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Open Session

Other Pilot Activities

Speaker	Pilot Project
Center for Supply Chain Studies Robert Celeste	Authorized Trading Partner
LSPedia Michael Ventura	Investigator Pilot (for verification and verification exceptions management)

(NOTE: Some projects involve partnering entities that are not listed in the table.)

FDA DSCSA PILOT PROJECT PROGRAM AND ENHANCED DRUG DISTRIBUTION SECURITY

CREDENTIALIZED DSCSA ATP PILOT

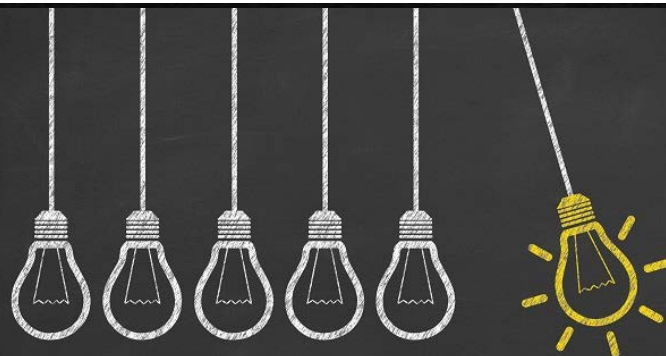
December 8, 2020

DSCSA

Trust

Digital

Framework



Agenda

- Introductions
- Key Objectives
- Key Outcomes
- Next Steps
- The Pilot

ATP Pilot

Participants

Types of participants

Regulatory Compliance
Wholesale Operations
Manufacturer Operations
Issuer Operations
Systems Validation
Information Technology
Manufacturer,
Wholesaler,
Dispenser,
VRS Provider,
Credential Issuer,
Wallet Provider

Trading Partner Participants:

- AmerisourceBergen
- Bristol-Myers Squibb
- Johnson & Johnson
- Novartis / Sandoz

Trade Association:

- HDA

Standards:

- GS1

Trading Partner Observers:

- AbbVie
- Atlantic Biologicals
- Endo Pharmaceuticals
- Fresenius-Kabi
- Gilead
- Lilly
- Merck
- Par Pharmaceuticals
- Kaiser Permanente

Solution Provider Participants:

- Credential Issuer
 - Legisym
- VRS Providers
 - rfxcel
 - SAP
- Wallet Providers
 - Spherity

Problem Statement / Pilot Overview

The DSCSA requires trading partners of a manufacturer, repackager, wholesale distributor and dispenser, may only be authorized trading partners.

These transactions are managed in a digital world and ATP must also be managed in a digital world.

The HDA Verification Router Service (VRS) project presented an opportunity to digitally ensure that the ATP requirement is met.

Working with SAP, Legisym, Spherity, HDA and industry partners, we identified a method, designed and piloted successfully using wallet credentials from trustworthy sources that meet DSCSA ATP definitions and assure participants in the system are Authorized Trading Partners.

This system meets the DSCSA ATP requirements between partners including:

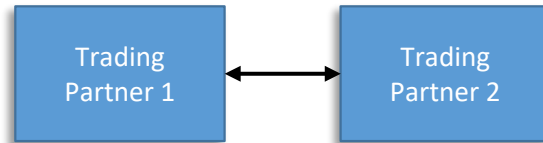
- automation,
- efficiency, and
- accuracy

Our next steps are to develop system standards and assure interoperability so this digital services model can be used by the supply chain and partners to assure full compliance.

Opportunity

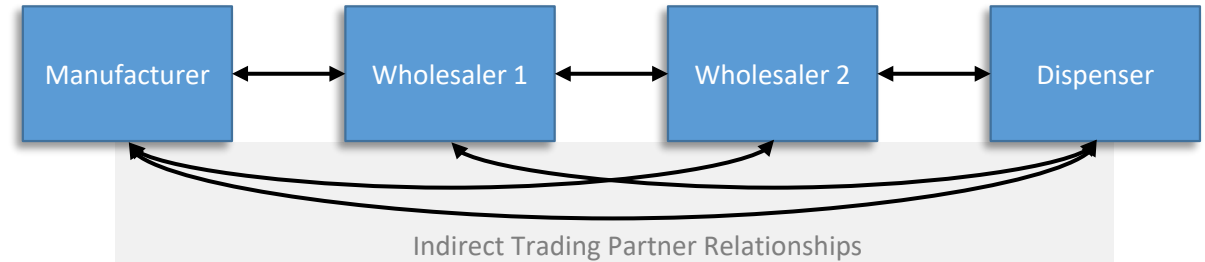
Determining DSCSA Authorized Trading Partner Status for PI Verification

Traditional “Trading Partner” Relationship

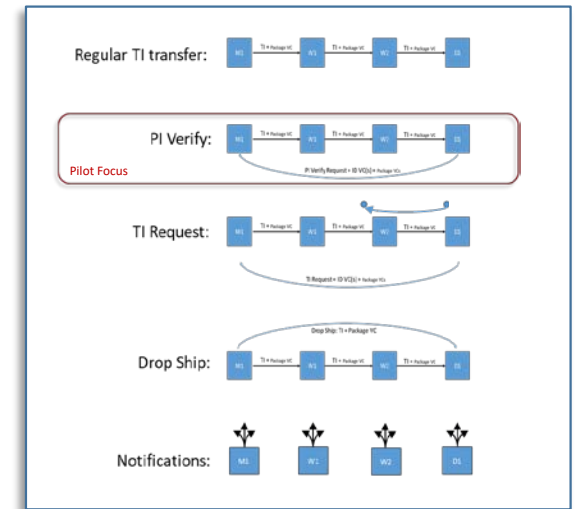


1. Due Diligence (Days?)
2. Individual Digital Connection (i.e. AS2)

“Trading Partner” Relationships Driven by DSCSA



1. Due Diligence (< 1sec)
2. Networked Digital Connections (i.e. VRS, API)
3. Indirect Trading Partner Relationship (< 1sec)



Key Objectives

- ✓ Demonstrate the use of W3C standard Decentralized Identifiers and Verifiable Credentials to prove DSCSA ATP status of both trading partners involved in Verification of Product Information
- ✓ Identify workable credentials
- ✓ Establish a workable credential issuing process and due diligence.
- ✓ Prove the auditability of the eco-system for investigations.
- ✓ Demonstrate real-time PI Verifications and failures due to license or identity issues.
- ✓ Remain within the industry established performance requirement for PI Verification (< 1sec)
- ✓ Consider other DSCSA use cases
- ✓ Identify industry governance requirements
- ✓ Identify standardization opportunities

Key Outcomes

A sample of team member comments

DSCSA Compliance

"A cross functional team realized there was a compliance issue with digital systems and assuring an Authorized trading partner (ATP.) is using the digital system. The credentialing process is the first proven industry digital process that addresses ATP compliance gap of knowing if the company is an Authorized Trading partner per DSCSA requirements using the system This is a foundation for 2023"

... Dave Mason, Novartis Supply Chain Compliance and Serialization

Inspection Readiness

"Assurance that the the FDA's Data Integrity compliance indicators and the DEA Standards for Electronic Transmissions (Authentication, Nonrepudiation and Message Integrity) are incorporated in this solution."

... Sharon Webster, Novartis Pharmaceutical, AD Market Product Quality

Technical Requirements

"As a VRS solution provider, all we had to do was a simple API-call to the wallet to retrieve or verify credentials and some small changes to handle the response from the wallet. All in all, this technology allows to implemented the ATP check to the existing – and established – processes without disruption."

... Oliver Nuernberg, Chief Product Owner, SAP Life Sciences

"Including the ATP credential in the message to secure the network is a good idea. The upfront due diligence by the issuer in creating the credentials would be important to the archive/audit trail that was piloted. This solution would need broad adoption."

... Rosemary Hampton, J&J Information Technology

"The ATP pilot is the most comprehensive effort to address the upcoming Authorized Trading Partner requirement for DSCSA. rfxcel was impressed to see how seamlessly it integrated with our solution. All participants work well together and rfxcel is excited to see this adopted by other solution providers and the industry."

... Herb Wong, VP Marketing & Strategic Initiatives, rfxcel

Interoperability

"The piloted solution requires no change in GS1 Light Weight Messaging Standard currently used for PI Verification. The team intends to submit Application Programmer Interface (API) and credential schema designs to GS1 US for Standardization or Guidance inclusion."

... Bob Celeste, Founder, Center for Supply Chain Studies

Adoption

"The team is producing a Roadmap for Adoption and has established the necessary facilities to move to production in the next phases."

... Bob Celeste, Founder, Center for Supply Chain Studies

Key Outcomes

Ready for production

- ATP Pilot end to end User Journey
- ATP Pilot – Architecture Handbook
- API Documentation
- ATP Credentialing Audit Analysis
- ATP Security Analysis
- Identity Credential Schema
- ATP Credential Schema
- ATP Pilot Explainer Video
- ATP Pilot Click-Through Demo
- ATP Pilot Report

Socialization and Adoption

Next Steps

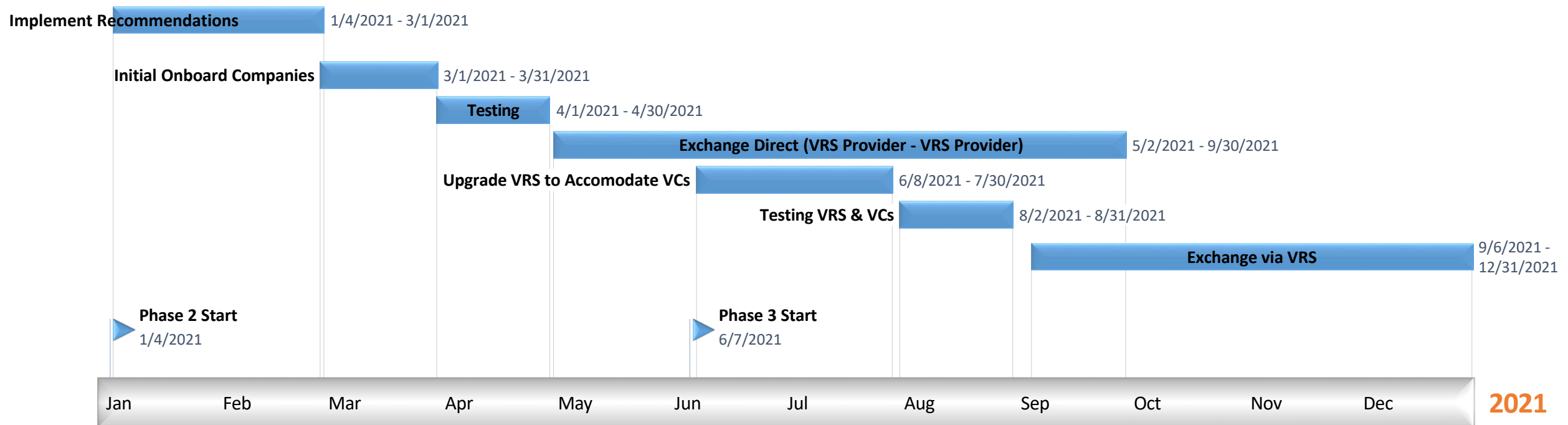
Next Steps: ATP Credential Roadmap

Pre-Production

- Phase 1 – Socialization & Acceptance
- Phase 2 – PI Verification (wholesaler – manufacturer, No Routing)
- Phase 3 – PI Verification (wholesaler – manufacturer, Routing)
- Phase 4 – PI Verification (dispenser – manufacturer)
- Phase 5 – TI Request (Trace)
- Phase 6 – Additional DSCSA use cases

Phase II & III Roadmap

Production: Direct and VRS enabled exchange of VCs

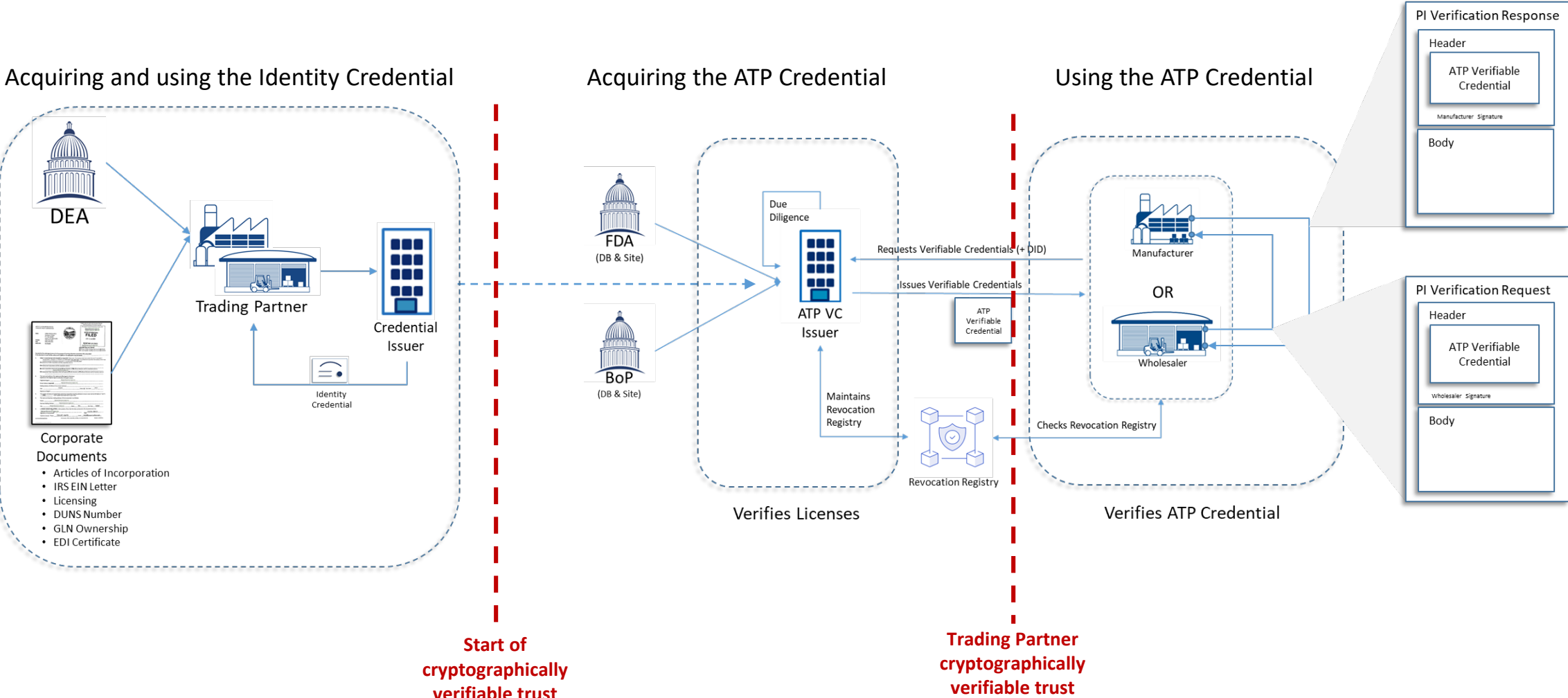


Due Diligence, Process, Technology

Pilot Solution Overview

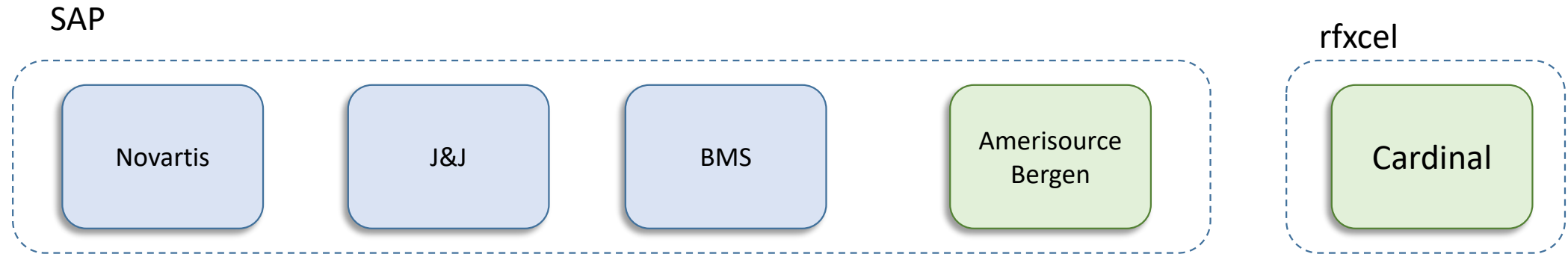
Process Overview

The establishment of verifiable trust between adjacent and non-adjacent trading partners



DSCSA ATP Pilot

Product Information Verification for Saleable Returns – Capabilities tested



Onboarding & Maintenance

- 1. Identity Wallet Acquisition & Initialization
- 2. Identity Credential Acquisition
- 3. ATP Credential Acquisition
- 4. Identity Credential Revocation
- 5. ATP Credential Revocation

PI Verification: DID, Verifiable Credential Usage

- 1. PI Verification – Success
- 2. PI Verification – Wholesaler: Credential Failures
- 3. PI Verification – Manufacturer: Credential Failures
- 4. PI Verification – Wholesaler: Revoked Credential
- 5. PI Verification – Manufacturer: Revoked Credential

Auditing & Investigations

- 1. Audit: Onboarding Information Availability Walkthrough
- 2. Audit: PI Verification Information Availability Walkthrough
- 3. Investigation: Wholesaler Initiated
- 4. Investigation: Manufacturer Initiated

Contact Information

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<https://www.c4scs.org/atp-pilot>

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An industry pilot of a DSCSA Authorized Trading Partner Credentialing ecosystem to support existing Product Information Verification scenarios for DSCSA saleable returns requirements. *The DSCSA ATP Pilot*




Explainer Video: Establishing Authorized Trading Partner status for Saleable Returns.

This short video explains the value of and how Verifiable Credentials are used to establish DSCSA Authorized Trading Partner status in the Saleable Returns process.



Demo: Step through the onboarding process.

This demonstration walks you through the process of acquiring a Company Identification Verifiable Credential, acquiring a DSCSA ATP Credential and communicating your Decentralized Identifier to your VRS provider.




Certified Issuers of DSCSA Identity and DSCSA Authorized Trading Partner Verifiable Credentials.

Legisym, LLC

- Contact: Sales and Onboarding
- 254.933.4452 option 3
- info@Legisym.com
- DID: did:ethr:spherity:testnet:0xb22d82c0e0ed58a018b67bdc6bcd0d10ca9f8ba7

DSCSA Identity and ATP Credentials



Certified Identity Wallets

Spherity

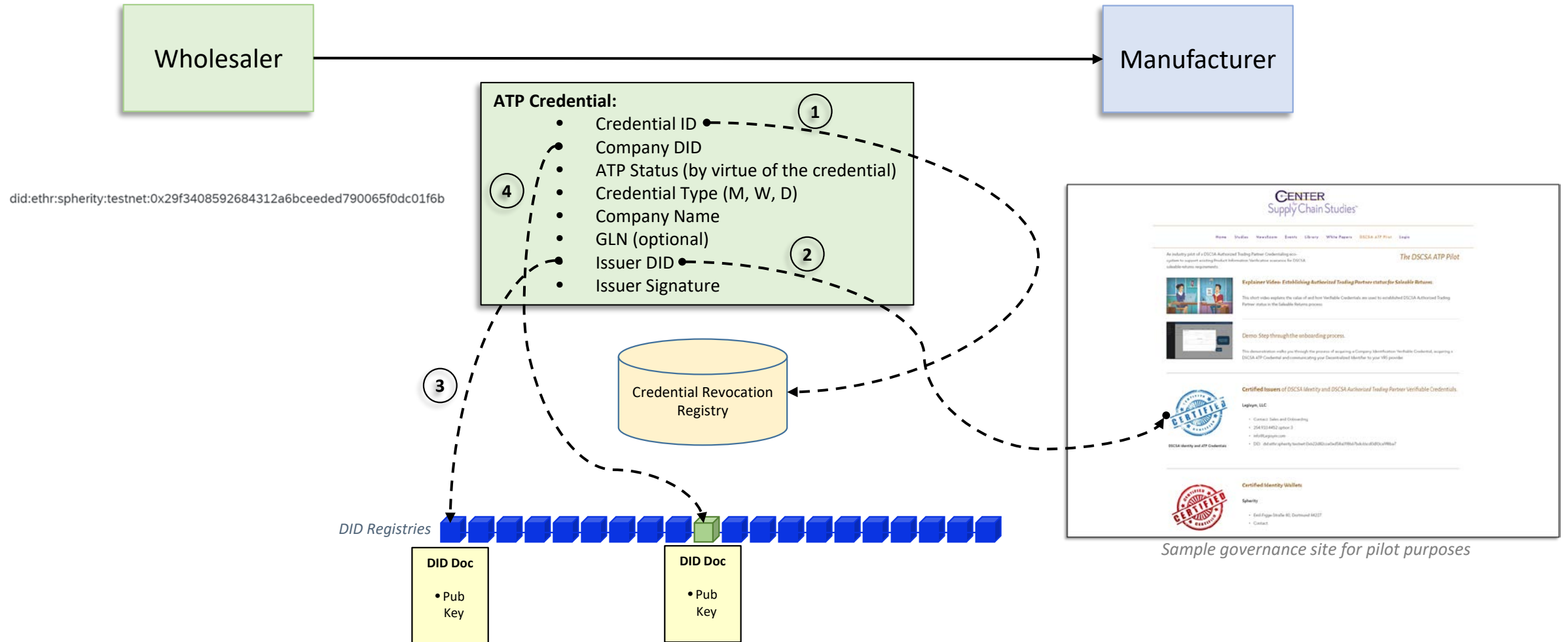
- Emil-Figge-Straße 80, Dortmund 44227
- Contact:

Determining DSCSA Authorized Trading Partner Status for PI Verification

Additional Material

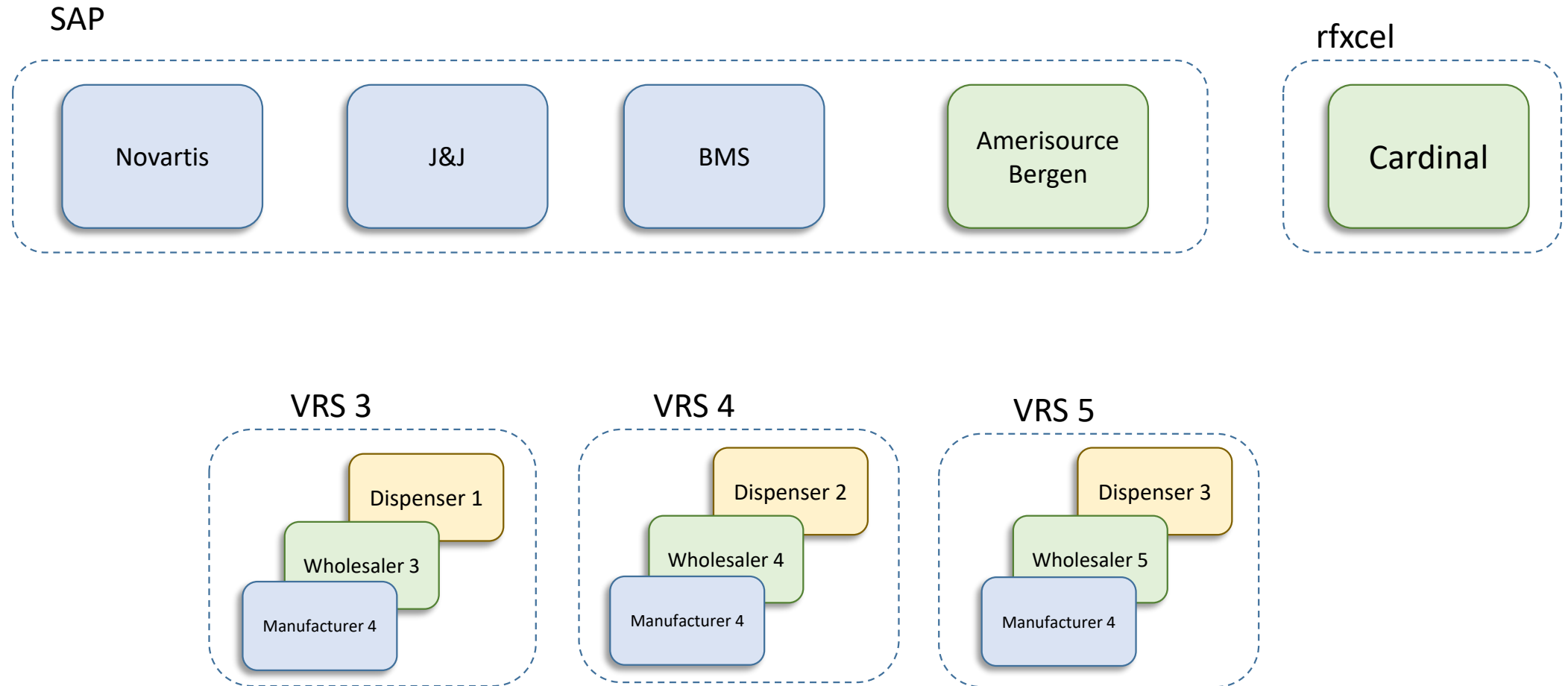
Technical Components

How they support verifiability between adjacent and non-adjacent trading partners



DSCSA ATP Pilot

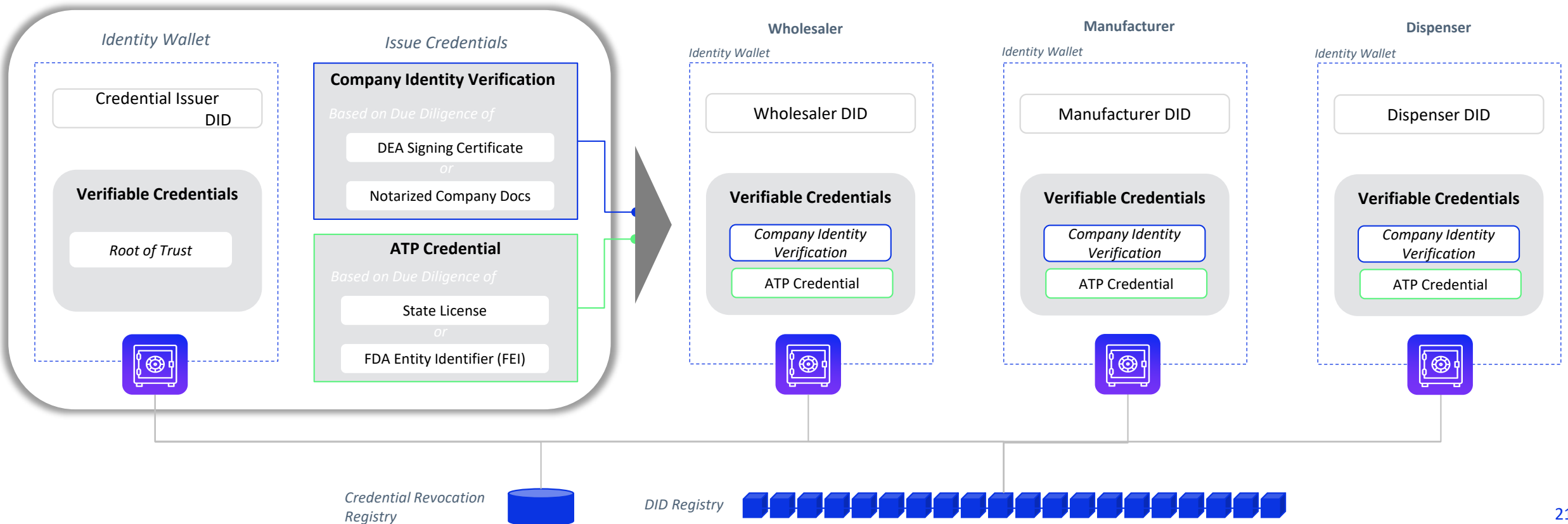
Potential for added tests before Pilot environment is dismantled



Trading Partners use Identity Wallets to manage Verifiable Credentials that are issued by trusted credential issuers

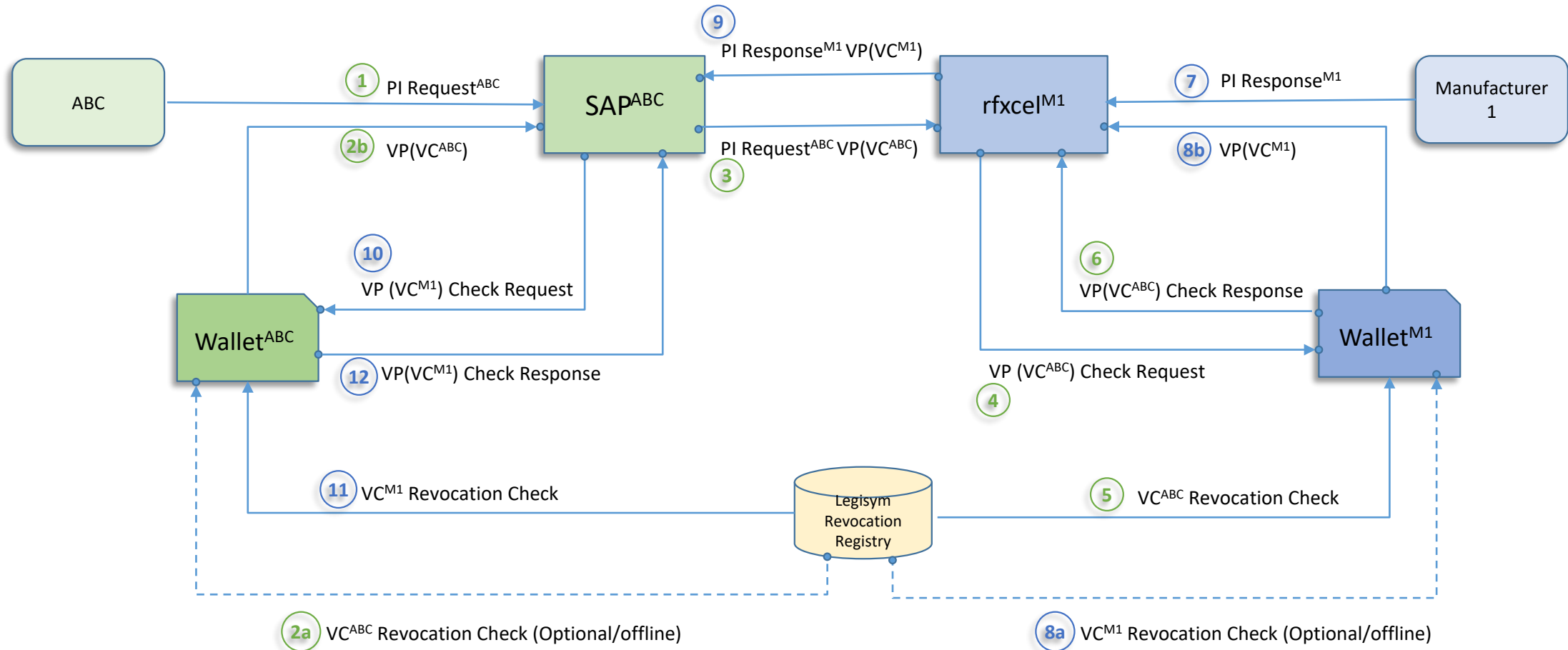
Identity Verification Provider

Trading Partner



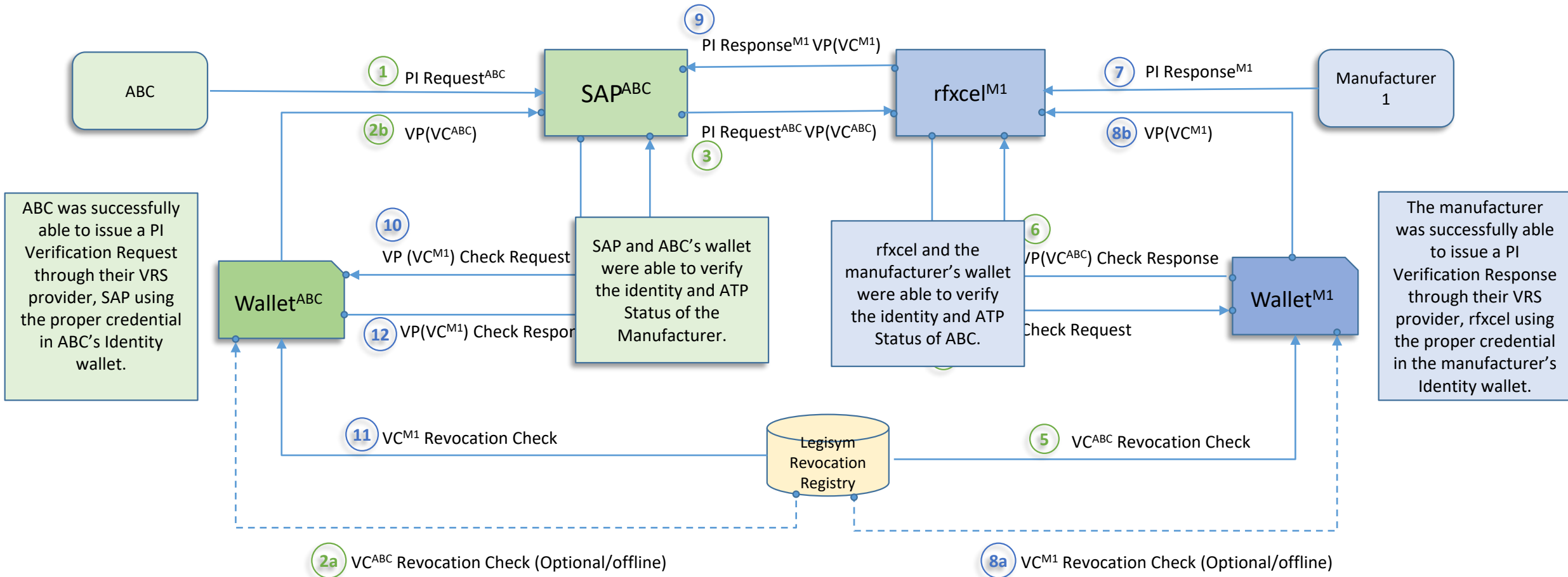
Sample Scenario Executed

Successful PI Request/Response



Sample Scenario Executed

Successful PI Request/Response

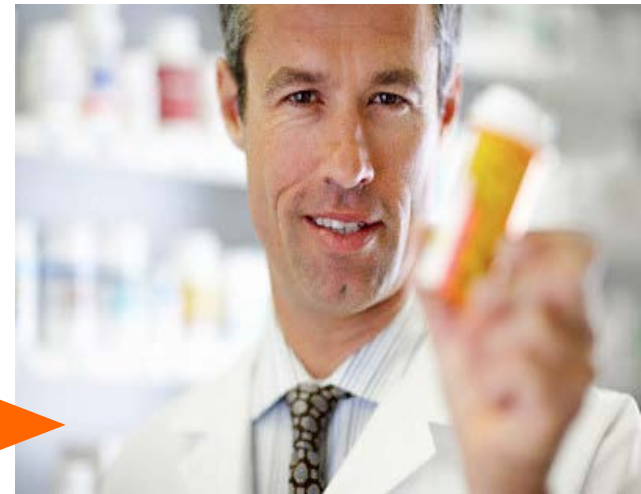


FDA DSCSA Public Meeting – Investigator Pilot Readout



Michael Ventura

December 2020



Investigator Pilot Champions – Thank you!



Matt Sample
VP Manufacturer Operations
AmerisourceBergen



Kelly Lacy
Product Owner Manufacturer Operations
AmerisourceBergen

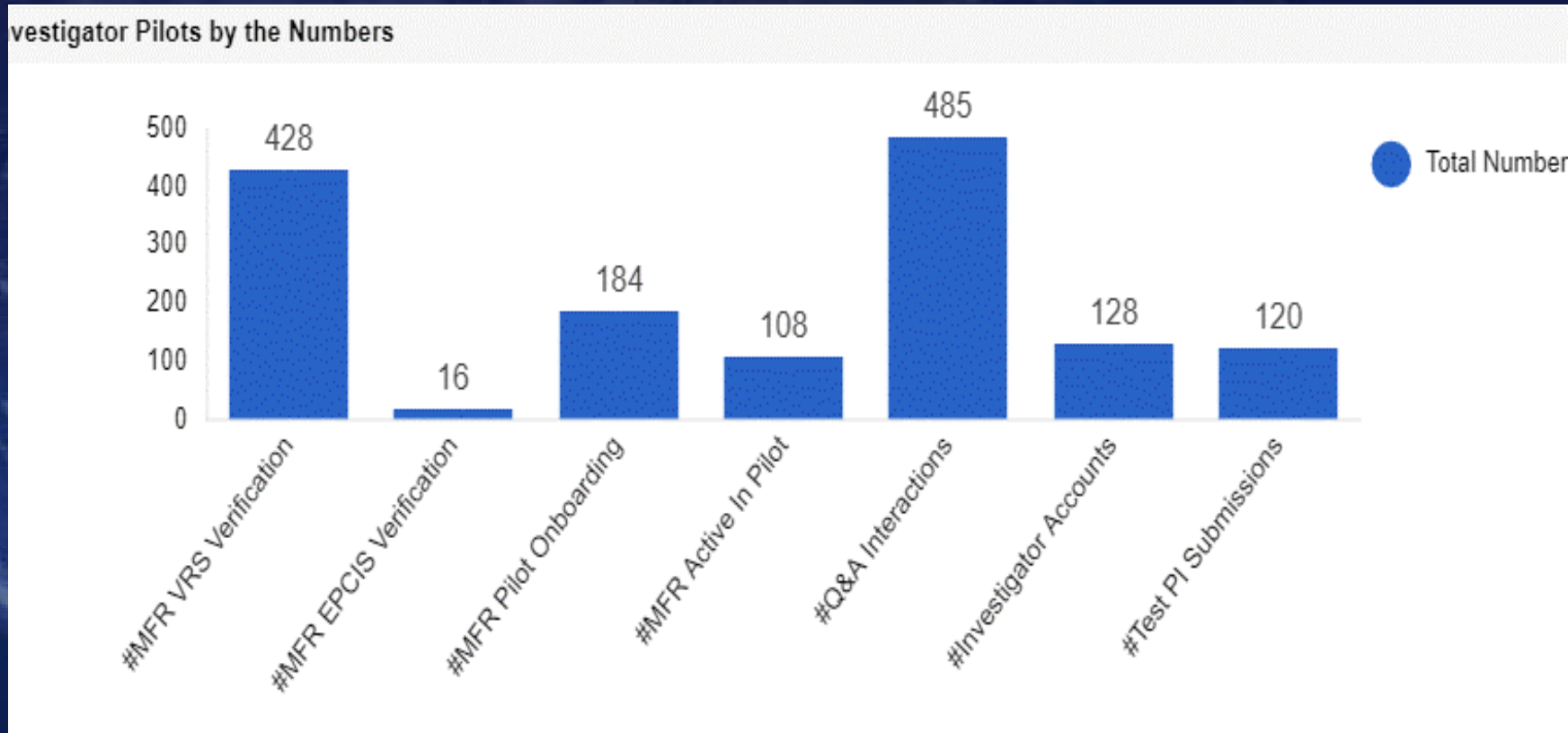


Brad Pine
Adm. VP, Brand Rx & Regulatory
Smith Drug Company



Pam Clements
General Manager/Director of Operations
Smith Drug Company

Investigator Pilot – By the Numbers



Challenges of False Negatives

- Inability to verify and rescue viable product
- Risk of supply chain continuity
- Shortages for patients
- Unable to identify, quarantine, investigate
- Failed FDA reporting for illegitimate products (3911)



AmerisourceBergen

- 57,000 daily returns
- 16,000 daily negatives
- No shelf space



Smith Drug Company

- 1,731 daily returns
- 260 daily negatives
- No shelf space

Pilot Process and Achievement

- Bi-weekly open offices
- Collaboration with 118 manufacturers
- Established and proposed:
 - SOP's
 - Policy
 - Functional requirements
- Effort defined via collaborative discussion and debate – *never a dull moment!*

LD records
before Pilot
19,004



LD records
after Pilot
47,270



OneScan



Enhanced Issue Tracking

The increasing amount of investigations, fueled by rising cargo theft and high-volume negative verifications, challenge the industry's capability to mitigate the functional impacts as well as regulatory requirements. Manufacturer, wholesaler, retail pharmacy need enhanced issue tracking system to identify, investigate, and reporting suspect products. Architected with corporate data security and built with new technologies, process flows, and collaborative workspace, LSPediA's enhanced issue tracking system, OneScanInvestigator, enables a scalable and sustainable approach to meet and succeed the FDA's compliance requirement and customers' business requirement.

OneScan Investigator

Investigator provides an effective DSCSA workflow to manage suspect product investigation and legitimate drug product notification. Upon receiving a product notification, Investigator enables manufacturer to create an investigation therefore putting good product back to inventory or conduct suspect legitimate product investigation with in-app email and camera. Built with FDA compliance 3911 workflow, Investigator facilitates and keeps full investigation and 3911 reporting history.



140

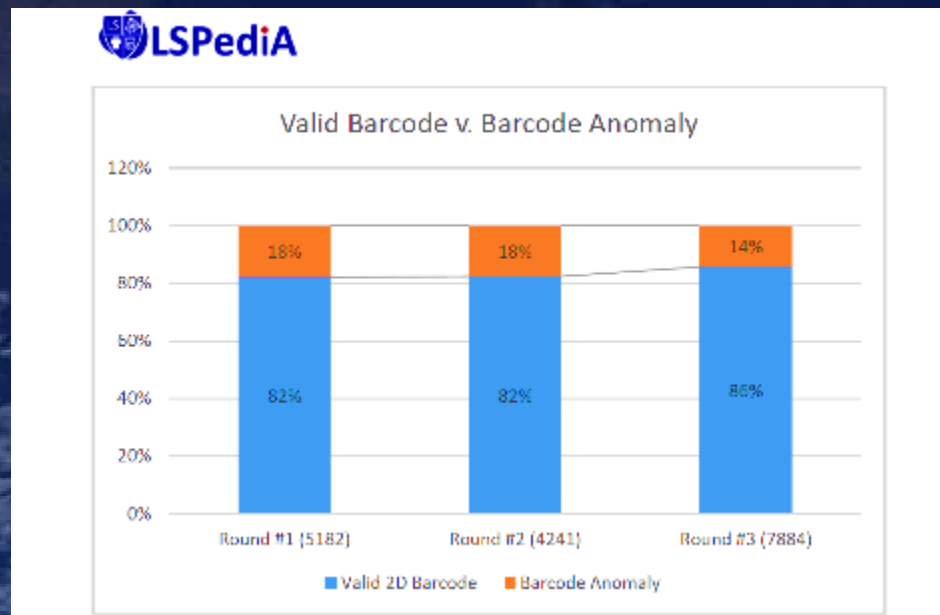
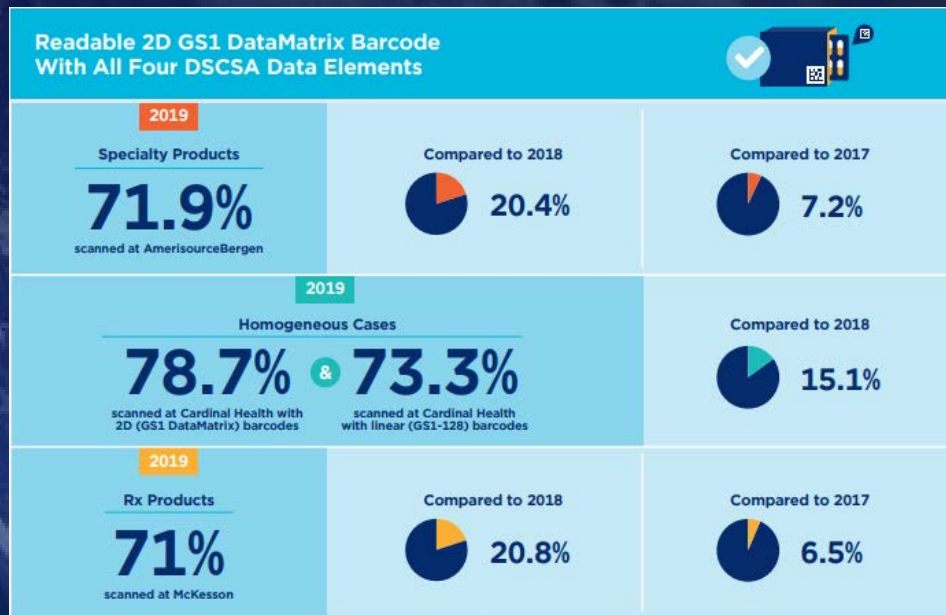
Requestors

109

Responders

GS1 2019 Barcode Study

LSP FDA DSCSDA Pilot



1 of 7 packages has barcode issues

How Investigator Facilitates Response

VRS

Access Look-up Directory to route verification request

Positive Verification allows restocking

Negative Verification points to Investigator

Investigator

Identification of Root Cause of Failed Verification

Automated Email Notification

False Negatives cleared by clicking the link and restocked (99%+ of volume)

True Negatives Quarantined and escalated to Manual Investigation

Manual Investigation

Wholesaler engages manufacturer in manual investigation in accordance with agreed and established SOP's

False Negatives cleared and restocked

True Negatives dispositioned in accordance with agreed and established SOP's (inclusive of FDA 3911)

Why Investigator

- **Infrastructure and process**
 - Manage volume (*Commercial Business Value*)
 - Manage risk (*Regulatory Compliance*)
 - Manage cargo theft (*Product Security*)
- **Supplier collaboration**
 - Shared workspace
 - Supplier self service
 - Automated workflow
 - Audit trail for all partners
- **Compliance and beyond compliance**
 - Turnkey FDA compliance
 - No phone calls
 - No need to “staff up”
 - Reduce waste



Controlled Tests Before Go-live

7 GS1 scenarios

Integration with
VRS / EPCIS

Automate
notifications at
point of initial scan

Facilitate the
automated
workflow with
suppliers

Leverage
investigator to
identify root cause

Track all negatives
by single-source-
of-truth in
Investigator

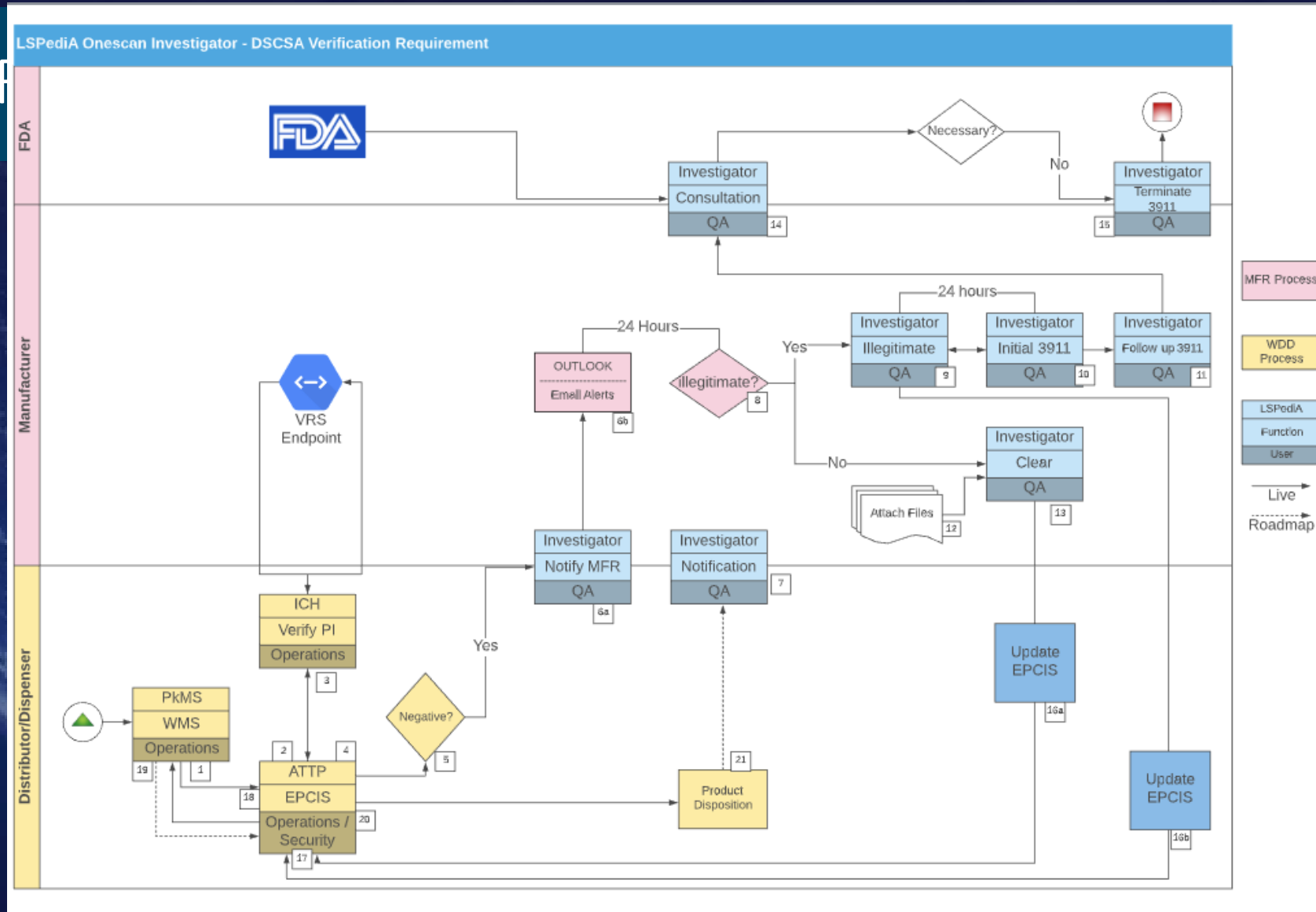
Restock and
disposition process

Escalation process

Responsibilities
and SOP
development

The Investigator Pilot - Verification Process

Process Flow



Restock



Disposition



DSCSA@lspedia.com

