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# DSCSA Pilot Project Program

## Participant Results (3)

| Program Participant/Speaker<br>*(All partnering entities are not listed)* | Pilot Project |
|---|---|
| Rymedi<br>Jason Cross | DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers |
| KitCheck<br>Tim Kress-Spatz | Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies |
| IBM/KPMG/Merck/Walmart<br>Mark Treshock | DSCSA Blockchain interoperability Pilot |
| IDLogiq<br>Kelly Nguyen | IDLogiq Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment |
| LSPediA<br>Riya Cao | Router Service Solution for Verification/Notification and Interoperability 2023 |

**We will have a Participant Panel Q&A after the above presentations.**

Rymedi

# FDA DSCSA Pilot Presentation

December 2020

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# FDA DSCSA Pilot: Rymedi Consortium

## Tracking Healthcare System Specialty Medicine Transfers: Integrating Quality Management Systems & Real-World Evidence

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# Key Objectives

## Assess High-Visibility Process Tracking Technology Deployment

Blockchain, IoT, AI-integrated process and data compliant architecture

Advanced temperature monitoring sensor integration

Simple, mobile-based UX and labeling systems

Legacy IT system integration

Supply and clinical workflow coordination

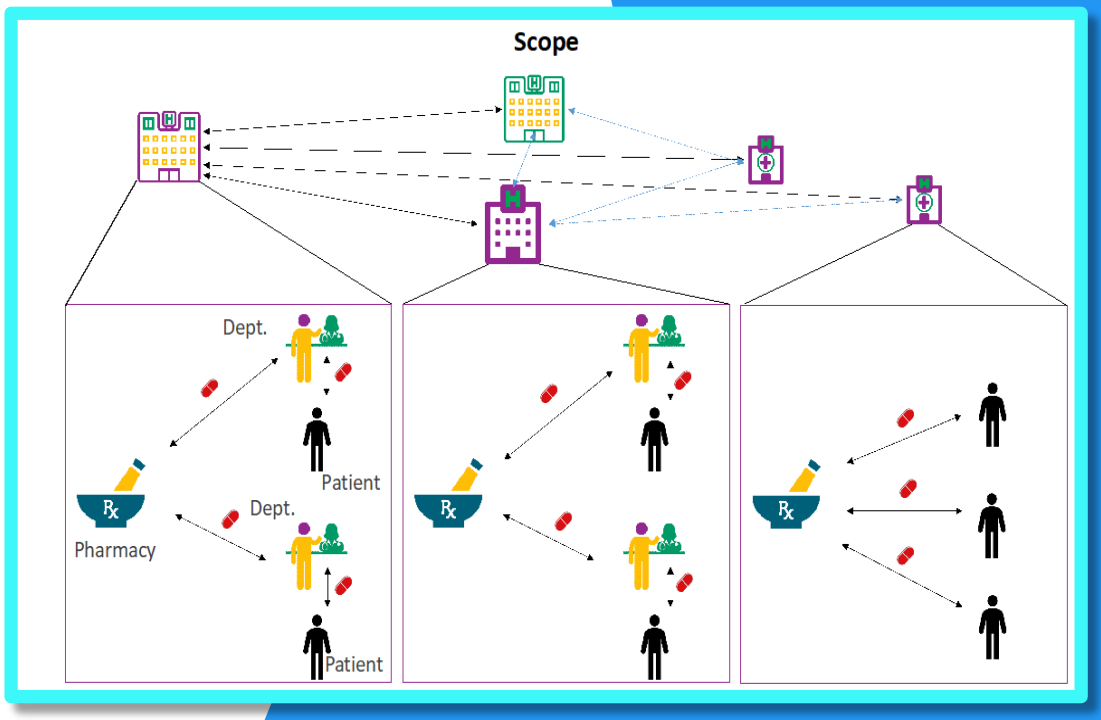
## Evaluate Adoption Feasibility and Supplemental Value Propositions

Clinical care workflow enhancement

Operations and administration efficiency improvement and risk reduction

Standard-of-care and R&D Real-World Evidence insights

Trading partner Real-World Evidence and operations insights

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# Key Outcomes

## Promise of QMS-RWE Integration for Learning Health Systems

Improved quality control for more sensitive medications

Operational efficiency improvements and risk reduction

Agile standards compliance and data-driven evolution

Standard-of-care and R&D analytics

Clinical trial streamlining and regulatory approval acceleration

## Challenges in Adoption of Quality Tracking to Patient Use

Workflow integration

Interoperability

Business case definition

Administrative and organizational structure and responsibilities

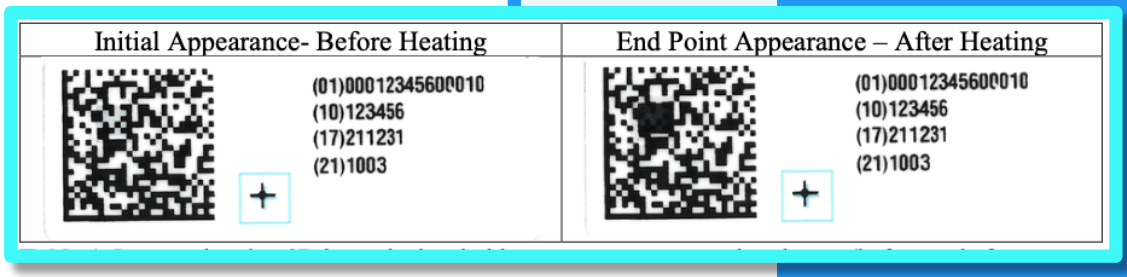

**Opidivo**

**Keytruda**

**Zarxio**

**Curosurf**

**Retacrit**

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# Key Conclusions & Recommendations

## Value-Driven Stepwise Change Management for Medication Manufacturers and Trading Partners

Business case for secondary approval acceleration for in-market medicines

Treatment divisions leveraging companion digital therapeutics

Existing research site partners at leading edge of digital integration

## Ease of Permissions Management & Data Rights Standards

HIPAA, GDPR and Research Subjects Protections standard compliance architecture ecosystem

Patient data rights management standards coordination

Simplified e-consents and multi-factor authentications

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# It takes an ecosystem…. Feel free to reach out!

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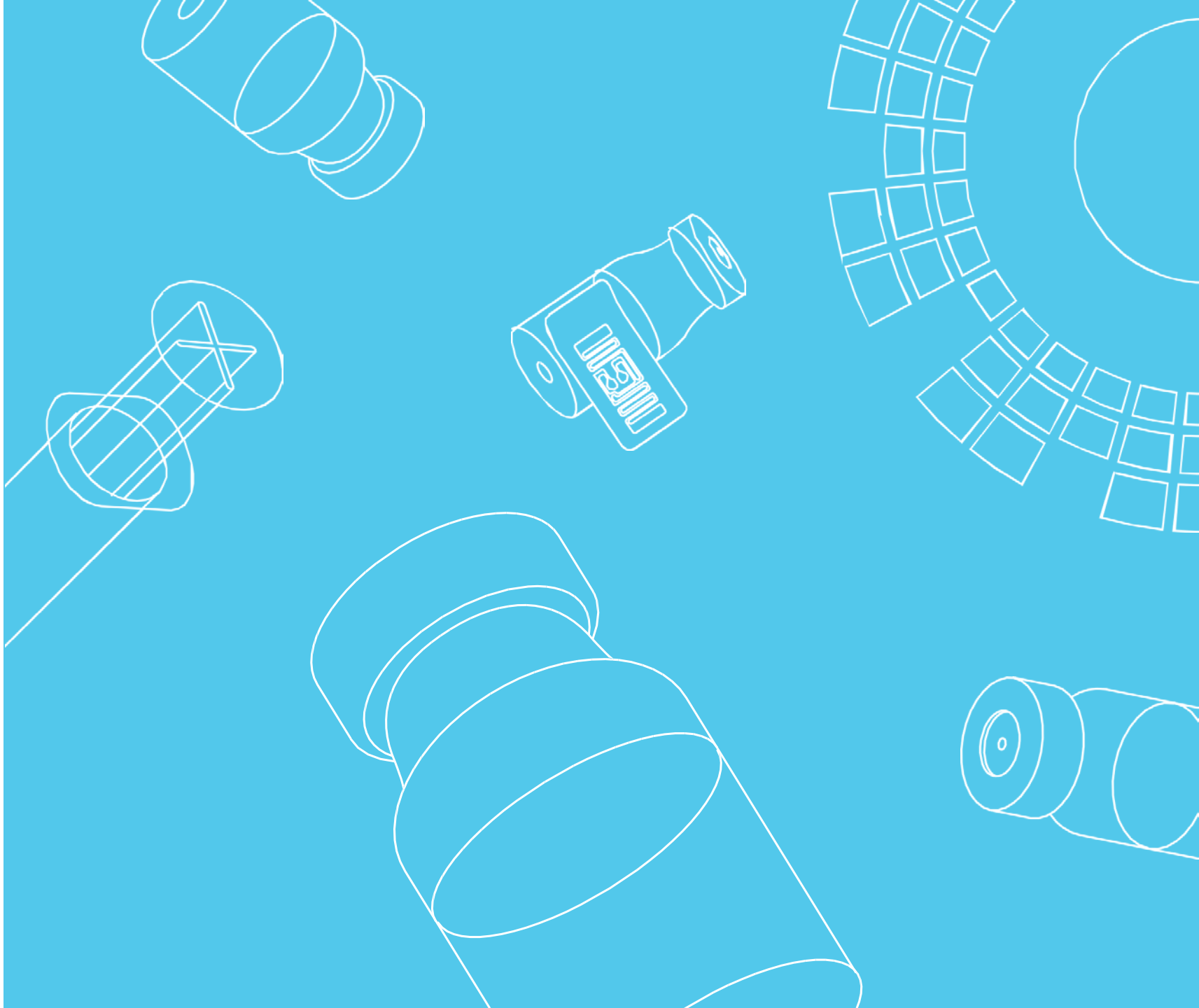
KITCHECK

POWERED BY BLUESIGHT

# FDA DSCSA Pilot

## Kit Check + Sandoz Findings



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KITCHECK

SANDOZ A Novartis Division

CORAL GABLES
Hospital

HackensackUMC

# Key Objectives

**Improve accuracy of tracking items throughout the supply chain**

**Improve DSCSA compliance**

- **Increase data accuracy (reduce rework due to errors)**
- **Reduce cost**

**Ensure interoperability between supply chain stakeholders**

KITCHECK
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# Key Outcomes

## Centralized Item Repository

- **Unlimited item attributes and events**
- **Not constrained by barcodes printed at the time of manufacturing**
- **Compliments other tech and standards**
  - Examples: Blockchain, SN in ASN/EDI, GTIN

## Serialized item lookups

- **Expiration & “Beyond Use” Dates**
  - Example: Refrigerated drugs
- **Recalls**
  - Closed loop with manufacturer tracking
  - Partial batches
  - Manufacturer & crowdsourced notifications
- **Suspect & Illegitimate Product**
  - Manufacturer notifications
  - Automatic detection (TID & implausible occurrences)

KITCHECK
POWERED BY BLUESIGHT

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# Key Outcomes

## Manufacturer Aggregation & Packaging

- **RFID benefits over barcode**
  - scan many at once, no line of sight, anti-counterfeit
- **RFID tags increased unit-dose cost by an average of 5-7 cents**
- **Using RFID improved SC efficiency because the data carrier didn't necessitate line of site**

## Cost-neutral, overall

- **Tags are more expensive than barcodes**
- **SC Efficiency**
- **Reduced aggregation errors**

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# Conclusion

**FDA should allow RFID as a data carrier for DSCSA data (with backup barcode)**

**FDA shouldn’t dictate technologies & implementations**

- **Example: dictating “how” data gets exchanged**
- **Allow for simplicity and flexibility**

# Conclusion

**Manufacturers should consider RFID-based aggregation workflows**

- **Address data integrity gaps for aggregation**
- **Reduce efforts to gather SN data for an investigation**
- **Enable downstream workflows & technologies**

# Conclusion

**Unit-dose Serialization + MDR**

- **Already proven that customers are willing to pay for this on over 100 million drugs**

**Helps with**

- **Inventory Management**
- **Recalls**
- **Suspect/Illegitimate Product**
- **Automation**
- **Data for manufacturers and FDA**

# Conclusion

**DSCSA ≠ full supply chain security**

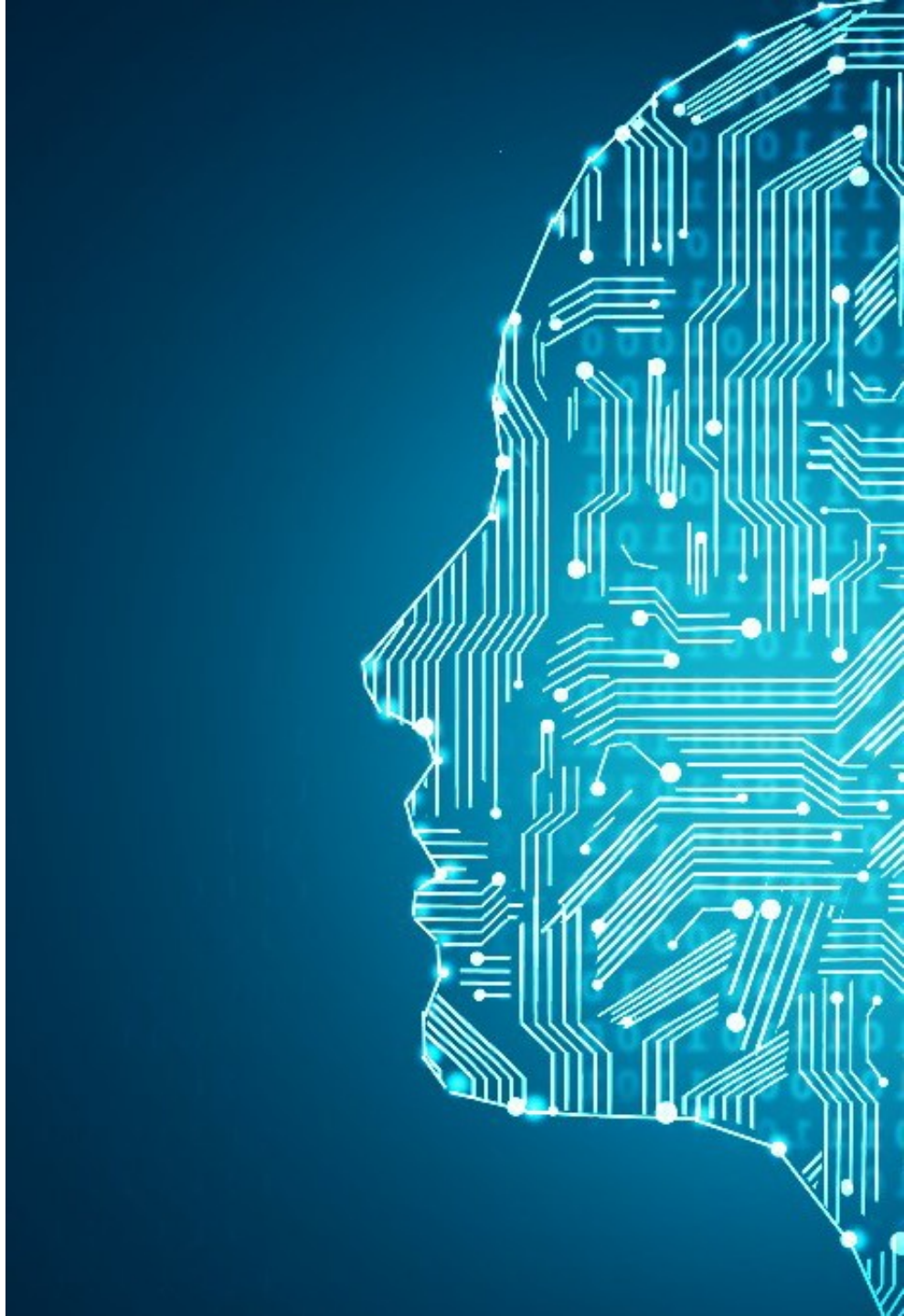
> That serial number
> [in the salable-unit barcode]
> is only good
> until it encounters a pair of scissors.

**The real goal is full supply chain security, which means the combination of:**

- **unit-dose serialization**
- **a centralized master data repository**

# Next Steps

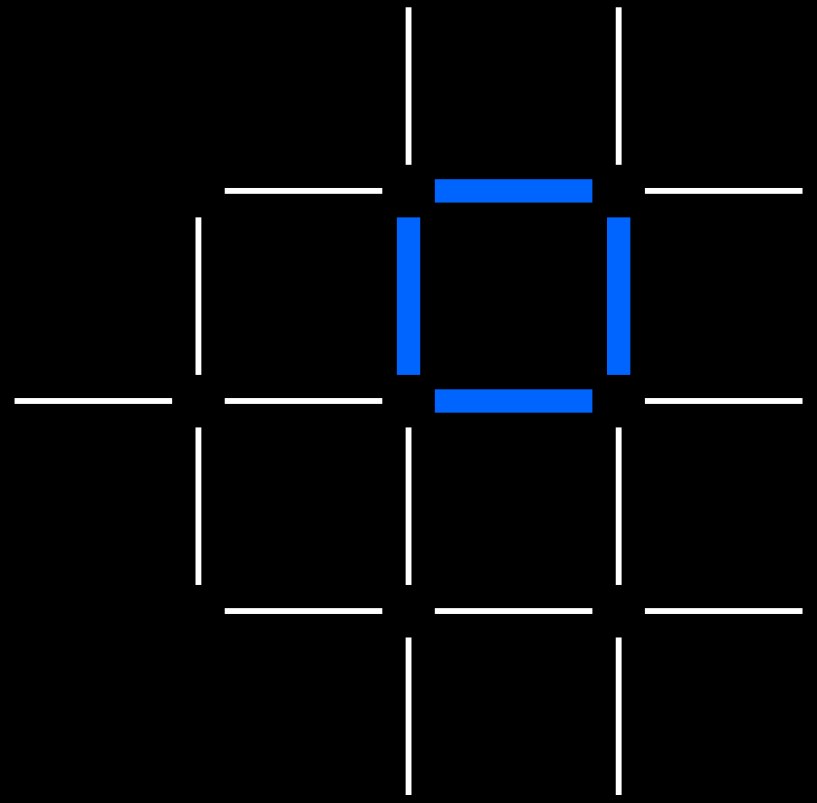
1. Sandoz launching 6 RFID-tagged products in Q4-Q1
2. Kit Check bringing other pharma manufacturers live
3. Pilots with other service providers to show inoperability
    - Digital recalls
    - Efficiency of gathering data for investigations
    - Verifications using RFID technology as a data carrier
      (small increase in cost addresses many of the data errors and gaps)
4. Thinking Beyond 2023
    - Interoperable platform
    - Tools for high-speed manufacturing lines



# FDA DSCSA Blockchain Interoperability Pilot

FDA DSCSA Pilot Project Program
Participant Meeting

December 8, 2020



IBM KPMG MERCK Walmart

# 00 Agenda

**01** Objectives

**02** Key Features

**03** Value Beyond Compliance

**04** Recommendation

# 01 Objectives

Supply Chain Provenance

Demonstrate that blockchain can provide a **common record of product movement** by connecting disparate systems and organizations to meet DSCSA 2023 interoperability requirements in a secure way.

Patient Safety

**Improve patient safety** by triggering product alerts and increasing visibility to relevant supply chain partners in the event of a product investigation or recall.

Pilot

The Pilot was successful in demonstrating both stated objectives.

# 02 Key Features

**Integrated** manufacturer enterprise system to private permissioned blockchain and enabled **post of product commissioning** transaction.

Recorded subsequent **receive, ship and dispense actions** from manufacturer, distributor and dispenser on the blockchain ledger including established order and one up / one down privacy of information sharing.

Created **product query function** to verify product data.

Enabled **alerts** to be sent to product holders in the event of an investigation

Enabled **product recall communications** to be sent in a targeted manner

# With a digital record following product movement, new opportunities to solve key challenges can be explored:

**Cold Chain Logistics**

Add data collected from IoT sensors to create an environmental history for each serialized product.

**Drug Shortages**

Analyze aggregated data across the platform to identify and address product shortages before they occur.

**Inventory Management**

Streamline processes to introduce a lean supply chain with optimized inventory management.

# 04 Opportunities

To foster industry adoption, an egalitarian, inclusive, open-sourced commercial solution should be considered to help launch a blockchain network intended for information exchange of the pharmaceutical product transactions in the United States.

## DSCSA

1. Accelerate the formation of supporting **policies**
2. Assisting the pharmaceutical supply chain stakeholders with **guidelines** to help extend existing industry standards to support this solution
3. Establish a **communication channel** with industry players who are developing similar solutions to share findings, received guidance, and actively collaborate

## Beyond DSCSA

1. The number of **cold chain products** is rapidly increasing with new biologics, biosimilars and vaccines, urging the need for temperature-control monitoring.
2. Expanded capabilities may require **cross-agency, global collaboration** to assist in **drug recalls,** mitigating **drug shortages** and other public health events.
3. A **platform centric approach** that meets the needs of many agencies and enables DSCSA will accelerate deployment and adherence.

# Thank you

Cryptographic Identity Authentication (CIA)

# IDLogiq Inc.
# FDA DSCSA Pilot

# Pilot Project Key Objectives

01

**Interoperability**

- Information Exchange
- Trading Partners

02

**Product ID**

- Method to issue and manage SN
- Compare diff use of NDC, GTIN

03

**Barcodes**

- Reliability
- Optional: Alternate data carrier (NFC), Built-in GS1-compliant Cryptographic Anticounterfeit


04

**Aggregation / Disaggregation**

- Impact
- Exception handling: errors, accuracy

05

**Verification / Notification**

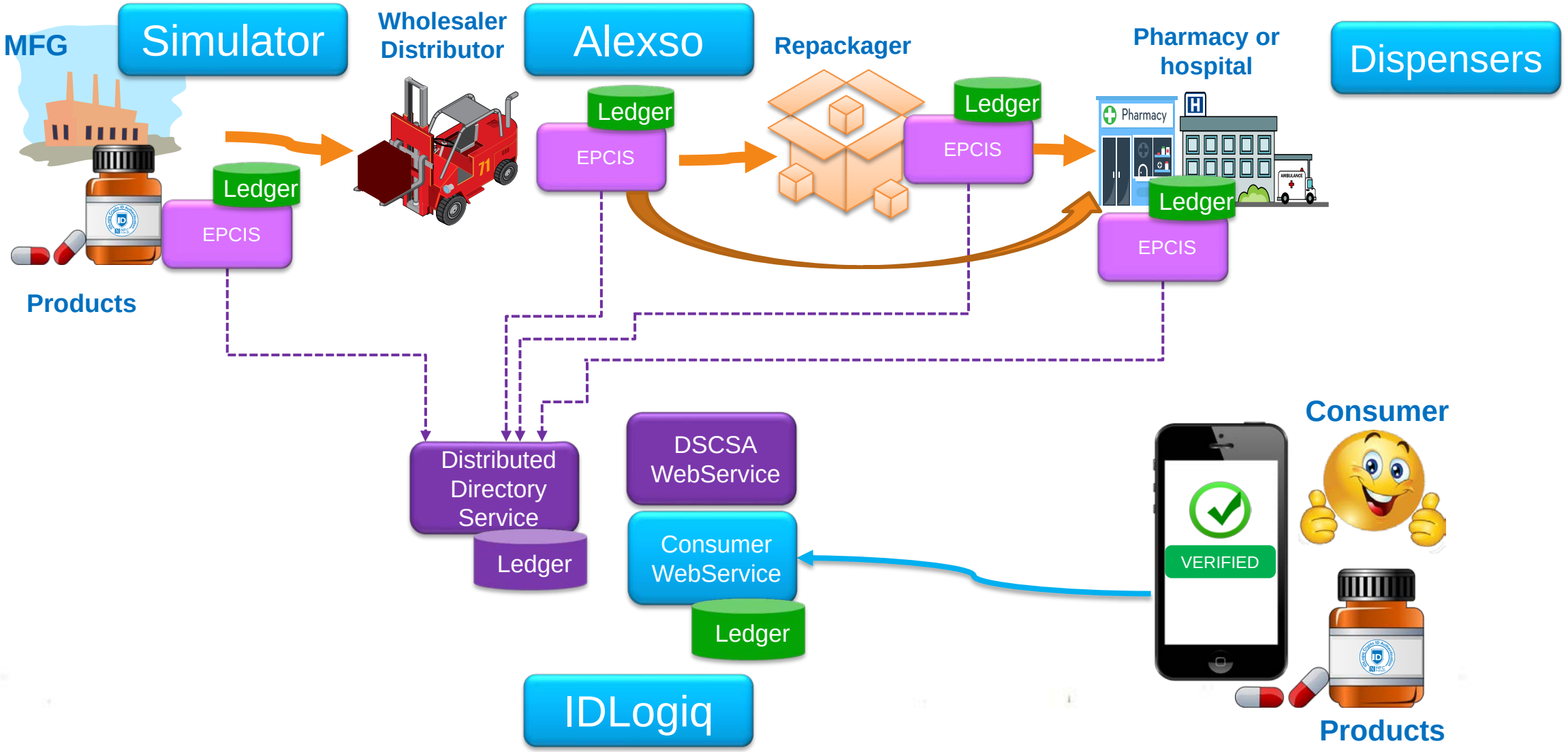
- Real time response system
- Optional: Cryptographic Anticounterfeit

06

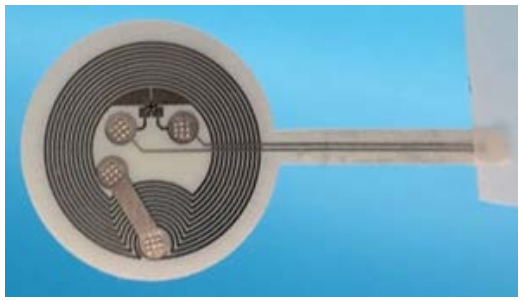
**Exception Handling**

- System handling of exception conditions, errors, inconsistencies

# Introduction – Workflows of Entities Participated in the Pilot

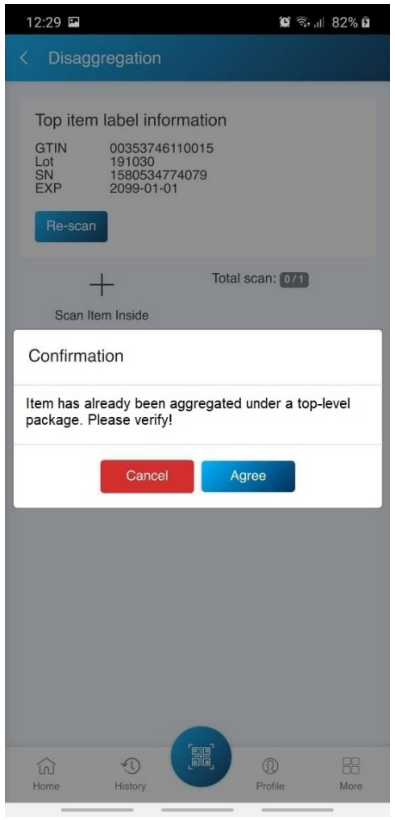


# Examples / Demo

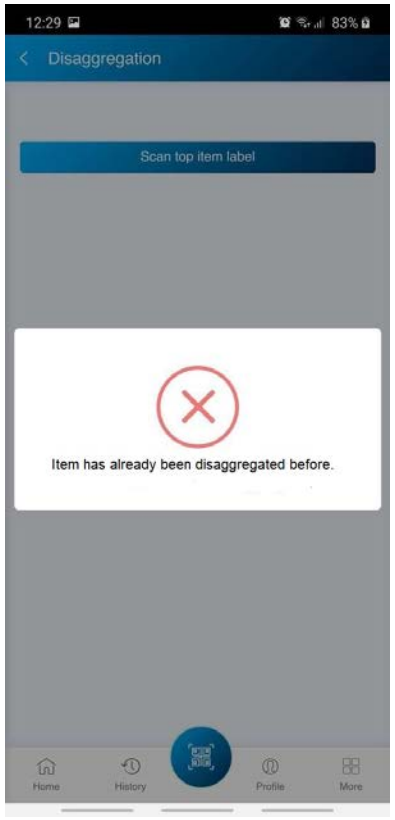



# Example Screenshots of Errors, Exception Condition

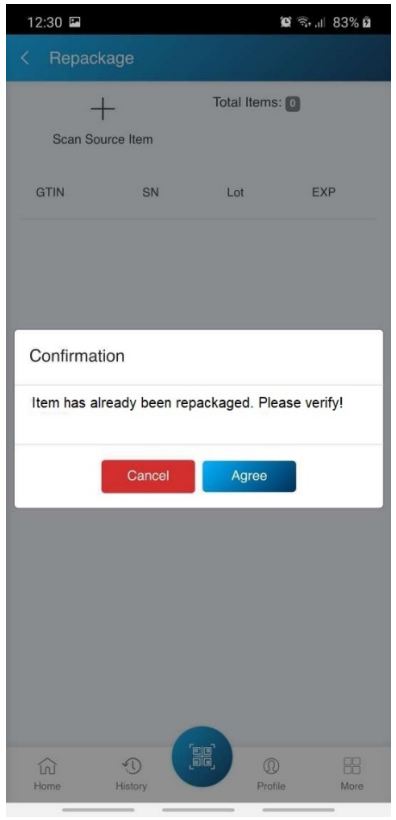

Repackaging: Invalid ownership of product



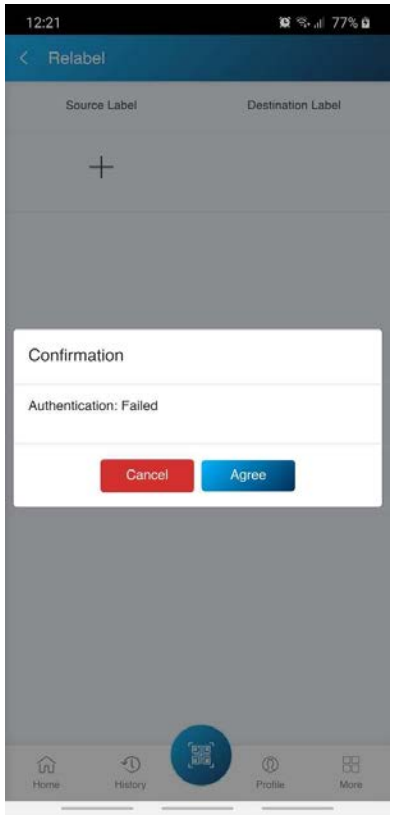

Aggregation: Items has already been aggregated




Dis-aggregation: Item has already been disaggregated

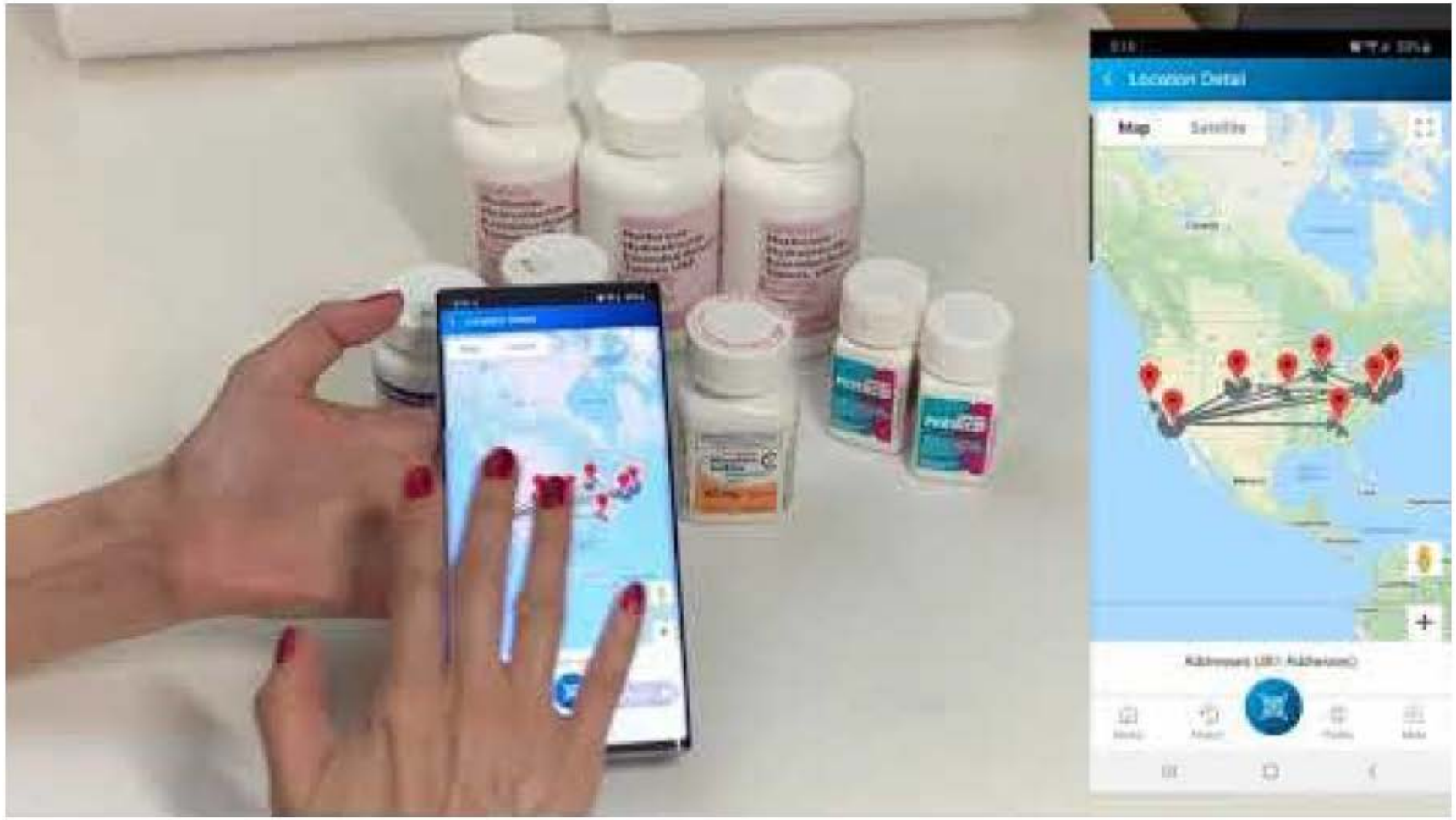



Repackaging: Item has already been repackaged




Counterfeit detected via Cryptographic ID Authentication

# Video Track and Trace of a Product Life Cycle



# Example: TI Reports

| Shipping Information | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Shipped Date** | 2019-11-19T22:19:41.000Z | | | | | | | | | | | |
| **Shipped From** | SA3, LLC | | | | | | | | | | | |
| **Shipped To** | Alpha Medical Pharmacy Inc Gabriel Blvd | | | | | | | | | | | |
| **(TI) Item Shipped** | | | | | | | | | | | | |
| **ID** | Shipped Date | Product | NDC | UPC | Dosage Form | Strength | Container Size | MFG | Qty | Lot | Serial Number |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3606440918495544 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3616870985969605 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3661003717595213 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3682584920443046 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3753489221457785 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3781595217834361 |
| **488c53b4 65a4 43c2 b2c6 a4f853e41646** | 2019-11-19T22:19:41.000Z | Naproxen Sodium | 69420-1375-1 | "00369420137513" | TABLET, FILM COATED, EXTENDED RELEASE | "375 mg/1" | 100 TABLET, FILM COATED, EXTENDED RELEASE in 1 BOTTLE (69420-1375-1) | SA3, LLC | 1 | 191113 | 3781763940180028 |

# Example: TH Reports

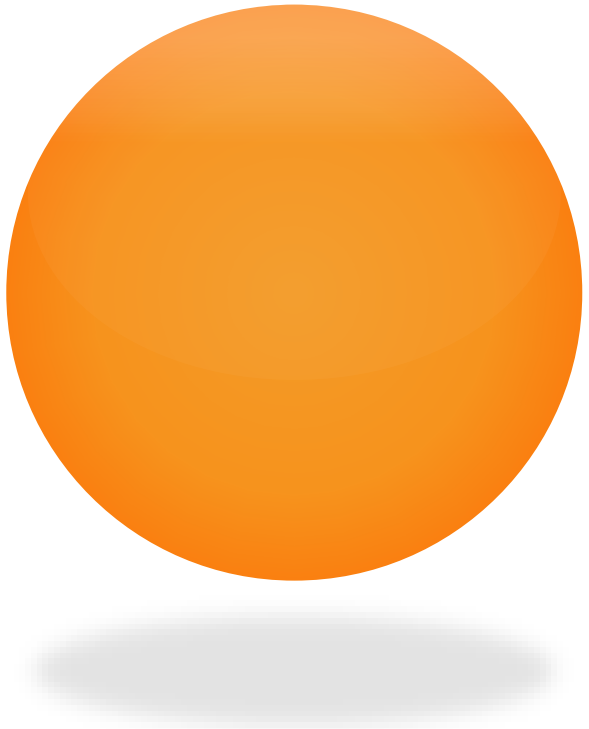
| GTIN | Serial Number | Timestamp | Transaction Type | Lot Number | | Description |
|---|---|---|---|---|---|---|
| 00369420137513" | 3606440918495544 | 2019-11-19T22:19:41.000Z | SHIPPING | 191113 | 8/30/2021 | Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd |
| 00347781153014" | 4689415182531103 | 2019-11-19T21:19:15.000Z | Repackage | 191113 | 8/30/2021 | SA3 repackaged from 00347781153014.4689415182531103 to 00369420137513.3606440918495544 |
| 00347781153014" | 4689415182531103 | 2019-11-15T10:18:02.934Z | SHIPPING | 191113 | 8/30/2021 | SHIPPING from Alvogen Manufacturer to SA3 |
| 00369420137513" | 3616870985969605 | 2019-11-19T22:19:41.000Z | SHIPPING | 191113 | 8/30/2021 | Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd |
| 00347781153014" | 3623183817940961 | 2019-11-19T21:19:15.000Z | Repackage | 191113 | 8/30/2021 | SA3 repackaged from 00347781153014.3623183817940961 to 00369420137513.3616870985969605 |
| 00347781153014" | 3623183817940961 | 2019-11-15T10:18:02.934Z | SHIPPING | 191113 | 8/30/2021 | SHIPPING from Alvogen Manufacturer to SA3 |
| 00369420137513" | 3661003717595213 | 2019-11-19T22:19:41.000Z | SHIPPING | 191113 | 8/30/2021 | Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd |
| 00347781153014" | 5661445665230668 | 2019-11-19T21:25:11.000Z | Repackage | 191113 | 8/30/2021 | SA3 repackaged from 00347781153014.5661445665230668 to 00369420137513.3661003717595213 |
| 00347781153014" | 5661445665230668 | 2019-11-15T10:18:02.934Z | SHIPPING | 191113 | 8/30/2021 | SHIPPING from Alvogen Manufacturer to SA3 |
| 00369420137513" | 3682584920443046 | 2019-11-19T22:19:41.000Z | SHIPPING | 191113 | 8/30/2021 | Shipping from SA3 to Alpha Medical Pharmacy Inc Gabriel Blvd |
| 00347781153014" | 7170071169111973 | 2019-11-19T21:30:36.000Z | Repackage | 191113 | 8/30/2021 | SA3 repackaged from 00347781153014.7170071169111973 to 00369420137513.3682584920443046 |
| 00347781153014" | 7170071169111973 | 2019-11-15T10:18:02.934Z | SHIPPING | 191113 | 8/30/2021 | SHIPPING from Alvogen Manufacturer to SA3 |

# Pilot Project Key Outcomes

- Interoperability
  - ASN EDI 856 legacy or vendor-specific proprietary XML still widely used
  - Issues with getting cooperation from a different technology provider. We think this will continue to be a major hurdle for the industry because it is more political than technological problems.
- Serialization
  - Common trend: use GTIN
- Barcode
  - Successful on both curved and flat surface
  - Also, NFC was successfully used together with barcode
- Aggregation/Disaggregation
  - Without good process automation software, production could be heavily impacted
- Verification/Notification
  - Human errors due to mismanagement should be seriously considered
  - Without robust automation software, this would be a very challenging task

# Key Conclusions and Recommendations

- Interop will require cooperation from ALL parties.
  - Not so much a technology issue, but a complex topic politically
  - Recommendation: FDA to promote corporation between all technology developers and trading partners.
  - Interop test lab, test suites
- Automation software is necessary for package level tracing at all phases of production and DSCSA events to mitigate errors / exception condition due to technical and human errors.
  - Aggregation, Disaggregation, Repackaging, Shipping, Receiving, simple ownership transfer
- Would be helpful if FDA defines a standard and examples for the details of the report and terminology inside TI and TH.
  - Potential interop issues



# THE END

Contacts:
Email: info@dlogiq.com,

# FDA DSCSA Pilot Project Program

LSPediA

## Router Service Solution for Verification/Notification and Interoperability 2023

December 2020


LSPediA

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# LSPediA FDA DSCSA Pilot Project

## Agenda

- Goals & Objectives
- Partnering Entities
- Evaluation Method
- Products
- Results
- Lessons Learned
- Recommendations
- Summary
- Q&A

## Presenters

Riya Cao
CEO

LSPediA

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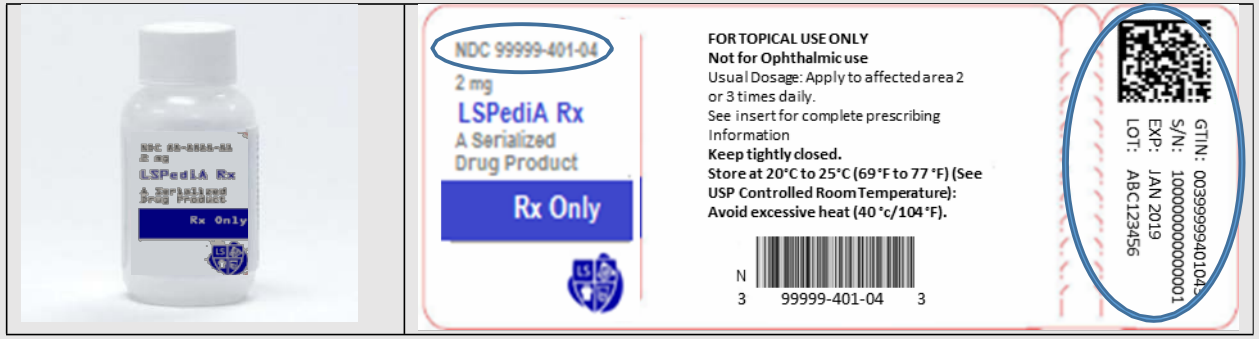
# Objectives

- Use existing technology
  - Router Service Network
  - LSPediA OneScan solution
- Effectively meet DSCSA requirements
  - Verification
  - Notification
  - Interoperability
- Utilizing Product Identifier

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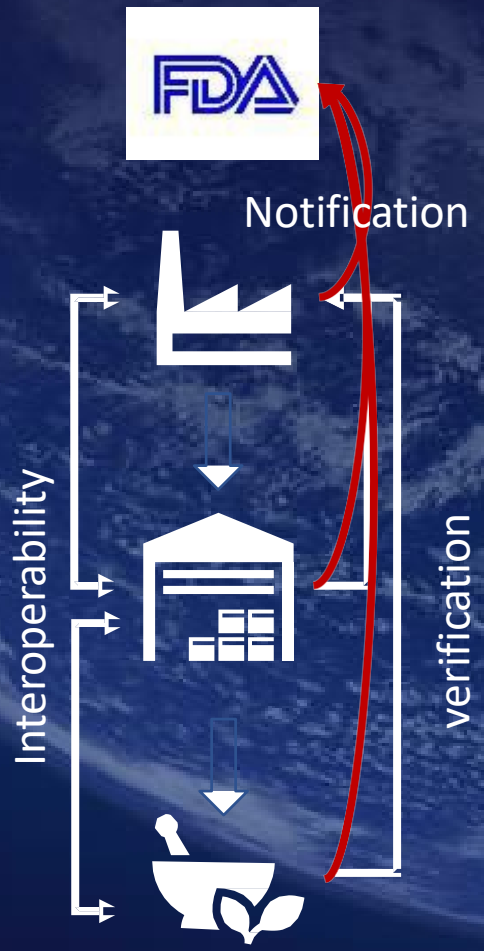
# LSPediA FDA DSCSA Pilot Project

## Partnering Entities




| Trading Partner | Name |
|---|---|
| Manufacturer | Kowa Pharma |
| | Ingenus Pharma |
| Wholesale Distributor | AmerisourceBergen |
| | Smith Drug |
| | Auburn Pharma |
| Dispenser | SpartanNash |

This Photo by Unknown

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## Live Inventory

## Seeded Bottles




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# End to End Supply Chain Test

## Round 1 – Test Scenarios

## Round 2 – Test Scenarios

| Requestor | |
|---|---|
| Pilot Scan Round | |
| Round 1 (red #1) | |
| Round 1 (red #2) | |
| Round 1 (red #3) | |

| Requestor | |
|---|---|
| Pilot Scan Round | Return Code |
| Round 2 (green #1) | 200 Not Verified |
| Round 2 (green #2) | 200 Not Verified |
| Round 2 (green #3) | 200 Not Verified |

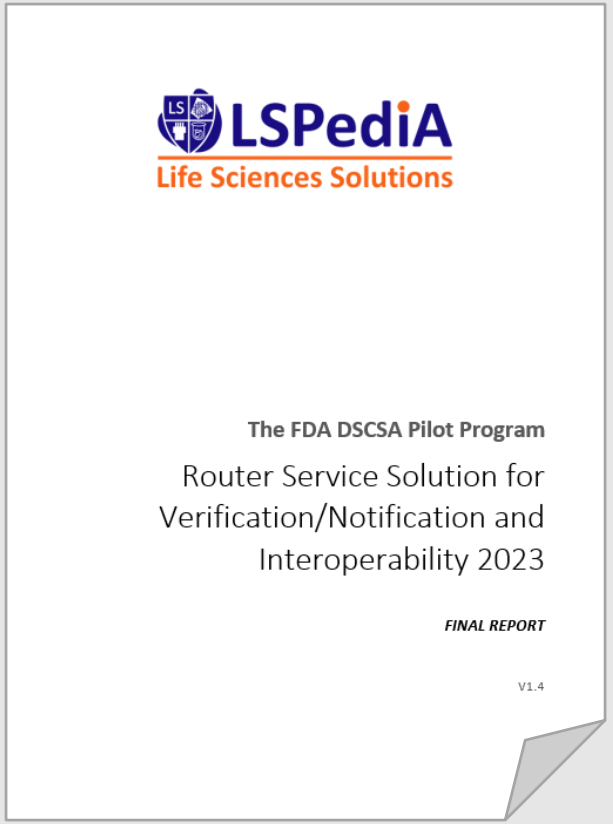
## Round 3 – Test Scenarios

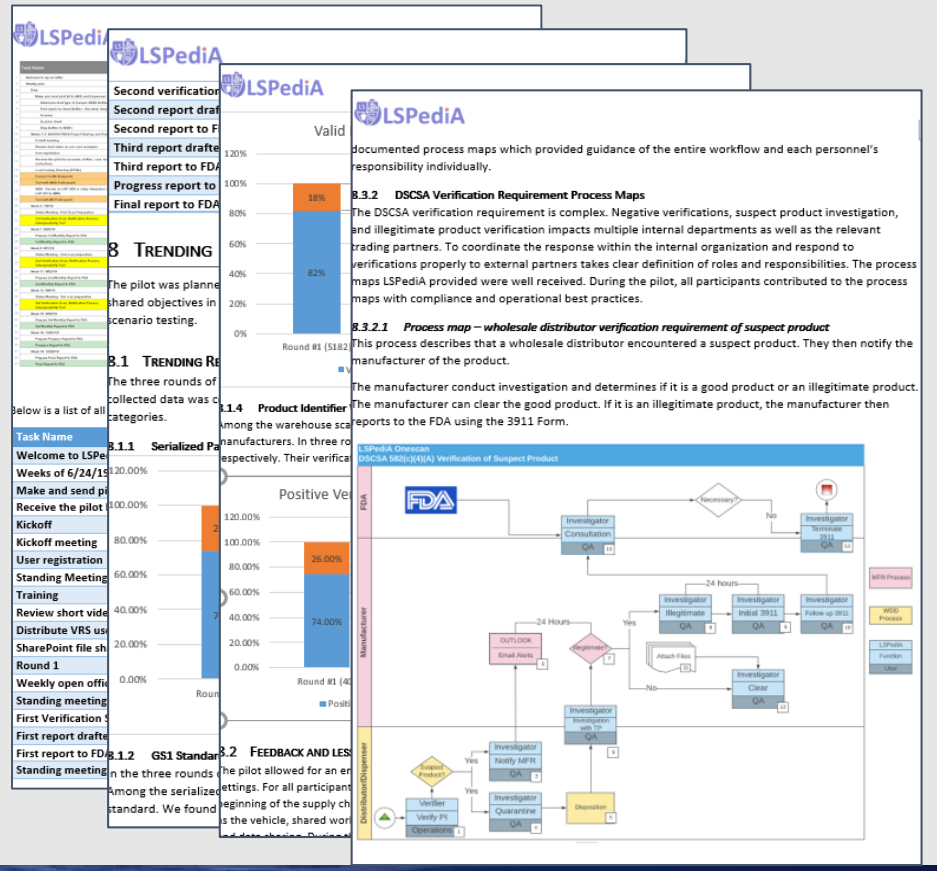
| Requestor | VRS | | | Responder | | Requestor |
|---|---|---|---|---|---|---|
| Pilot Scan Round | Return Code | Reason Code | VRS Automatic Activity | | | |
| Round 3 (blue #1) | 200 Not Verified | No Match GTIN SERIAL LOT EXPIRY | Investigation Record created. Email Notification sent to Responder | Responder receives Email and Investigates Item. Item is not verified - Responder determines item is suspicious | Responder changes status of Notification to SUSPECT for further investigation. Responder Initiates 3911 | Requestor will rescan item. Item will scan Not Verified -Suspect |
| | | | | After further investigation, Responder determined item is Illegitimate | Responder changes status of Notification to ILLEGITIMATE. Responder does F/U 3911 | Requestor will rescan item. Item will scan Not Verified, Illegitimate. Item needs to be quarantined. |
| Round 3 (blue #2) | 404 | | | | | Requestor – Put in Quarantine – Manual follow-up with Mfg. |
| Round 3 (blue #3) | 200 Verified | Manufacturer – Suspect | | | | Requestor - Put to quarantine. |
| Round 3 (blue #4) | Test for Interoperability | | | The Transaction Information/ Transaction Statement report for the item will show. | | |
| Round 3 (blue #5) | Test for VRS Security | | | A notification email will go out informing the responder of a sGTIN being scanned by more than 1 GLN within 24 hours. | | |

# LSPediA FDA DSCSA Pilot Project

## Outcomes

- LSPediA FDA DSCSA Pilot Project Final Report





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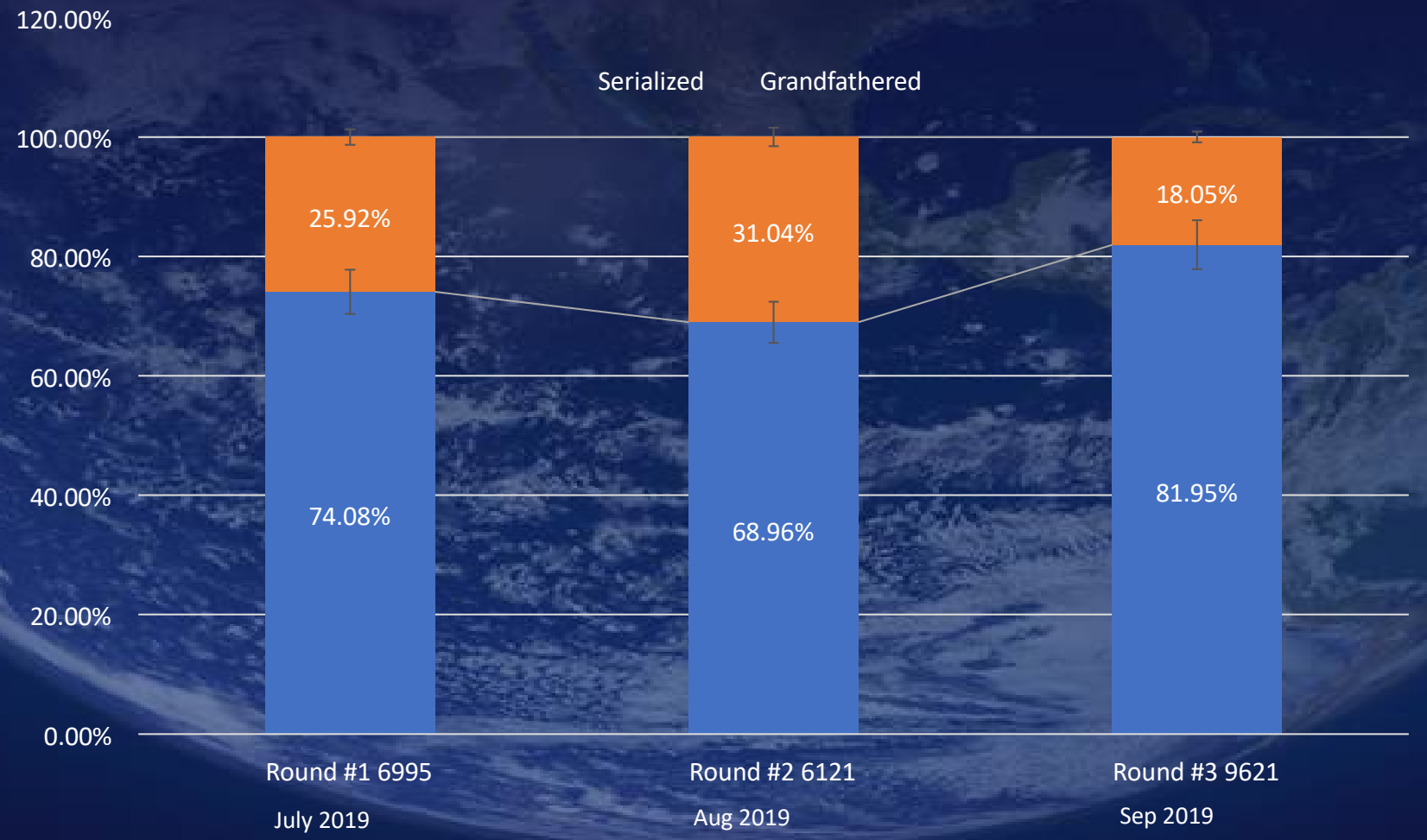
# LSPediA FDA DSCSA Pilot Project

## Outcomes - Serialized v. Grandfathered





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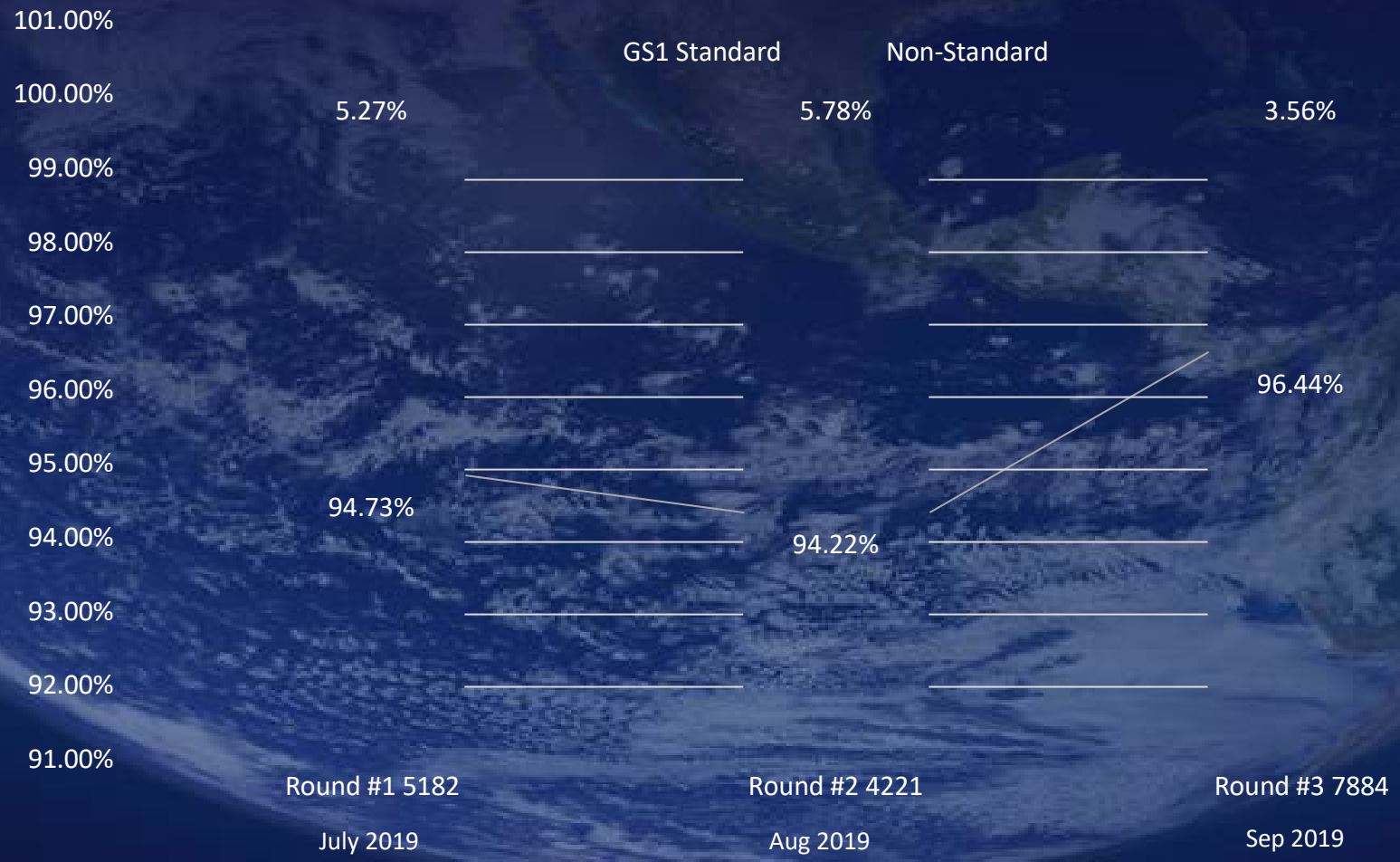
# LSPediA FDA DSCSA Pilot Project

## Outcomes - GS1 Standard v. Non-Standard





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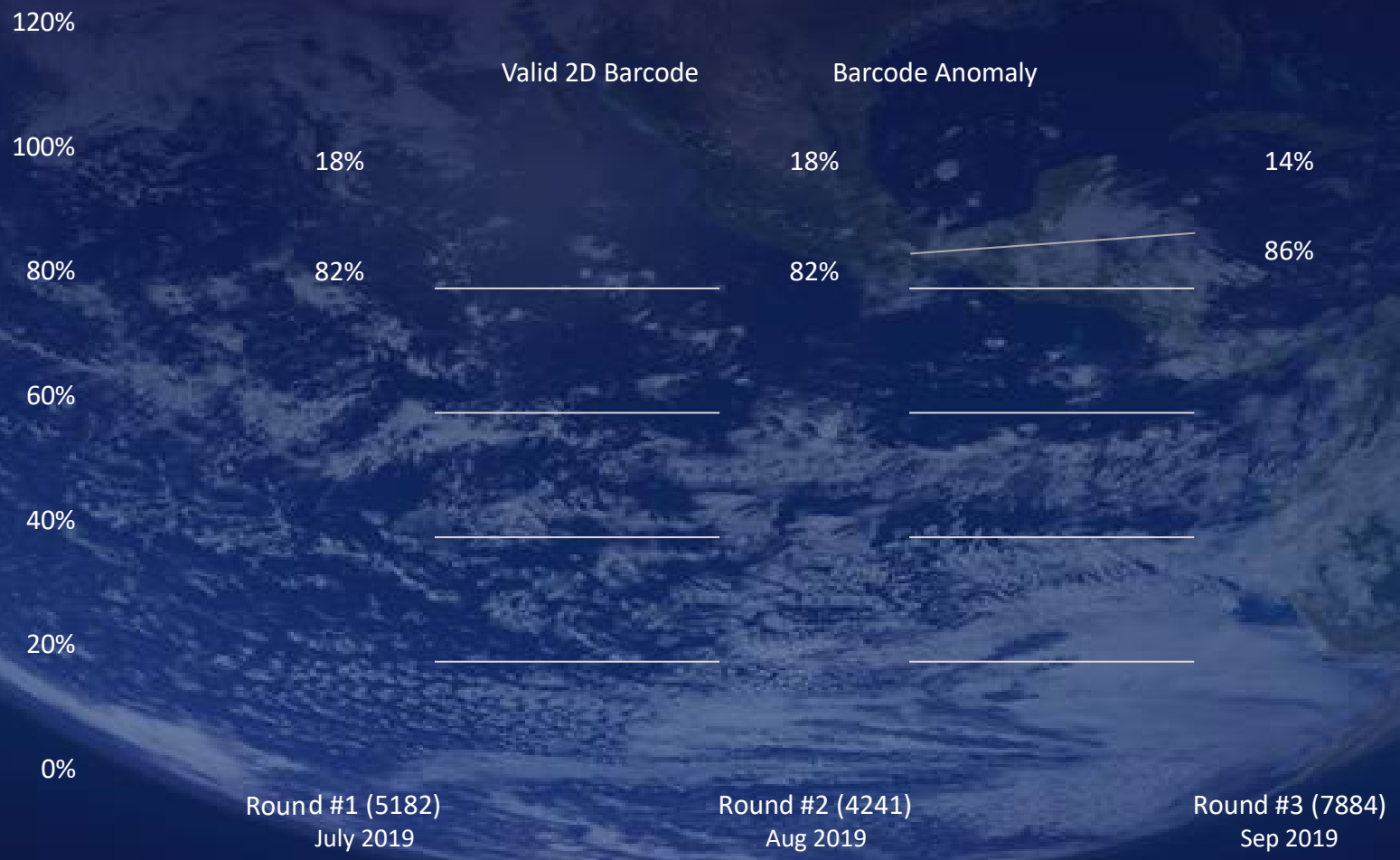
# Outcomes - Valid Barcode v. Barcode Anomaly

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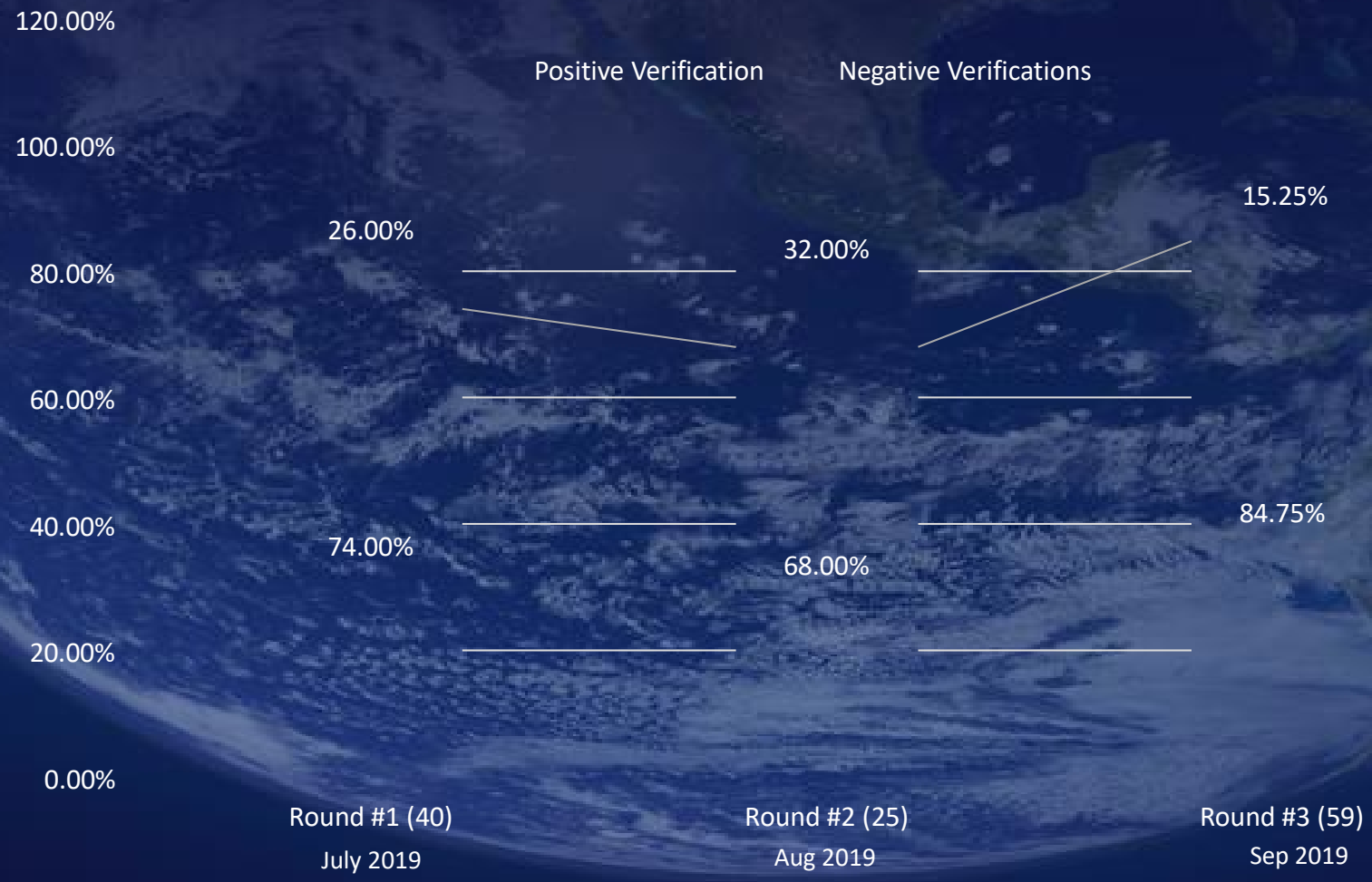
# Outcomes - Positive Verification v. Negative

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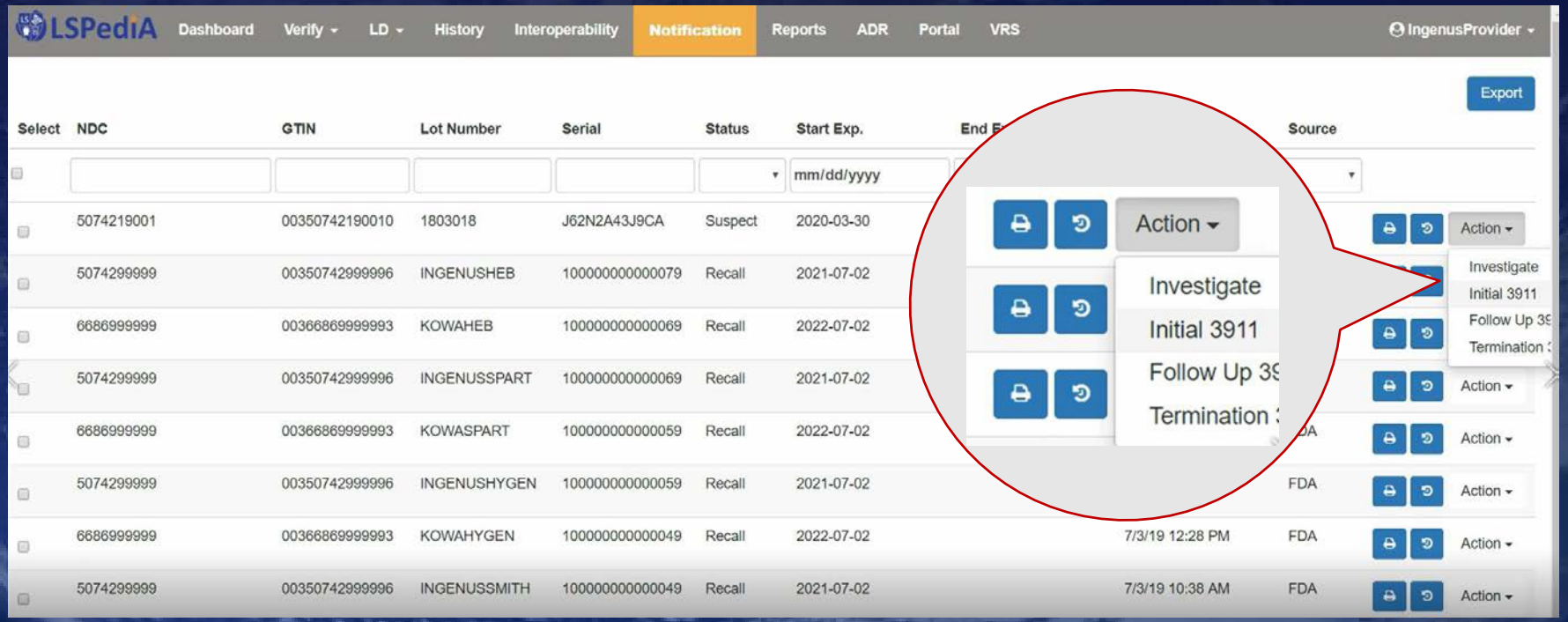
# Notification

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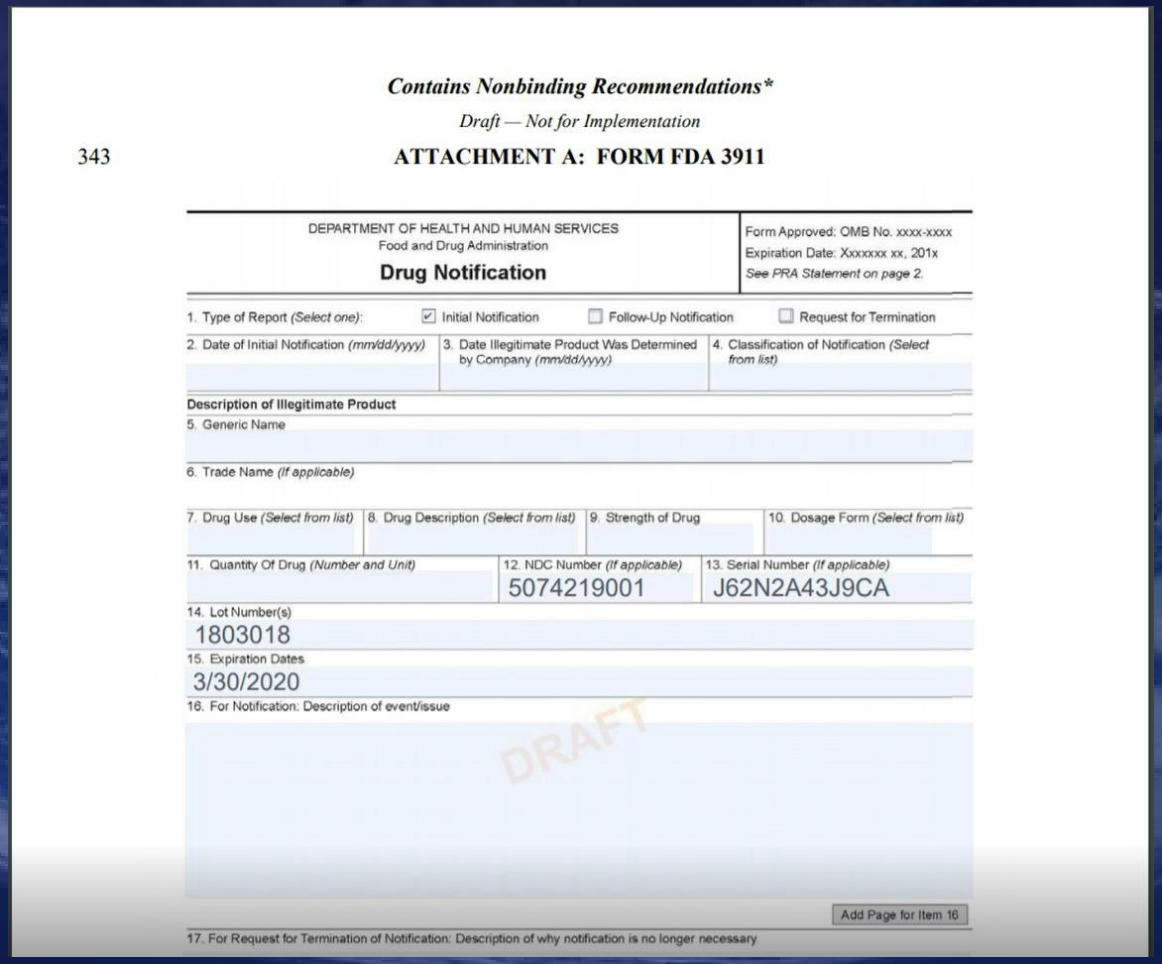
# 3911 Initiated with PI



*Contains Nonbinding Recommendations**

*Draft — Not for Implementation*

343

**ATTACHMENT A: FORM FDA 3911**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Drug Notification**

Form Approved: OMB No. xxxx-xxxx
Expiration Date: Xxxxxxx xx, 201x
*See PRA Statement on page 2.*

1. Type of Report *(Select one)*: ☑ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Date of Initial Notification *(mm/dd/yyyy)* | 3. Date Illegitimate Product Was Determined by Company *(mm/dd/yyyy)* | 4. Classification of Notification *(Select from list)*

**Description of Illegitimate Product**

5. Generic Name

6. Trade Name *(If applicable)*

7. Drug Use *(Select from list)* | 8. Drug Description *(Select from list)* | 9. Strength of Drug | 10. Dosage Form *(Select from list)*

11. Quantity Of Drug *(Number and Unit)* | 12. NDC Number *(If applicable)* 5074219001 | 13. Serial Number *(If applicable)* J62N2A43J9CA

14. Lot Number(s)
1803018

15. Expiration Dates
3/30/2020

16. For Notification: Description of event/issue

DRAFT

Add Page for Item 16

17. For Request for Termination of Notification: Description of why notification is no longer necessary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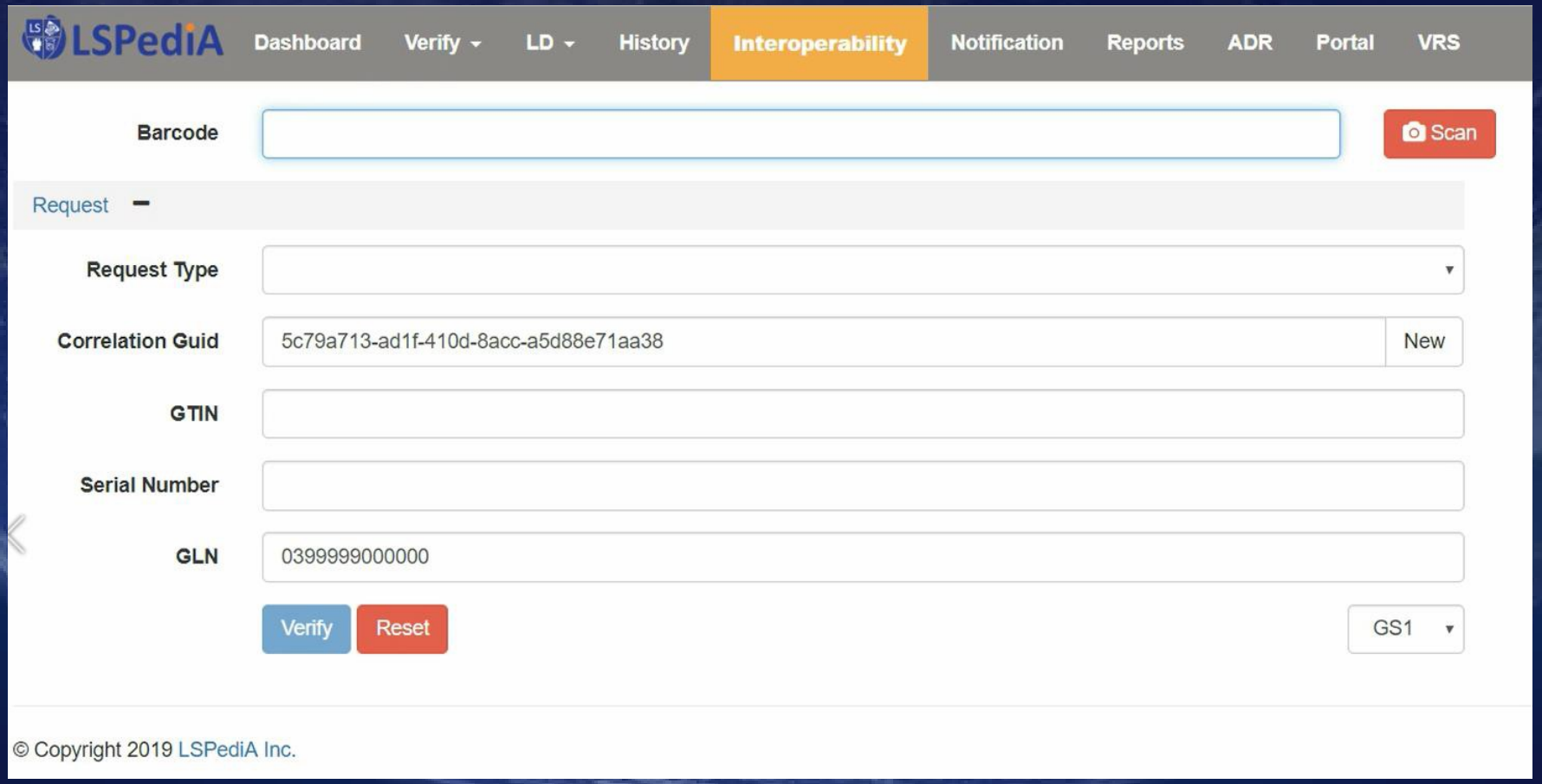
# Interoperability Utilizing Product Identifier





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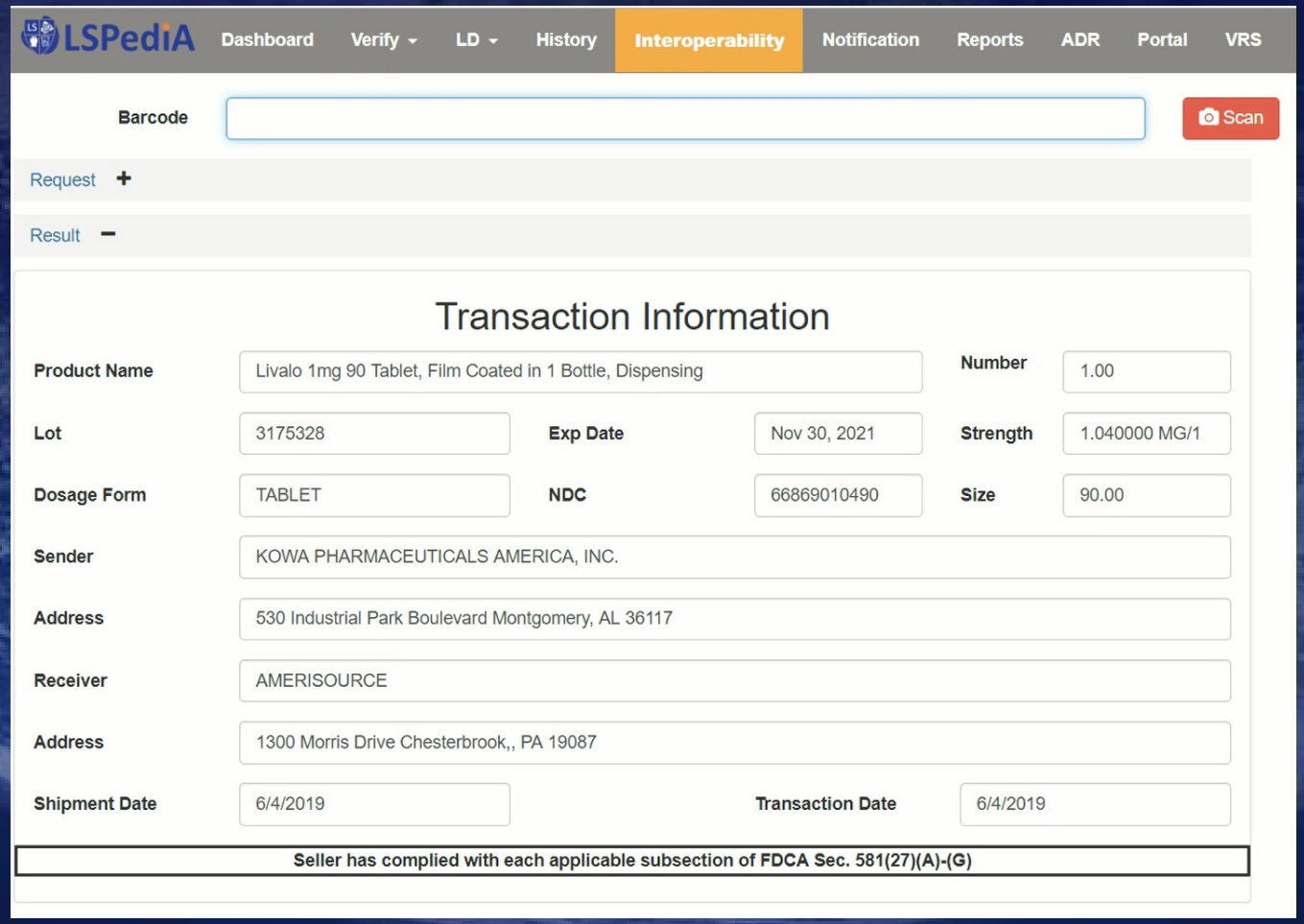
# Returns TI and TS

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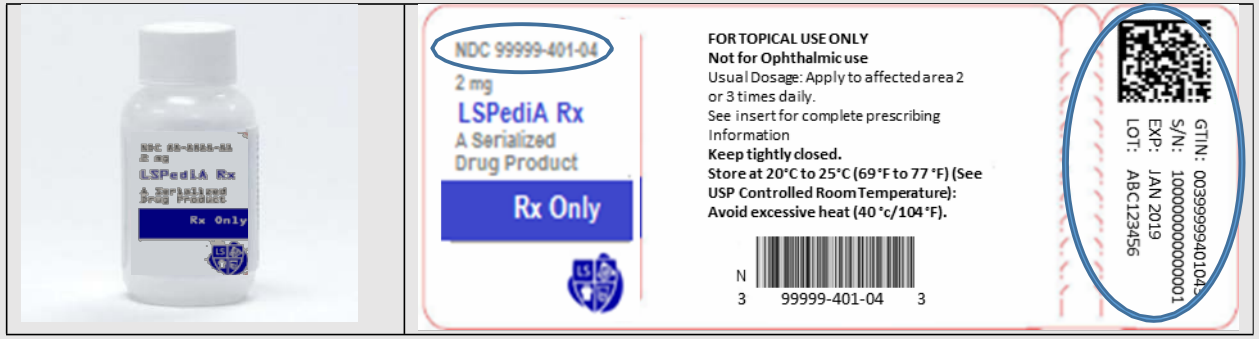
# Conclusion

- Existing technology viable for 2023
  - Router Service Network
  - LSPediA OneScan solution
- Effectively meet DSCSA requirements
  - Verification
  - Notification
  - Interoperability
- Utilizing Product Identifier

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# Lessons Learned

- Training
- Cross functional team
- Human factor


- Process maps
- SOPs
- Change management

- Enable process
- Enable people
- Viable today


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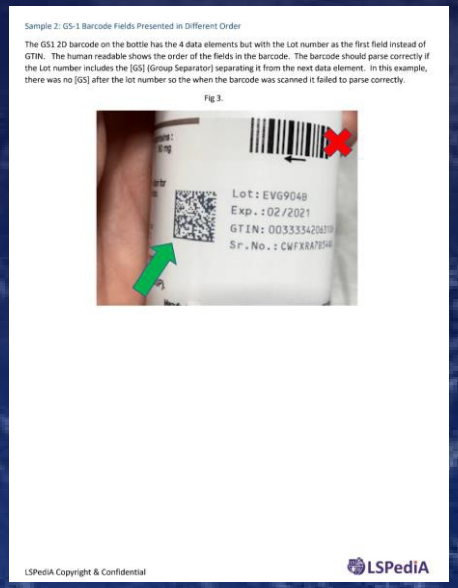
# Training Developed



Sample 2: GS-1 Barcode Fields Presented in Different Order

The GS1 2D barcode on the bottle has the 4 data elements but with the Lot number as the first field instead of GTIN. The human readable shows the order of the fields in the barcode. The barcode should parse correctly if the Lot number includes the [GS] (Group Separator) separating it from the next data element. In this example, there was no [GS] after the lot number so the when the barcode was scanned it failed to parse correctly.

Fig 3.



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Label Samples for training warehouse scanners

Sample 1: Bottle with multiple 2D Barcodes and Product Insert on bottle

Label has Two 2D barcodes on the label. One for the actual GS1 2D barcode (Fig 1) and one that is part of the package insert (Fig 2). The package insert portion of the label is meant to be removeable. The rest of the label has a more aggressive adhesive that is not meant to be peeled off. The GS1 2D barcode label will also usually have the human readable showing next to the barcode for GTIN, Serial, Lot, Expiry.

Always scan the label on the left.

Fig 1. shows the GS1 2D barcode.

Fig 2. shows the barcode for the package insert.

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Sample 3: Bottles with Package Insert on Top of Bottle

These bottles have a package insert with a 2D barcode on top. Bottles also have a GS1 2D barcode and a UPC barcode on the bottle label (Figs 5 and 6). The correct barcode to scan is the GS1 2D barcode on the bottle. The GS1 2D barcode will also have the human readable next to the barcode as a guide. Never scan the package insert barcode. Only scan the GS1 2D barcode on the bottle. See green arrows.

Fig 4.

Fig 5.

Fig 6.

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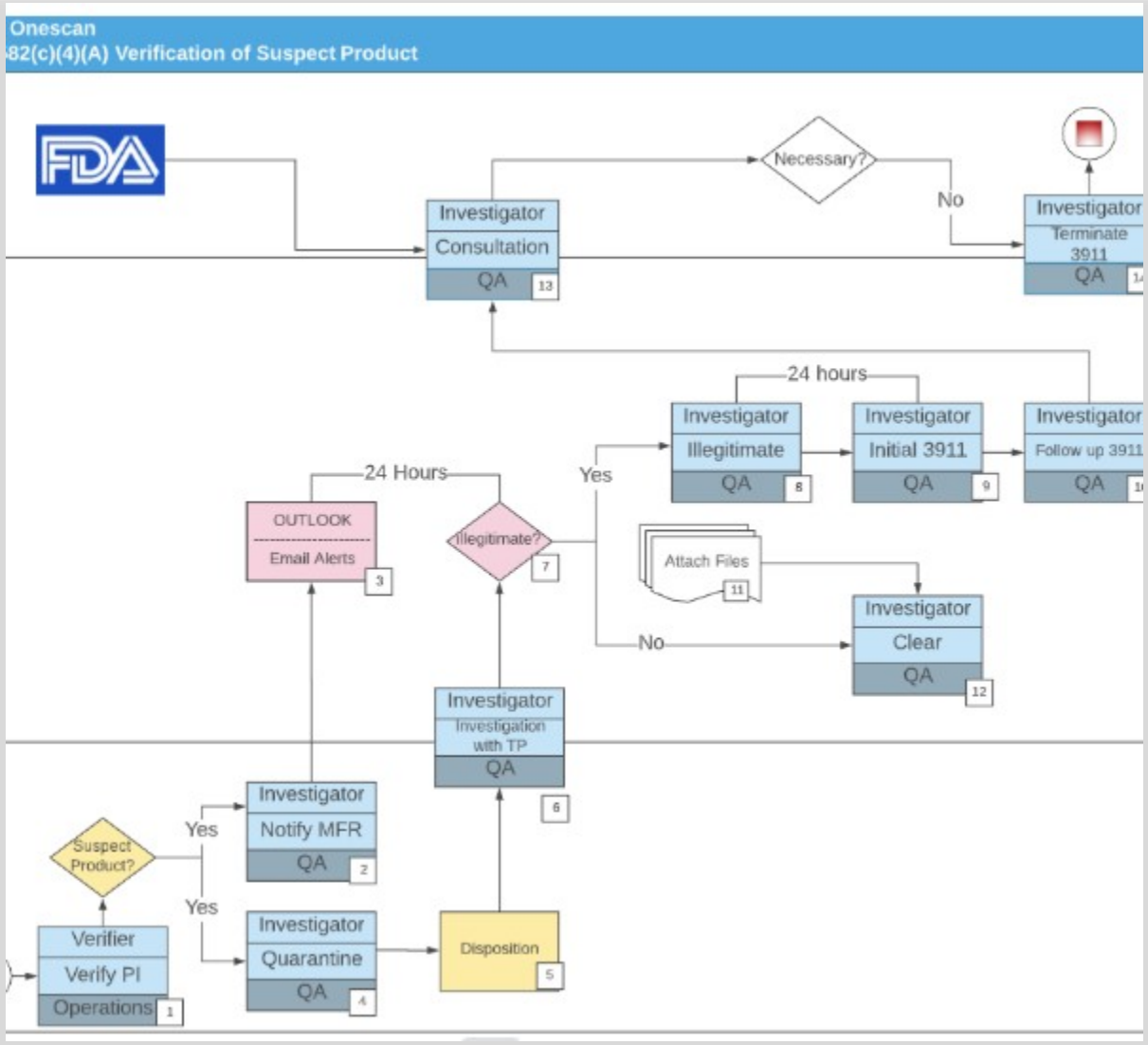
# LSPediA FDA DSCSA Pilot Project




**Best Practice Recommendation**

Suspect Product Process Map

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# Next Steps

- Pilot program
- Feedback
- Communication


- New perspective
- Don’t wait
- Collaborate

- Turn systems on
- Load production data
- Continuing the pilot work


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# DSCSA Pilot Project Program

## Participant Results (3)

| Program Participant/Speaker<br>*(All partnering entities are not listed)* | Pilot Project |
|---|---|
| Rymedi<br>Jason Cross | DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers |
| KitCheck<br>Tim Kress-Spatz | Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies |
| IBM/KPMG/Merck/Walmart<br>Mark Treshock | DSCSA Blockchain interoperability Pilot |
| IDLogiq<br>Kelly Nguyen | IDLogiq Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment |
| LSPediA<br>Riya Cao | Router Service Solution for Verification/Notification and Interoperability 2023 |

**Participant Panel Q&A**

- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.