not a primary focus of this pilot, the pilot team did analyze some of the ways that patients and consumers are engaged and notified during a recall event.

- Overall, there is a great sense of urgency to ensure that patients are not impacted or harmed by recalled product, but the exact steps to take can be complicated by many factors.
- Pharmacies can elect to block affected NDC's through prescription claims processing to highlight where affected product may have been supplied to a patient.
    - But dispensing records may not contain dispensed NDCs and generally do not contain Lot information. So it is difficult to identify impacted patients. Pharmacies cast a wider net by informing as many patients of ongoing recall and possible impact.
- Pharmacies may elect to ensure broad coverage by informing as many patients as possible of an ongoing recall and its potential impact if they are unsure if a patient may be affected. This is often done through a variety of communication means including text, phone, email or web.
    - It has been noted, though, that this broad outreach can lead to confusion among patients, creating uncertainty if they really do have the recalled product, and whom they should contact (pharmaceutical company, pharmacy, doctor/healthcare provider).
- In addition, for medicines that are in short supply or are being used to treat critical conditions, the removal of a medicine from the patient's hands leads to immediate questions of whether additional unaffected stock of that specific medicine is available in the supply chain.
- It was clearly noted that pharmaceutical companies do not have a clear picture of the impact of a recall at the point of the patient or consumer and would like to capture better feedback upon the actions taken and their impacts.

Monitoring of the Recalls Process and its Effectiveness

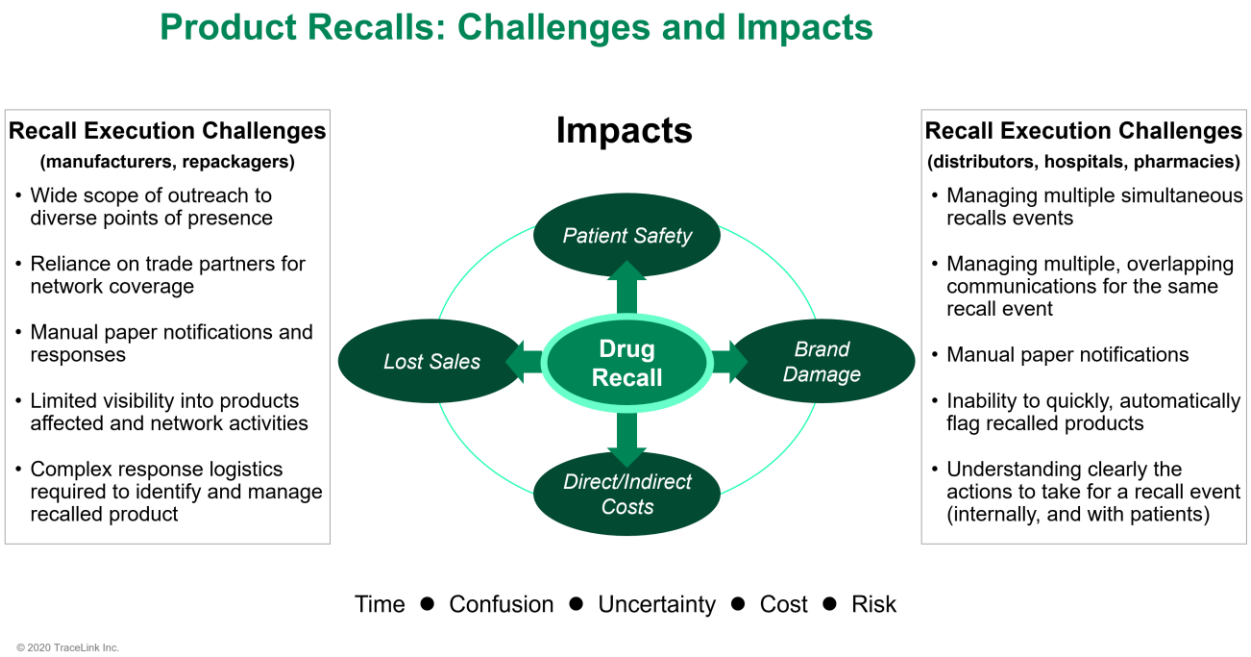
Given the challenges that pharmaceutical companies have with respect to precise visibility of the quantity, location, and status of their medicines in the supply chain, monitoring the progress of a recall event and performing effectiveness checks is difficult and imprecise.

- The effectiveness checks required by the FDA for a product recall, generally managed by the quality organization, require the company to monitor and periodically report status of recall effectiveness and recalled products removed from market. How this is actually executed is unique on a per-company basis.
    - At global level for multi-national pharmaceutical companies, the quality team tracks the number of recalls, but generally not the details of execution. The local organization is typically charged with tracking effectiveness checks on a per-recall basis.
    - The pharmaceutical company provides the returns processor with copies of product labels so that they can reconcile recalled product.
    - In the outsourced model, the returns processor captures and tracks effectiveness metrics and generates monthly reports to the quality team at the pharmaceutical company.
    - Oftentimes, as part of a recall a dispenser will only return the existing product in inventory or on the shelf at a specific point in time or in a specific time window. Outside of this timeframe, if a patient returns with recalled product, that product is collected for destruction, but is not returned back as part of the recall process and thus is not counted as part of the effectiveness check.
- Multiple organizations and activities need to be orchestrated as part of the recall execution process.
    - Returns processors where engaged are responsible to destroy the recalled product and provide certificate of destruction to the pharma company for audit compliance. They are also responsible for managing the crediting process.
    - CMOs may be engaged for reworking on the recalled product that need not be destroyed.
    - Direct trade partners (wholesale distributors, retail pharmacies, hospital/healthcare organizations) capturing, identifying, and shipping returned product as part of the recall event.
- There is a significant diversity today in how companies engage with the business response cards, a compliance document used as part of the auditing process by the FDA, and the actions that are taken by pharmaceutical companies based on these engagements.
    - Depending on the specific organization, there can be more of a focus on completion and return of the BRCs and not necessarily on the impacts of the actions taken with respect to the recalled product by the downstream supply chain entity. The pharmaceutical

company has specific documentary requirements in reporting upon their outreach into the supply chain and the response gained to that outreach.

- The trade partner may respond in a variety of ways when a BRC is received. They may fill in the BRC but look upon that response as an "acknowledgement" that they received the BRC and not specifically that they have taken action. Others may tightly align the BRC response to detailed actions taken (removing product from inventory, etc.). Some trade partners may not fill in and return the BRC if they don't have the affected product. Other trade partners may not fill in a BRC but will check for and return affect product under the recall.
- Typically, the returns processors is the entity that performs the effectiveness checks on behalf of the pharmaceutical company, but the pharmaceutical company is the responsible party for reporting such progress to the FDA, including the rate of return for recalled product and projections for expected termination and closure of the recall event.

Overall, there is a consensus that the execution of the recalls process today across the supply chain is highly complex with significant challenges faced by all stakeholders. The effectiveness of this process is highly gated based on manual processes, less than perfect data on the recalled product, and the general inability to quickly and precisely identify its location in inventory across the supply chain.



The Potential and Opportunities for a Digital Recalls Network

Given the current manually-driven methodologies for initiating, notifying, executing, and closing a recall event, the pilot team started to foresee a vision for a standardized interoperable digital recalls network. Such a network would leverage new types of information, bring to bear advanced network approaches for connecting companies and sharing information, and coordinated processes to orchestrate the entire end-to-end supply chain. This also included a review of the envisioned 'To-Be' state, the current 'As-Is' status, the changes and transition steps that would be required to happen in order to achieve the identified benefits; and the efforts and potential adoption barriers for enabling this transformation across the supply chain. Ultimately, thinking from the patient backwards, how can we improve protection for patients from potentially unsafe medicines under a recall while designing a digitalized recalls process that incorporates the diverse needs of the tens of thousands of entities across the supply chain? This holistic view was critical in developing a vision that could support and improve the recalls process for the entire diverse supply chain and not just for a single segment.

The team discussed the goals and objectives of the digital recalls network, and formalized a discussion framework in order to evaluate the future vision. Specifically, how would we describe this digital recalls network, how would we identify the points and systems where the recalling company and consignees can leverage different information that is being developed for different reason such as DSCSA compliance, and how would downstream trade partners and other stakeholders connect to and engage with such a network.

The diversity of the pilot team, augmented by additional research and workshops which were conducted prior to the launch of the pilot, helped to bring to the table divergent viewpoints and inputs on the benefits across different archetypes by improving recall notifications, bi-directional communications, and response times across the execution phase. This included specific work in looking and how to enhance the predictability and accuracy at assessments of how much recalled product is actually in the supply chain at the initiation of the recall event and how much product is expected to be returned from the supply chain. There are significant opportunities to test the assumptions and findings of this blueprint with follow-up field tests.

Discussion Framework for Analyzing and Constructing a Digital Recalls Network

Discussion Framework for Constructing a To-Be Digital Recalls Network

Supply Chain Stakeholders Activities	Product and Traceability Information	Digital Messaging Model	Information Routing Rules	Evaluation Metrics
• Business process impact • Operational impact • User roles and teams	• Product traceability data • Product serialization data • Product master data • Company master data	• Data fields • Query parameters • Pointers to records • Dashboard	• Data ownership • Visibility controls • Configurations	• Time and precision in identifying affected consignees and network participants • Time to create recall notification and response • Time and precision in identifying affected products in the supply chain • Time to verify if product is recalled • Time to receive responses • Time to view progress of recall

The discussion and analysis framework was designed to focus the pilot work and clarify the specific data, processes, and other elements which could be included into a future digital recalls network framework.

- In discussions on recall communication and execution steps, we looked at stakeholder activities and impact at each step to ensure the digital recalls network blueprint is flexible enough so that it can apply to different scenarios. A big multinational pharma company may have a very different products, supply chain processes, and recall mechanisms than a specialty pharma, but the same general rules and framework must still be applicable for lots of diverse archetypes in the supply chain.
- We took a deep look at the different kinds of emerging information, and in what systems that information resides, to be leveraged for improving recall processes. This analysis then extended to understanding a fundamental data model for this information and a flexible, standards-based data exchange model for this information across different entities.
- Data ownership and visibility of digital recall information was a critical topic in our discussions. This included visibility of information within an organization and when information is exchanged across a broad supply chain including entities that have direct trade relationships and entities that may be connected given a recalls event but who do not have an existing trade relationship. We discussed the business rules and configurability required around day to day business to place controls on who can see what, when and how.

- Finally, we examined evaluation metrics. As the blueprint is tested, it will be critical for stakeholders to measure both initial results as well as to analyze how those results inform the long-term business and patient benefits that we expect a digital recalls network to deliver. So the team created some future value metrics from a digital notifications perspective, from an execution perspective, and from a closure perspective.

Digital Recalls Network Blueprint

The discussion framework helped the pilot team identify the capabilities, data, and other tools which may be available, enabling the pilot team to structure a high level blueprint which aligned the insights and considerations developed. From this, the team created a core set of concepts and key principles for a digital recalls network, and specifically for a digital recalls notification communication and execution model which would underpin such a network.

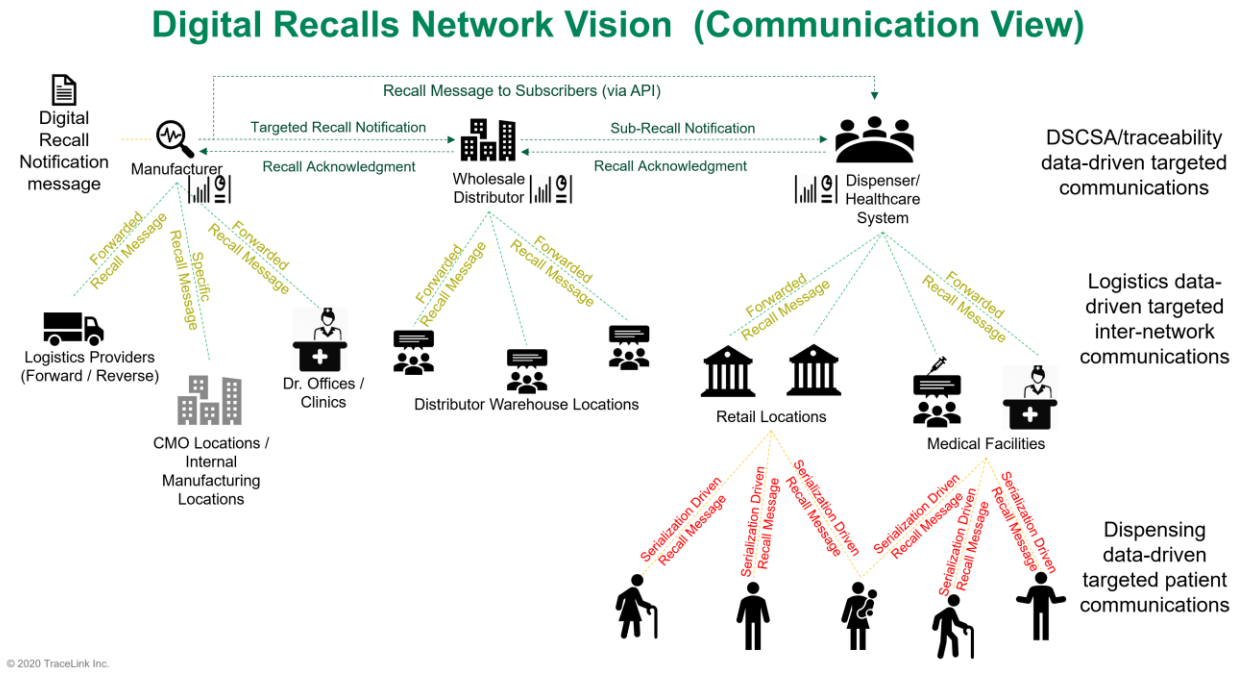
High Level Principles for a Digital Recalls Network

There are several principles which emerged through the analysis relating to the operations of a digital recalls network and the benefits of such a network to all stakeholders across the supply chain. These principles were identified as offering potentially significant benefits in reducing time, cost, and/or risk in managing product recalls compared to the existing broadly adopted manual methods in use today.

- Digitalization of today's manually-driven, disconnected recalls notification and acknowledgement process into an electronic, bi-directional, recall communication workflow.
- Interconnectivity and interoperability between the systems used for recalls initiation and management, and those systems used for product identity, traceability, and inventory mgmt.
- Development of a harmonized network-shared data model for recalls which would leverage DSCSA-driven information, such as the lot-level Transaction Information and the serialized product identifier, cross-tying it with existing information that is captured and shared today in recall notices, BRCs, and other documents.
- Setting and sharing unit-level product status across serialization, traceability and inventory systems to better inform inventory, distribution, pharmacy, and other operational processes with data about a potential recalled product in an organization's possession or control.
- Enhancing linkages between the organizations and processes involved in a recall event, across forward and reverse logistics, to establish closed-loop visibility into the status of a recall.

There are several ways in which the above principles could be realized in a digital recalls network, and while some of the principles are interconnected, others are decoupled and could be phased in over time. In addition, there are no hard specifications as to specific technologies or systems that would need to be used to realize such a digital recalls network. In fact, the ability to leverage open, interoperable standards would be paramount in ensuring such a network was available for all parties and entities.

Faster and More Precise Notifications Speeds Recalls Execution and Reduces Work



A significant initial opportunity for the industry is to enhance the initiation and execution of recall notifications and acknowledgements from stakeholders in the supply chain.

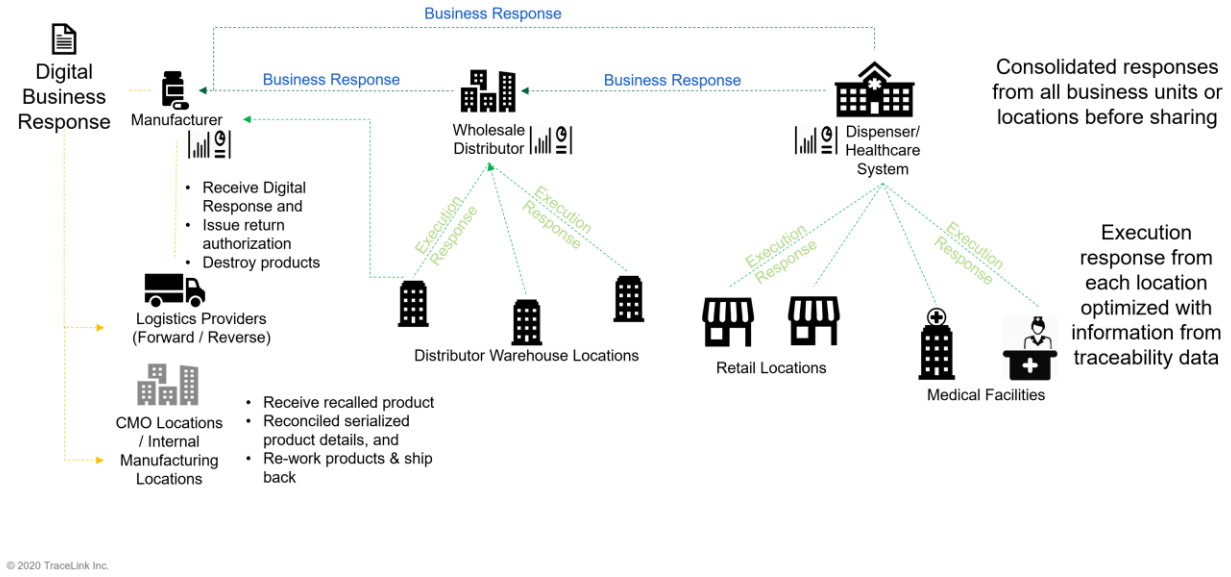
- The electronic recalls notification message can integrate with and leverage DSCSA traceability data to correctly identify affected consignees to whom recalled product was sold/shipped, and send recall information faster with targeted notification alerts to designated recall coordinators at those companies.
- Standardized electronic recalls notification form fields including recalled product NDC, lot, and serial number could be filled by the designated compliance manager at any recalling company with details of the recall event. This information could be used to enrich the recall message notification. When information such as a FDA-assigned recall ID is accessible, such details could be added when available to enhance a shared view of the recall event across the supply chain.
- The standardized electronic recall notification and acknowledgment messages could be efficiently and securely shared between recalling pharmaceutical companies and specified partner companies that have been registered and verified on an interoperable digital recalls network. The option could exist to send the recall notification to all trade partners, or the enriched data could be used to promote targeting of the notification to only those companies where there is evidence that they may have received the recalled product.
- The recall notification message could also be broadly communicated securely to any company on an interoperable digital recalls network to facilitate notification to entities where there

doesn't exist a direct trade relationship with the recalling pharmaceutical company. Such broadcasts would require configurable controls and would need to rely on a network with strong identity and credentialing management.

- The initial notification and acknowledgement can open a recall workflow event instead of a send and forget communication. In such a network-based event, initial and subsequent information updates could be added, and follow-on questions could be asked and answered, to ensure that the initial recall communication is understood and that there is a shared understanding of the next process steps the recipient will take before the notification is truly marked as "acknowledged". Besides helping improve the initial snapshot of how well the outbound recall notification is performing, it has the added benefit for audit compliance purposes in meeting FDA desires to more closely tie an acknowledgement to a specific action being taken rather than just acknowledging receipt of a message.
- Designated recall managers and recall coordinators across different consignee companies in the supply chain could connect to and leverage the digital recalls network to receive timely and targeted recall notification messages from multiple pharmaceutical companies. Access to this collected and unified information on recall events could provide downstream entities with a cohesive view of the outstanding recalls "on the board" either in-process or waiting acknowledgement.
- Standardized electronic recall acknowledgment messages would allow designated recall coordinators across different companies to electronically acknowledge receipt of specific recall event notifications and instructions to signal risk mitigation actions in progress.
- Standardized electronic recall notification messages on a recalls network could be integrated with a consignee healthcare provider company's dispensing and health record systems to quickly identify and flag affected patients IDs in response to a Class 1, patient level recall.
- For retail level and patient level recalls, the direct account consignee of a recalling company who receives an initial recall notification could electronically forward official recall notification messages, securely appending templated instructions to the affected endpoints in response to sub-recall process instructions for recall events.

Timely and Precise Location and Quarantining of Recalled Product Speeds Recalls Closure

Digital Recalls Network Vision (Business Response and Execution View)



A digital recalls network can not only facilitate faster recall notification, but also speed the identification and quarantining of affected product under the recall. There are several opportunities to use emerging data on products and transactions developed through DSCSA implementation in the United States, and better connections between recall management systems, inventory management systems, and traceability systems, to enhance locating and marking recalled product for quarantine in entities and locations across the supply chain.

- The workflow event that was opened as part of the initial notification and acknowledgement messages could be extended to the overall business response. This would help to ensure that instructions provided are being followed by the downstream consignees and that the process is being conducted in compliance with FDA product recall guidelines. It would also help enhance the shared visibility on the steps taken or to be taken and the progress on those steps. The electronic business response could be used initially to augment existing manual BRC processes as part of a transitional process to a fully digitalized recalls methodology.
- Designated recall managers and recall coordinators across different consignee companies in the supply chain would have access to rich electronic information in the recall event on the recalled product shared as part of the initial notifications to help them identify and locate recalled products in their organization. If the organization didn't have tightly integrated enhanced inventory and pharmacy systems, the digital information would also be easily accessible to share with other stakeholders across the organization to leverage in the interim using existing manual means or smart user interfaces to such systems.

- Selected key data from DSCSA-related lot-level Transaction Information and serialized product identifiers on recalled product, captured as part of the standardized network recalls management system and made available in a controlled fashion to verified entities/users across the network, would allow entities to check for potential recall status as part of critical shipping, receiving, or internal product transfer operations.
- For hospital, healthcare organizations or retail pharmacies, information on lot or specific product identifiers included in a recall event could be made available at point of dispense areas or to systems being used to support healthcare procedures to provide an additional safety net to stop recalled product from being dispensed. This linkage would also help facilitate record reviews to help determine if patients had previously received specifically recalled medicines prior to the formal recall event notification being received.
- To enhance FDA recall effectiveness check processes, a standardized electronic business response message would allow designated recall coordinators across different companies to electronically inform recalled product disposition status to confirm risk mitigation actions taken for their company locations.
- Standardized electronic response messages containing dispositioned serial number information could be integrated into returns processors' systems to reconcile recalled products that have been shipped back as per recall notification instructions, providing closed loop visibility to the recalling company into recall effectiveness, enhancing accountability and accuracy, and reducing patient risk.
- To enhance record keeping and internal controls, electronic exchange and integration of standardized recall notification, acknowledgment and response messages with recall-related activities, could allow recall managers and recall coordinators the ability to electronically maintain a harmonized audit log of all recall actions taken at company locations for compliance audit and reporting purposes, reducing time and effort in maintaining paper audit logs.

Pilot Team Questions and Observations

The team had open and vigorous conversation about some of the assumptions and questions that they foresaw in looking at the phased implementation and adoption of a digital recalls network. Below are some of the additional commentary shared by pilot team members.

- It was identified that although DSCSA-related information on specific products and product identifiers, transactional data of movement of products between trade partners, and related information such as quantity of specific products transacted upon is hugely beneficial, the access and use of this information in the supply chain is highly variable today based on how DSCSA compliance solutions have been implemented across the supply chain. Many companies are still in the midst of integrating their lot-level traceability and master data systems tightly with warehouse, inventory management, and other product management systems within their organization. So the digital recalls network needs to be flexibly designed and provide incremental benefits as the underlying product data set available becomes richer and more

universally available and this information is more closely tied to and integrated with specific locations. There will be no perfect start time on this evolution.

- In addition, serialization of the medicine supply today is progressing but is not complete. Today and in the near-term, not all companies and locations across the supply chain will physically scan barcodes on serialized product identifiers nor are many internal business and operational systems "serialization-aware". So mass access to serialized product identifier information (GTIN, lot, expiration date, serial number) to be leveraged for the recalls process will be an evolution. One accelerator for this evolution will be the other potential benefits, particularly in the pharmacy and healthcare environment, for the use of this data, particularly electronic access to expiration dating tied to location of product.
- There is a great diversity of opinions today, particularly at retail pharmacies and use in healthcare, as to where potential scans of serialized product would happen and how that information would be connected to the recall information. Scanning early upon initial receipt of product by the company or organization may be the easiest from a logistical perspective, but as product moves through internal inventory distribution channels the precise connection of a recall to the specific identity and location of a potentially affected product in a dispensing organization becomes harder to manage. Scanning at shipment to or at receiving of pharmacy location may provide an intermediate solution. Scanning at point of dispense or at point of use would provide an ultimate safety net for catching medicines about to leave the supply chain or to review historical information of products previously handled, but there are questions around potential impacts in the time to fill a script or finish a procedure.
- With increasingly rich and precise information on recalled product becoming more and more available to patient-facing organizations (retail pharmacy, healthcare organization, payer/provider, mail-order pharmacy) through a digital recalls network, the potential opportunity also grows to enhance the patient notification process. The pilot team did discuss at a high level some of the potential opportunities of such a recalls network to (1) speed notifications to patients; and (2) limit the risk of notifications going to patients who are actually unaffected by the recalls. The group agreed that the potential opportunities were significant while acknowledging the potential risks and downsides to missing recalled product at a patient due to incorrect notification rules. This potential warrants additional future study.
- Change management processes and retaining on new recalls management processes should be incorporated into the overall digital recalls adoption and maturation methodology for companies. This would include redefinition of SOPs and staff education/retraining programs.
- There should be a holistic view of the net impact on human resources and work. The implementation of a new recalls process or an additional step into an existing process for recalls may be an initial increase, but the enhanced information that is available to the overall organization due to implementing capabilities to work on a digital recalls network may save labor in other areas.
- In the spirit of enabling a harmonized view of a recall event across the supply chain, there was a lot of interest in trying to create a unified identifier for a recall event. The use of an FDA-

assigned ID was discussed but given several of the activities in the lifecycle of a recall event may occur before an official FDA ID is assigned, there was a question about what other unique identifier could be generated and maintained, eventually linked to the official FDA ID. Another option to explore was the potential to gain a true FDA-assigned ID earlier in the recalls process, although the team identified multiple considerations to review in this area.

- Finally, a key opportunity discussed was the potential for how to create a more closed-loop process on the returns execution side, given the multiple parties involved in sweeping product, shipping product to returns and reverse logistics locations, and consolidating information about those products back to the recalling company or their external returns/recalls partner to enhance the effectiveness check process. This may mean that the role of returns processors may change or grow over time, for example depending on how a returns processor may manage engagements with non-responders.

Digital Recalls – Considerations and Recommendations

Throughout our discussion, the pilot team continued to generate and highlight additional insights that may offer additional venues for fruitful exploration.

- **Interoperability standards** - Several information standards or commonly adopted interoperability approaches are available today for exchanging electronic messages, in product packaging/distribution, or in compliance with DSCSA requirements. The pilot team reviewed these data sets and interoperability guidelines, concluding that these information standards provide a very strong standards-based foundation for the information management requirements of a digital recalls network. The team did highlight certain opportunities where such standards could additionally be enhanced to better support an end-to-end digital recalls process which is an area that the industry could further explore.
- **Transition and change management** - Today's product recalls processes have remained relatively unchanged for more than a decade. As a result, the benefits and limitations of today's approach are quite well understood by most stakeholders across the supply chain. The question of how to handle a transition to a digital recalls future was often discussed by the pilot team. It was noted that different organizations in the supply chain may have different preferences for how this transition would take place, with some wanting to chart a path to a direct switch over to digital based on specific products or partner relationships while others wanting to use a digital recalls network to augment and inform the existing methodologies for an interim period to test and confirm assumptions on how the digital recalls network would operate.
- **Value frameworks** - There was considerable diversity in how companies today measure their performance in managing product recalls. Given this, the pilot team brainstormed a value framework to help identify the key metrics across this process. Various dimensions such as time to notification, recall response rate, recall effectiveness, and recall execution costs were

examined as potential key metrics on the digital recalls dashboard. Opportunities were identified to drive more open conversation on the key principles and metrics for a digital recalls network, helping to inform and measure progress for individual companies and for the supply network in the large throughout this transformation.

- **Best practices and guidelines** - As with any network transition across a diverse set of stakeholders, the question of governance arose in facilitating open interoperability across the industry, in helping to set new best practices and guidelines in how a digital recalls network should operate, and in helping chart a transition process from the existing manual product recalls practices. A cross-industry consortium could help to jumpstart some of these conversations and develop the foundation for an industry blueprint for the development and adoption of a digital recalls network.
- **Recalls beyond pharmaceuticals** - While the primary focus of the pilot workstream on digital recalls was to study pharmaceutical product recalls, the pilot team did discuss similarities and differences to the current recalls process and related regulations for other product areas such as medical devices, over-the-counter medicines, and nutraceuticals. There was significant interest in further exploring how a digital recalls network could provide a harmonized approach to recalls management across multiple product types by those pharmaceutical companies with related product divisions in these areas, and in particular by the downstream supply chain participants who must manage recalls daily across their diverse product inventory.
- **Regulations and guidance** - Finally, it was clearly identified early on that the FDA is a key partner in this process. As we look at existing reporting requirements around product recalls and guidance on processes and procedures to follow, it is clear that there is a measure of uncertainty across the industry today given existing rules and regulations. Questions and differences of opinion rose in areas such as what actions need to be tracked today under a recall, what information should be shared with other stakeholders in the supply chain about these actions, and how the data used on these actions is interpreted. Having an open discussion and collaboration with the agency as we chart a path going forward will be critical. It will be important to look in detail at how a digital recalls network may change how recalls could be managed and how these new approaches fit within today's regulatory framework. The pilot team identified some initial opportunities to reexamine some of the existing rules and regulations with the agency to further advance the shared goal of quickly and precisely identifying and removing recalled product from the market. Such conversations with the FDA could be part of an industry consortium effort or through focused public meetings on the topic.

There are significant new emerging opportunities to enhance the initiation, notification, execution and closure process for product recalls by leveraging enhanced networking, communications, and product / transaction information across the end-to-end product recalls process.

It will take a collaborative effort among stakeholders to (1) create a blueprint which acknowledges and embraces the diversity of the supply chain; and (2) build a roadmap to adoption that supports and incents change from deeply embedded processes and SOPs from today.

To achieve the vision of a digital recalls network and gain some of the expected benefits from such a network does not require single “silver bullet”, big-bang approach but instead can be built incrementally upon a foundation of open, interoperable standards and shared collaboration among stakeholders across the supply chain. Such an incremental approach would build confidence in the direction and provide immediate value for stakeholders on this transformational process journey.

Pilot Workstream 2: Trace Histories

Introduction

The team focused on discussing and documenting a baseline understanding of the DSCSA 2023 product traceability information and business process ecosystem, starting with a deep understanding of how the pharmaceutical supply chain operates "as-is" today and examining the incremental and transformative changes which both new DSCSA 2023 regulations and evolving technologies may impose.

We consciously sought out for discussion some of the more difficult use cases and subjects associated with the reality of how the supply chain operates and what a product traceability network must support. Our report describes those discussions and captures the wide variety of viewpoints rather than limiting ourselves to "happy path" subjects where clear answers or consensus is simple.

Discussion throughout the pilot was technology agnostic, with the intent of looking at the entire ecosystem of systems, processes, information, and stakeholders that are used today and which may potentially be leveraged for 2023. This allowed us to explicitly explore and compare the pros and cons of potentially contentious issues such as whether blockchain-centric and non-blockchain approaches may be most relevant in a given business or operational situation. We believe we succeeded in this approach.

This business process focused and technology agnostic approach resulted in key learnings and takeaways from the pilot that have formed a framework for analyzing the strengths and weaknesses of any proposed electronic network model for DSCSA 2023. This litmus test will be valuable over the next four years regardless of the technical approach ultimately pursued by the industry.

Trace Histories – Goals, Objectives, and Methodology

Goals

The goal of this workstream was to evaluate the ability of supply chain members to gather transaction information upon request to efficiently establish a chain of custody, the associated system attributes (interoperability, scalability, flexibility, etc.) necessary, and the related environmental factors (such as governance and trust) that may be necessary to support the diversified U.S. pharma supply chain. To accomplish these analyses, we leveraged a solution developed by TraceLink that is based on distributed ledger technology (DLT), sometimes known as blockchain. This solution enables information exchange based on a novel "gather upon request" model that would work with existing serialization and traceability repositories owned and managed by individual stakeholders. Critically, this approach does not explicitly require participants to track the full chain of custody of all products at all times, embraces interoperability across diversified enterprise and business systems, and acknowledges the desire of stakeholders to manage and maintain control of their own confidential commercial data. The team also lightly explored additional patient safety and business opportunities based on full traceability.

Objectives

To meet our collective goal of assessing the supply chain's ability to meet 2023 transaction information gathering requirements, this workstream's objectives were to explore business processes and supporting technology that can address or provide real-world insights on the following issues:

- **Interoperability and Integration** – Learn what is going to be important to truly gain industry interoperability across different supply chain partners and multiple solution providers. Which network components are going to require industry standards? What special considerations are needed to ensure accessibility and adoption by smaller companies or those with lower technological capability? How heterogeneous do we believe this environment will be?
- **Data Management and Ownership** – What special considerations will be needed to ensure the secure creation on-demand of a chain of custody when core commercial and transactional information resides with each stakeholder rather than in a central repository? What happens when a firm merges or goes out of business and how can the industry and regulators ensure that trace data remains accessible and trusted? How can information requests reach the newly responsible party? How will the established chain of custody be impacted by M&A operations?
- **Business Processes and Change Management** – How are drug products managed today from production to dispensation across different business segments and archetypes, and how will that be impacted by mass adoption of serialized product identifiers and the requirements for traceability at the package level? What new SOPs and other preparation will be needed by companies in conjunction with the technical solutions that they may leverage and across what timelines would these preparations need to be started?
- **Technical Infrastructure** – What unique benefits and challenges may blockchain and distributed ledgers confer and what unique requirements will the usage of these technologies impose upon related serialization and traceability systems. What considerations are necessary for implementation and upkeep, timelines and costs, to ensure performance, scalability, and accessibility for all sizes and types of supply chain entities?
- **Identity Management** – How do we ensure network identity integrity and authorized trading partner status across compliance activities? How do we maintain and check for such credentialing over time? How do we prevent such participants from requesting or receiving information if they should not be permitted to do so?
- **Governance and Trust Models** – What trust models may be necessary and what governance activities may be required by the industry stakeholders given a DSCSA 2023 compliance ecosystem. What standards organizations, such as GS1, or governance organizations, such as the Partnership for DSCSA Governance (PDG), may be well positioned for some of these questions?

In addition to the group objectives focused on industry goals, individuals representing a diverse range of companies across the pharmaceutical supply chain engaged in the pilot process with a set of personal objectives surrounding their company and team preparedness for 2023, including:

- Gain a better understanding of DSCSA 2023 requirements and related business processes.
- Understand supply chain partner requirements, processes, challenges, and how participants can support their direct trade partners leading up to DSCSA 2023.
- Review how IT and technology can enable the integrity of the supply chain and support any new business processes that may be necessary.
- Uncover related serialization best practices and opportunities for standardization or improved interoperability across a broadly diverse and heterogeneous technology ecosystem.
- Highlight any areas in which value beyond compliance may be unlocked by meeting the new requirements, including how to leverage DSCSA solutions for business insights across the distribution landscape.

Methodology

Processes

Pilot participants explored and discussed numerous product trace request and response processes:

- Creating, responding to, and reporting on a product trace at different points in the supply chain.
- Recognizing trace data errors or data manipulation, and investigating and correcting such issues.
- Creating, storing, sharing, and using a network identity for trace request and response.
- Recognizing an illegitimate participant or identity and responding to such an event.
- Validating or rejecting trace requests from other networks dependent upon authorization.
- Responding to valid trace requests across multiple heterogeneous traceability networks.

Technology

TraceLink's Trace Histories solution was used throughout pilot discussions and workshop activities to illustrate and explore concepts associated with a product traceability network, including product traceability workflows, a wide range of product and data flow use cases, and trace rejection workflows and error handling. TraceLink developed a functional Trace Histories solution for use in the pilot program, so discussions and scenarios explored were interactive with real or simulated data, and the requirements on the underlying serialization and traceability solutions were designed to be agnostic to any one vendor's solution.

The Trace Histories solution utilized TraceLink's supply chain network infrastructure based on interoperable standards to gather DSCSA transaction information. Trace Histories is intended to enable information exchange for product traceability based on a "gather upon request" model that is designed to work with existing serialization and traceability repositories owned and managed by individual stakeholders. As described earlier, this solution approach, as opposed to alternative industry approaches for blockchain-based information sharing, does not explicitly require participants to track the full chain of custody of all products at all times, embraces interoperability across diversified enterprise and business systems, and acknowledges the desire of stakeholders to manage and maintain control of their own confidential commercial data. The Trace Histories solution approach uses

blockchain as a method to ensure data immutability and manage data permissions, while storing commercial transaction data off-block in the data owner's serialization and traceability systems. The cumulative transaction information resides with the supply chain entity who initiates the product trace request. Routing the trace based on serial number allows a complete trace without disclosing excess information on other products, possible product pathways, or supply chain participants. The team iterated upon the Trace Histories solution based on team feedback to support our discussions.

The presence of blockchain as a supporting technology in the Trace Histories solution allowed us to explicitly explore and compare the pros and cons of blockchain and non-blockchain approaches to DSCSA 2023 product traceability whenever relevant. However, much of the discussion throughout the pilot was technology or platform agnostic.

Analysis and Evaluation Methods

Throughout pilot discussions covering the objectives outlined above, our focus was on the following metrics when evaluating potential product traceability processes and supporting technologies:

- Capability to consistently execute a trace and gather transaction information in a timely manner.
- Difficulty of process or solution implementation, including assessment of alternative implementation pathways and/or models.
- Cost drivers of process or solution implementation as well as ongoing product trace activities.
- Level of collaboration and consensus within pilot, and estimate of required areas for industry collaboration or standardization.
- Any weaknesses or implementation challenges, either foreseen or discovered.

The pilot analysis and discussions took place across the 6 month period of the pilot, involving continuous conversations that incorporated more than a dozen team meetings and workshops.

Trace Histories – Results

This bottoms-up, foundational approach resulted in numerous learnings and takeaways to help form a framework for analyzing requirements, strengths and weaknesses of any electronic traceability model.

Framework for DSCSA 2023 Product Traceability Process and Solution Value Analysis

1. DSCSA 2023 Product Traceability Environment: Processes and Challenges
    a) Product and Data Flow Use Cases
    b) Operational Environment
2. Potential and Opportunities for a Product Traceability Network
    a) Relevant Areas for Interoperable Standards
    b) Network Architecture

This litmus test will be valuable over the next four years regardless of the selected technical approach.

The DSCSA 2023 Product Traceability Environment: Processes and Challenges

Pilot discussion of the DSCSA 2023 product traceability environment was shaped by the level of difficulty that is involved in understanding complex current processes, envisioning the way those processes may change over the next four years, and accounting for various understandings of regulatory requirements as well as the potential routes industry groups may take in the future. Numerous discussion templates were developed to help facilitate various operational environments and product and data flow use cases. Several of these templates are included where relevant.

The templates for operational environment and product and data flow use case discussion outlined below are living documents that were added to and evolved in practically every meeting over the course of the pilot. They are not intended to be exhaustive, but rather to illustrate the complexity of the supply chain landscape that must be accounted for in any discussion of a potential product traceability network. We have included a substantial part of this conversation and analysis to facilitate industry discussion and understanding of what that complexity means for each individual supply chain participant as well as the industry as a whole between now and 2023.

The dozens of permutations formed by combining operational environment and product or data flow use cases led to new insights about the challenges of designing and implementing a product traceability network, as well as informing our report recommendations and key questions for future exploration.

Operational Environment

Operational Environment Framework

Request Type	Scenarios	Triggers	Teams	Systems
• Regulatory Agency • Direct Trade Partner • Indirect Trade Partner	• Suspect product investigation • Other regulatory requests (RFI, DEA/Board of Pharmacy, etc.) • Recalls (as denoted in DSCSA) • Quality and packaging issues investigation	• Regulatory inquiry • Consumer complaint or inquiry • Dispenser complaint or inquiry • Trade Partner complaint or inquiry • Audit • Theft • Suspicious appearance or circumstances	• Quality • Product Security • Compliance • Supply Chain Ops • Legal	• Serialization • Traceability • Network Information Exchange • ASN/EPCIS repository • WMS • Quality • Case Management • Change Control • Line Management

This template was used to guide discussion about the types of business scenarios and operational environments in which a DSCSA 2023 product traceability process may occur.

Request Type – There was significant discussion in how a company's processes or a product traceability network may a respond to a primary request, when the product trace request is received directly from a Regulatory Authority, and a secondary request, when the supply chain participant receives the product trace request from a Direct or Indirect Trade Partner. This was seen as having a potential impact on responsibilities surrounding credentialing and authorization, timing, and data communication. In particular, the secondary request may be particularly challenging given credentialing requirements. In addition, there was vigorous discussion in trying to determine the potential scope of who may be an authorized Regulatory Authority. Besides the FDA, the DEA, state regulators, U.S. Marshalls Service, and other law enforcement entities were among the entities highlighted as potential parties who may potentially have the right to initiate a trace request.

Scenarios – Currently, Illegitimate Product Notifications occur with low enough frequency under existing DSCSA regulations that participants feel their current systems and processes perform well. The change in frequency under DSCSA 2023 was unclear. Suspect Product Investigations and related Quality Investigations are handled more regularly today with their own set of processes. Most investigations are completed within a single organization, while some extend to trade partners up or back along the supply chain, usually through phone or email.

It was noted that there are differing interpretations of the start and end points of a Suspect Product Investigation versus a Quality Investigation and this significantly affects the understanding of the responsibilities for conducting a product trace and the implications for trade partner and regulatory communication. Numerous reasons were unearthed why different companies have compelling reasons for their interpretation and no consensus was reached on a harmonized view. Another scenario that the pilot did not reach consensus on was the expectations surrounding the timing and circumstances of product trace requests in conjunction with a recall scenario as denoted in DSCSA 2023.

Additional scenarios were originally considered for inclusion in pilot discussion. Ultimately, cold chain scenarios were moved out of the pilot scope due to time constraints and to a process focus on 'custody' more than on 'ownership.' There was also some interest among participants to review 'upstream' traceability on APIs and materials, but this was ultimately left out of scope as a potential future topic.

Triggers – There was generally consensus on the types of triggers for a product trace process, based on the FDA suspect product guidance and industry discussions. One trigger that sparked some conversation was that of theft, with consideration of the challenges to trace initiation and routing, as well as whether gathering a transaction history would be of value in supporting a theft investigation.

Teams – Currently, Quality and Product Security teams typically take the lead in triage, escalation, and management of most investigations as they arise, based on SOPs. Emphasis on the number of internal teams and stakeholders involved in these processes was an area of consensus among participants. Any proposed product traceability network solution design would need to carefully consider each of the teams impacted, the processes followed by each, the data needed, and the interaction between teams.

Systems – As the pilot was business process focused, the types of systems that would be involved in product traceability in addition to a product traceability network of serialization and traceability systems was not exhaustively analyzed. But, consideration of the types of systems and their roles did influence the discussion on integration and interoperability covered in the next section of the report.

Other Considerations

Participants were generally satisfied with their systems and processes for DSCSA compliance and had pretty clear insights in how these systems may be called upon today in their businesses. But there was uncertainty in how DSCSA 2023 regulations may affect the frequency, timing, or expectations by regulatory authorities or trade partners whereby such systems may be called upon. Questions were identified surrounding future regulatory and industry interpretations of certain key DSCSA 2023 terms and definitions which will have a material impact on the business rules and operational functions. For example, regulatory interpretation of terms such as “promptly” and “electronic” frequently impacted discussion of product traceability solutions and business processes. The team dedicated time discussing regulations covering confidential trade information, as well as current understanding of the guidance timelines from FDA and their impact on a change management roadmap for 2023.

Finally, additional regulatory requirements not in DSCSA were identified which impact stakeholders across the pharmaceutical distribution supply chain. Requirements or guidelines by the FDA and other agencies in areas such as digital systems, data integrity, and more will need to be taken into account in the design of the processes and data management of an electronic trace histories approach.

Product and Data Flow Use Cases

Product and Data Flow Use Cases Framework

Core Scenarios	Decoupled Custody and Ownership	Resell / Repackage	Exempt or Special Scenarios	Other Situations
• Direct Purchase Distribution from Manufacturer • Secondary Wholesale Distribution • Loan/Borrow – Affiliate vs. Independent	• Drop Shipment • 340B • Consignment • Staging	• Manufacturer Reselling Finished Product from Another Manufacturer • Exclusive Distributor Reselling Finished Product from a Manufacturer • Wholesaler Direct Purchase from Repackager • Wholesaler Direct Purchase from Repackager and Resale	• Shipment to Health Organizations • Free Good Shipments/Samples – Direct to Physician • Donations • Patient Specific Rx • Public Emergencies	• Direct Shipment – Global Military Base (From US or from outside US) • Shipment to Territories (Puerto Rico, Guam, Marshall Islands, etc.) • Saleable and Non-Saleable Returns • Independent Broker or Clearinghouse (Secondary or Tertiary Market) • Aggregated Product Flows/Use Cases

This template was used to guide discussion about the various product and data flow use cases that a product traceability network would need to support. The pilot group felt the complexity of the supply chain, and the resulting flexibility a product traceability network would be required to have, was only fully appreciated after carefully considering in detail these product and data flows. This template was also considered as a checklist of use cases that an individual company should consider when reviewing their supply network and discussing DSCSA readiness with trade partners. Pilot discussion of these use cases also influenced the focus on cancel/correction workflows and error handling later in the pilot.

Core Scenarios – While most traditional supply chain analysis focuses on the Direct Purchase Distribution model from Manufacturer to Distributor to Dispenser, most of the complexity arose from the other common core scenarios. Secondary Distribution was highlighted as a particularly challenging area to address given the extensive number of supply chain stakeholders involved and the myriad of ways that they interact. Loan/Borrow transactions between hospitals and other pharmacy Dispensers was also highlighted as an area of great complexity once serialized product and unit-level traceability is introduced into this environment.

Decoupled Custody and Ownership – A request for a product trace may come to a supply chain participant who has custody of the product but is not the current owner. Two examples:

- *Drop Shipment* - the transfer of ownership is between the manufacturer and the dispenser, which parallels the Transaction Information flow, while the distributor participates in the financial transaction. For a product trace to be coordinated between the dispenser and the manufacturer, the dispenser needs to have processes and systems in place to access the transaction information. Today, often this access is provided by a URL printed on the packing slip linked to a portal with the data. Added complexity will arise if the dispenser who was involved in the financial transaction is acting as service provider to the dispenser. It is unclear to pilot participants if situations post 2023 will arise in which the distributor is directly contacted to provide a product trace, and if this does occur will need to be some process for them to access transaction information or forward the trace to the parties with access to that data as they do not have it today.
- *340B Products* – Today, the transaction history flows to the covered entity with ownership while the product flows to the contract pharmacy. This presents a great challenge if the contract pharmacy receives a trace history request by a regulatory authority when they do not have the DSCSA information. If the transaction information instead follows the product to the contract pharmacy, or the contract pharmacy can access transaction information through the distributor, this would enable gather upon request workflows. This issue will only get worse with DSCSA 2023 unit level traceability regulations. Most contract pharmacies do not segregate their 340B inventory from their other inventory, or may not know upon initial receipt whether or not a given shipment/product may end up being dispensed under a 340B program, both of which may create operational complexity when trying to respond to a trace request. A solution architecture that allows the responsible party to be notified about a pending trace request if they were not the recipient should be considered. More complex situations such as dropship of a 340B

product will also need to be considered, as will consignment product that may be designated 340B upon use.

Reselling / Repackage – Changes in the product form or identity, or changes in ownership across unique roles in the supply chain, present several interesting challenges in looking at how to perform a trace request across the supply chain, and how such a trace request may or may not directly follow across that change in for or identity.

- *Reselling Finished Product by Exclusive Distributor* – There was discussion of whether an exclusive distributor would be able to end a product trace request with themselves, or whether they would use the received TI from the original manufacturer to send the trace back a final step.

- *Repackaging* – Industry expectations for business processes related to tracing product history on repackaged serialized product as well as how a product traceability solution would need to support that data flow were discussed by the pilot team. This topic was not fully addressed in the pilot, but was seen as requiring additional research and potentially regulatory input.

The Potential and Opportunities for a Product Traceability Network

A traceability network that fully serves the U. S. pharmaceutical supply chain must have many key attributes. This includes support for the secure access, exchange, and vetting of identity, credentials, product data, and transactional information to enable efficient and effective traceability across a diverse set of stakeholders using a diverse set of technologies, which could potentially include a variety of blockchain and non-blockchain technologies. All of the above must be done at "operational speeds" to ensure that supply chain efficiency is not impacted and the medicine supply continues to flow unimpeded. A working assumption underlying pilot conversation was that interoperability would be necessary across a heterogeneous solution environment in 2023, and that the industry should work towards as much standardization as is achievable within that heterogeneous solution environment.

Below we share some of the pilot discussions concerning product traceability network issues related to identity management, data permissions and ownership, interoperability, and error handling.

Identity Management and Credentialing

The question of Identity "are you who you say you are" and Credentialing "do you have the right to make the ask or respond to a request" is an issue which has already driven significant discussion under DSCSA, particularly in looking at the saleable returns verification requirements. The following questions were outlined and discussed as areas in which the industry would need to form some measure of agreement in order to manage participant identities on a traceability network:

- Who has access to a Product Traceability Network?

- What regulatory authorities would have the right to initiate an inquiry and under what circumstances?
- What would a regulatory authority need to furnish as proof of identity?
- What would a direct trade partner need to furnish as proof of identity?
- What would an indirect trade partner need to furnish as proof of identity?
- What credentials would need to be produced by an identified party to either initiate or respond to a gather upon request?
- What of the above credentials would need to be visible to a direct trade partner? An indirect trade partner?
- Are there circumstances when a supply chain participant may desire not to respond directly to the requesting trade partner but instead may have reason to only work through the regulatory authority?

Discussion Takeaways:
Several possible identifiers were discussed for identifiers for participants in the supply chain, including GLN, DUNS, DEA, HIN, and State License Number. This diversity raised some interesting questions as to the potential scope of identifiers that a DSCSA 2023 infrastructure would need to manage. Several pilot participants involved with separate distributed identity initiatives added perspective on the potential for distributed or blockchain technologies to play a role in identity management. While technology can be flexible with identifiers used, without standard acceptable credentials within and across network solutions, there is the risk that a supply chain participant may receive a trace request from another participant they are uncomfortable with replying to, due to the type of credentials used to initiate the request. Some other current identity management issues the industry faces today formed part of the discussion, such as managing license expiry as part of the credential process for authorized trade partners. There was consensus that identity management would be a crucial part of a product traceability network, partially shaped by participant experience with Verification Router Services (VRS) during recent DSCSA phases.

Some scenarios for a traceability request have identifiers associated with them, such as an illegitimate product notification, or a Recall ID, which could be incorporated into a product trace request as proof of request validity, but other scenarios such as a suspect product investigation does not have such a clear event identifier. Thus the group was unable to reach consensus on what could be required as proof of valid reason for a traceability request. Another aspect of proving a product trace request valid that was discussed involved the possible role of proof of ownership as part of a product trace request. Although there was no consensus, some participants felt scanning would not be sufficient to prove ownership, and that other mechanisms for proving ownership will need to be considered. This led to discussion of a potential role for Transaction Statements in a product traceability network or as part of traceability business processes. No consensus or conclusions were reached and it was identified as a subject for possible future exploration.

In addition, the question of identity and credentialing of the regulatory authority was discussed. It is clear that further discussions are warranted with respect to whether a regulatory authority would have a clearly defined identifier and one that could be checked through machine methods. In addition, further exploration as to the scope of the potential regulatory authorities who may initiate a trace request is needed to help define if all authorities have the same credentials and data access or if there are degrees depending on the specific patient safety or legal situation which drives the trace request.

Data Permissions and Ownership

The following questions were outlined and discussed as areas in which the industry would need to form agreement in order to manage data permissions and ownership on a traceability network:

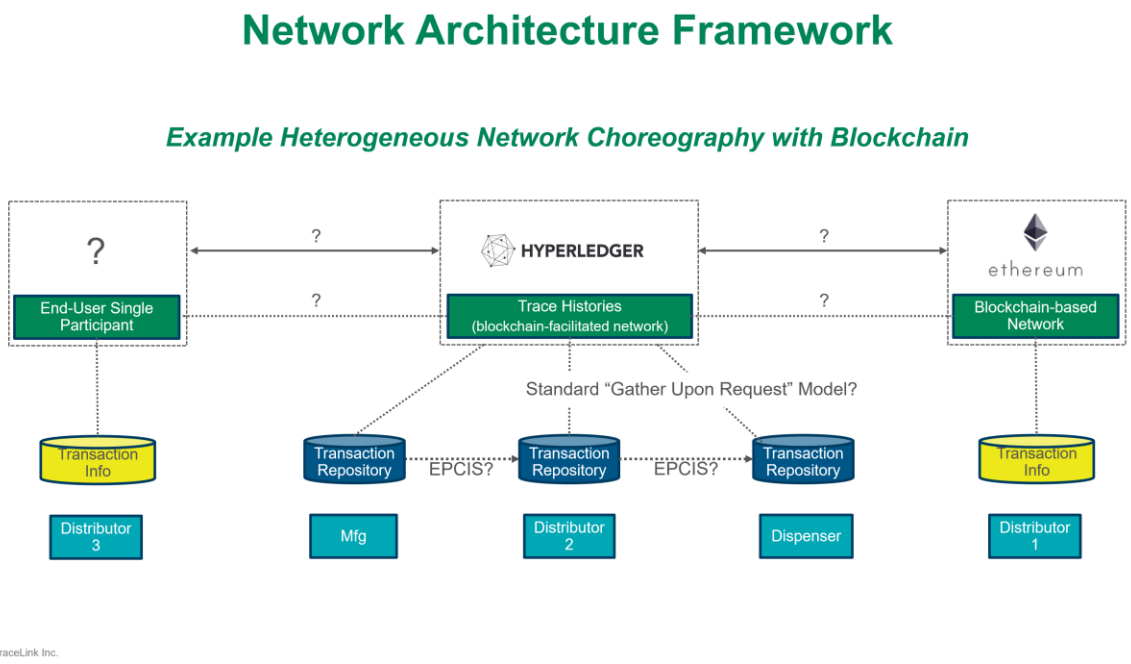
- What components of serialized transaction information would be visible to the regulatory authority? A direct trade partner? An indirect trade partner?
- In a blockchain-based or distributed solution, what components of serialized transaction information should be stored on-block, or off-block? What are the tradeoffs?
- How should a traceability solution preserve data control and ownership?
- What are expectations around wholesalers forwarding information to originating manufacturer, or terminating using received TI from the manufacturer?
- What role will reverse logistics partners play in a product trace, given they do not receive DSCSA information as part of the normal DSCSA compliance information flow?

Discussion Takeaways:

One strong area of consensus within the pilot group related to which components of serialized transaction information should be stored on-block, or off-block in a blockchain-based or distributed solution for product traceability. It was clear from the discussions of the strong desire to keep the serialized transaction information in the possession and control of the individual entities off-block in their own repositories. Several data security, data integrity, confidentiality, and operational efficiency reasons were raised for this view. The Trace Histories model was designed to test out this approach, whereby only the data necessary to identify parties and connect the separate serialized transaction information documents into a transaction history is stored on-block. The rest of the data is stored within network participant's existing serialization/traceability repositories.

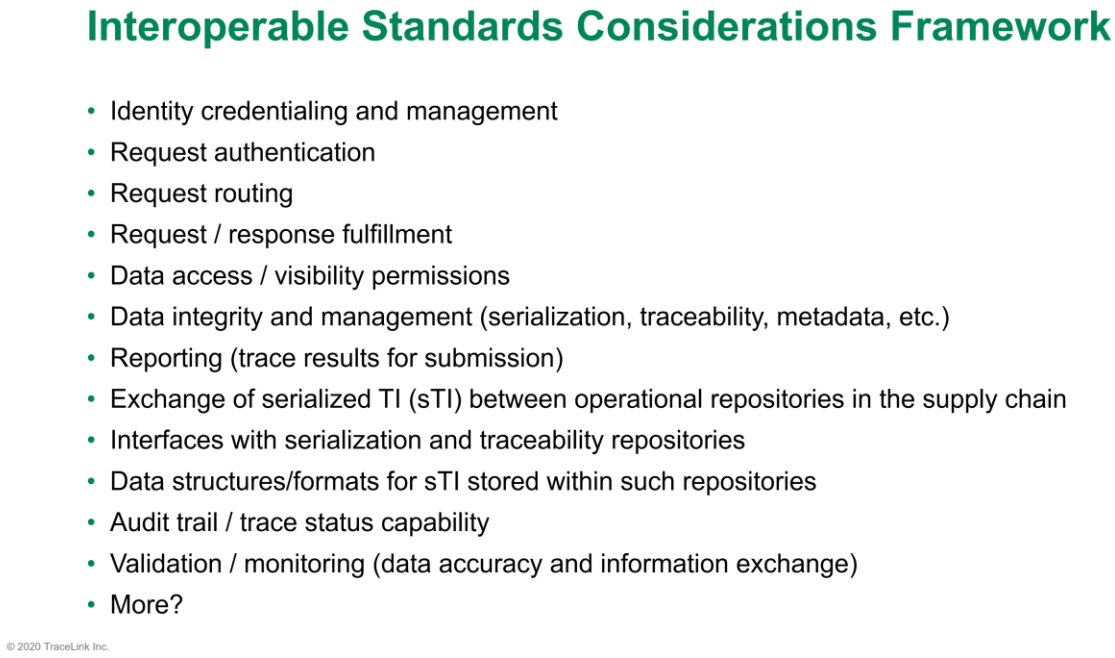
Pilot discussions focused almost solely on the data flow and sharing necessary for DSCSA compliance, and not additional data sharing use cases. However, there was reasonable consensus that participants would want functionality to add additional optional data to enable direct trade partners to assist each other with identifying and gathering the correct serialized transaction information, for example, purchase order information. This additional data would only be shared between direct trade partners in most cases, and data confidentiality must be preserved. So such systems would need to manage each participants opt-in or opt-out decisions across the chain, resolve conflicting decisions on data management, and provide secure, efficient opt-in functionality for participants to enable such "optional" data like this to be included in a core traceability network.

Interoperability – Network Architecture



This template was used to guide discussion about the types of interoperability necessary for a product traceability network to exist leveraging blockchain under the assumption that there will be a heterogeneous solution environment. The heterogeneity of the network in this framework also extended to the blockchain technology itself, as it is not believed that there will be adoption of a single, overarching blockchain technology by all participants in the pharmaceutical supply chain. This is not a recommendation or proposal for a product traceability network architecture nor is it an endorsement for any one foundational blockchain technology. Rather, it was used to help describe and test some of the areas within a traceability ecosystem where interoperable standards may need to be considered and it helped to identify some of the to-be-resolved interoperability requirements under such a framework if it were to be adopted across the supply chain.

Interoperability – Standards Considerations



This template was used to guide discussion about types of interoperable standards that would or may be necessary in order for a secure, efficient, and flexible product traceability network to exist within a heterogeneous solution environment. The discussion of potential interoperable standards was broadened to include those which may go through formal accredited standards body ratification and those which may become ipso-facto standards through common industry adoption and usage of industry guidelines or best practices. We believe that still more considerations may be uncovered.

Many of the interoperability areas above would be required for technological interoperability, some may be required for business process interoperability, and a few could be considered nice to have but not required. The pilot team did not try to reach formal agreement on categorizing each item by this criteria but it was felt more important to brainstorm the important areas for alignment and potential standardization in the future. There was consensus that each interoperable standard could encompass a variety of file or mapping or data storage formats, with standards for each one. Review of industry experiences across Manufacturer/CMO integrations for serialization was viewed as a valuable activity to gain lessons learned on integration and interoperability of unit-level identified medicines. Pilot participants representing both small manufacturers and small dispensers also requested future industry focus on the ability of smaller supply chain participants to comply with any proposed standards or guidelines.

Error Handling

Discussions within the pilot group on error handling covered two main workflows, one in which a product trace request contains an error and must be rejected, cancelled, or corrected in some way, and

one in which there is no prompt response to a trace request. Despite the shortage of consensus or clear answers available about system error handling, the group felt that initiating discussions on these scenarios at all was an important initial step, and that there should be future industry discussion focused on these workflows.

Trace Reject, Cancel, or Correct

It is expected that workflows surrounding rejecting, cancelling, or amending a trace could occur frequently, and should not be considered "corner cases" but assumed to be every day scenarios, such as a data mismatch due to quantity tolerances or unit quantity calculations based on case or pallet. There was consensus that a traceability network should not allow participants to "edit" a trace, but that modification desires could trigger a clearly audited cancellation and then correction of the trace information. Workflow discussion focused on how a traceability system could support communication and issue resolution even when a workflow required participants to initiate a manual process. For example, it was suggested that even if a follow-up phone call was needed, a traceability system could support the process by providing current contact information for the trace request recipient to reach out to the initiator.

Pilot participants generally agreed there would be value in having the network define standard trace reject and cancel/correct reasons, and suggested this be an additional area in which to consider interoperable standards. There was also some discussion of allowing participants to define custom definitions of reject and cancel/correct reasons, to be shared with the network as trace metadata. This discussion was partially informed by participant experience with Verification Router Services (VRS) during recent DSCSA phases.

There was also discussion of how to design a system which would facilitate data error resolution without giving away good data to a creator of a trace request containing a data error, as the data error itself could be considered a warning sign that the product involved could be suspect. It was determined that the recipient of a trace request containing a data error should request additional information in lieu of suggesting a corrected value for a specific field, and that a traceability solution be designed with the correct workflow in mind.

No Prompt Response to Trace Request

Within pilot discussion there was a lack of clarity on responsibilities following lack of response to a trace request sent over the traceability network. It was not clear what best course of action should be, and whether responsibility for following up would fall on the regulatory authority, the trade partner who was supposed to respond, or on the initiator. Finally, it was assumed that lack of response in certain instances could be due to a merger, acquisition, or even a company going out of business. There was no consensus on whether the network should play a proactive role in tracking such events, or whether it would be more of a reactive workflow, similar to any other trace request that does not receive a prompt response.

Trace Histories – Considerations and Recommendations

Additional Considerations for Future Exploration

The body of this report contains many discussion topics where the group did not reach consensus or suggested future exploration. Some additional key questions and considerations are highlighted below:

- What are realistic expectations for product trace timeliness and how might that be impacted across such a diverse set of product and transactional flows as exist across the supply chain?
- What are the expectations surrounding the timing and circumstances of product trace requests in conjunction with a recall scenario?
- How can the industry balance the desire to have single ways of doing things backed by strong, commonly adopted standards with the desire to allow for flexibility across the diversity of companies, organizational types, technical capabilities and legal interpretations? There was a lack of consensus on how to balance embracing a variety of acceptable standards with ease of integration, but some participants felt it was important to consider the cost involved in having multiple acceptable standards. It was suggested that either the FDA or a governance body such as PDG could have a role to play in working with the industry to outline guardrails.
- There was some discussion of DSCSA 2023 as requiring unique change management considerations as compared to previous DSCSA compliance deadlines. Some describes this as "business not as usual." It was felt that the change involved with serialization and unit-level traceability as underpinnings for DSCSA 2023 traceability will have greater impact on internal processes than previous deadlines and that not all impacts on operational processes and product supply are currently foreseen or understood. This impact on daily business operations should not be underestimated.

Recommendations

This report is not meant to serve as a specific proposal or blueprint for a product traceability network, but is intended to serve as an outline of the considerations in designing a product traceability network, and as a guide for industry collaboration over the next few years. Some final recommendations are listed below and it is our hope that these questions and ideas drive necessary, vigorous industry discussion among all industry stakeholders as well as regulatory authorities such as the FDA:

- It is hard to overstate how complex the business process and product and data flows are that a product traceability network will need to handle. Even pilot participants who have been engaged in this process for over a decade came away with new insights and challenges to address. The templates included in this report and the selected use cases offer an illustration of just a few examples of this complexity. Insufficient appreciation of this complexity has impacted other industry initiatives currently underway in the U.S., such as manufacturer/CMO integration, VRS, and lot-level verification, and is something that is seen in other markets such as Russia.
- There was consensus among pilot participants that there could be multiple technological approaches to DSCSA 2023. It became quite clear during our analysis of the overall complexity of

the pharma supply chain that there is a substantial amount of future learning and analysis which needs to be done to identify specific technologies and their roles in the overall DSCSA 2023 network architecture. While the results of our pilot neither prove nor disprove blockchain as a critical technology component supporting product traceability under the DSCSA 2023 guidelines, it became clear that the ability to expect or rely upon single technology or sole platform was extremely unlikely given the vast diversity of systems, processes, and stakeholders.

- It was clear that the industry will benefit from more insight and guidance from the FDA on clarification and definition of several key terms embodied in the DSCSA statute as they will have a significant material effect on the system and processes required. These included items such as definitions of what it means to "promptly" respond to a trace request and the circumstances whereby a recall could trigger a trace request.
- There was consensus that standards, processes, and systems for identity management and credentialing are essential to product traceability and digital, interoperable systems more generally. Further work on identity management and credentialing is a recommended next step for the industry. This includes evaluation of Decentralized Identifiers (DIDs) and Verifiable Credentials (VCs) which are W3C emerging or defined standards that promise potential for identity authentication, authorization and interoperability between supply chain actors.
- There are clear opportunities for regulatory agencies and independent organizations such as the Partnership for DSCSA Governance to continue work with the industry as a whole to endorse a common set of standards to be implemented in the areas discussed within this report.
- Finally, there should be additional focus on data integrity and workflows involving data mismatches, including a clearer understanding of how other FDA regulations in these areas relate to DSCSA requirements. Particularly those which require rejecting, cancelling, or amending a trace, as they could occur frequently. These should not be considered "corner cases" but assumed to be every day scenarios to manage.

The industry should view 2023 as an opportunity to apply lessons learned from initial DSCSA phases, including leveraging previous efforts as use cases in change management.

Pilot Project – Concluding Remarks

The pilot team believes that we covered substantial ground in review, analyzing, and preparing recommendations related to both the upcoming requirements related to DSCSA 2023 compliance as well as to the opportunity to enhance the pharmaceutical product recalls process in the supply chain. We hope that the insights, questions, and ideas embodied in this report lay the groundwork for further industry work in these two critical areas. The pilot team looks forward to the opportunity to further discuss these insights and findings with the FDA and other interested parties.

We would like to sincerely thank all of our pilot participants and their colleagues who so generously gave of their time and who so openly shared their thoughts and ideas throughout this pilot. This report and its findings would only be possible through the hard work and great insights of leaders like these companies and individuals.

We would like to thank the TraceLink pilot team members for their diligent work in driving such challenging and complicated discussions in collaboration with our industry leaders. In particular, we would like to thank Shweta Agarwal, Amanda Bettman, Ray Carvill, John Jacey, and Elizabeth Bernick for all of their research and support throughout the pilot study.

Finally, we would like to thank the FDA for the support we received throughout the pilot and for the opportunity to share our questions, insights, and ideas on these critical issues.

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