

# ***Interoperability Data Exchange Errors & Exception Handling***

**DSCSA Pilot Project – Final Report**

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## Problem Statement

In order to support unit level/serialized data exchange in 2023, the industry is currently aligning around peer-to-peer data transmission utilizing EPCIS file structures with GS1 standards, designed around meeting DSCSA requirements. These file structures are being used in many business driven scenarios, with the intent of leveraging these connections and file structures for 2023 compliance data.

However systems that claim to be compliant, generally are not meeting standards and guidelines based on initial industry data exchange. This creates variations and deviations making it difficult to receive data in an interoperable manner for 2023. There are deviations from older EPCIS applications and packaging lines not adhering to GS1 US Healthcare Standards which does not provide the data in a way that the standard requires to meet DSCSA data exchange requirements. All of which causes errors in being able to consume data as a downstream trading partner and to efficiently resolve data integrity errors. We notice today these errors in a variety of ways that we define in this document as “transmission errors”. These range from the simple to the complex formatting issues, time sequencing errors, incorrect syntax, and missing data fields. These types of errors cause entire files to fail and stops operational processes. As we encounter errors today, most trading partners are not capable of correcting these errors once product and data have been produced and sent.

There is also general industry acknowledgement that during regular transactions between authorized trading partners, there were instances in which product received and data received do not match, particularly in transactions in which individual units have been aggregated to a larger container and do not match the aggregated serialized data the seller sent to the buyer. This means a downstream trading partner has product but no record of receiving that product’s transaction data, including its product identifier. These mismatches are inevitable given the relative immaturity of processes and the volume of product that rapidly moves between authorized trading partners. It is expected that over time, as systems mature, the rate of mismatches will decline significantly. For the purposes of this pilot these were defined broadly as “aggregation errors”.

Given the volume of products involved and in order to avoid interruptions in patient care, it is important that there be ways to distinguish these commercially routine exceptions (transmission and aggregation errors) between established trading partners from true suspect or illegitimate product situations.

Trading partners need to have business processes for data reconciliation in place to resolve such issues. These processes may allow for a trading partner to resolve a data reconciliation concern internally. Other data reconciliation situations were not amenable to an internal resolution and required that the entity seek the assistance of its trading partner, likely the manufacturer.

For purposes of this pilot, we made the following assumptions:

- Serialized data was exchanged via EPCIS. Currently, EPCIS<sup>1</sup> is the only internationally recognized standard that met DSCSA requirements for this interoperable electronic exchange of product tracing information.
- Aggregation was provided in EPCIS data. While the DSCSA does not explicitly require aggregation, given the volume of products moving through the pharmaceutical supply chain daily and the importance of maintaining secure operations, trading partners will need inference and aggregation for package-level traceability. Without it, trading partners would have to open each sealed larger unit to scan each item within it before shipping to capture product identifiers. Such actions are contrary to supply chain integrity practices and are slow, inefficient and highly burdensome to implement.

## Goals/Objectives

This pilot focused on two types of errors within point-to-point serialized data transmission via EPCIS

1. Transmission Errors
  - Identification of technical errors due to data transmissions not following established standards.
    - Some of the errors we identified to date for example include; file structure format, data element format, event sequencing, serial number (EPC) chronology, late transmissions, missing data elements, missing serial numbers, miss-located data, and incorrect pallet serial numbers
  - Quantify the % of transmission errors received within our samples
2. Aggregation Errors
  - Identify how aggregation errors are discovered by downstream trading partners and the resulting impact.
  - Measure the accuracy of aggregation data within our samples

We have proposed approaches to reconcile both types of errors.

## Methodology

We reviewed EPCIS data received from upstream trading partners into Cardinal Health's Information Repository & Intelligence Server Repository (event management system) and recorded errors. These

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<sup>1</sup> Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

transmissions reflected data processed by several business units within the enterprise representing the following supply chain stakeholders: Manufacturers, Contract Manufacturing Organization(CMOs), 3PL, Repackager and Wholesale Distributor. We then categorized the errors into various types and compare the frequency of those errors.

To assess aggregation errors, we proactively checked both pallet and case level aggregation using internally developed tools - SNI Confirmation Application and QA Tool. At the pallet level, we scanned case barcodes from a pallet and compare the information to that transmitted in the EPCIS file received. At the case level, we opened sealed containers and compare the package product identifiers inside the case with those identified in the EPCIS file received. We took a statistically significant sample over periodic time-frames throughout the pilot.

Once a baseline set of data was captured and the various types of errors were enumerated, we assembled a broad group within Cardinal Health from various functional areas (Quality & Regulatory, Operations, IT, Sourcing) to brainstorm ways to resolve these errors and provided potential solutions. For aggregation errors, we outlined the impact they could have on product availability and identified methods to minimize consumer impact. Our goal was to suggest how companies can quickly reconcile these issues with trading partners, in a way that does not burden the industry.

## Participants

Headquartered in Dublin, Ohio, Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically-proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks among the top 25 on the Fortune 500. [www.cardinalhealth.com](http://www.cardinalhealth.com)

For the purposes of this study we engaged various business units who have different experiences/use cases with EPCIS data exchange:

*Cardinal Health Specialty Solutions - Third Party Logistics Provider (501 Mason Road, LaVergne, TN)*- representing several small-medium sized branded and generic manufacturers. Manufacturer specific data will not be shared unless there is written consent from the manufacturer. In the 3PL use case we accept serialized data on behalf of our manufacturer clients from a variety of CMOs and serialization providers with the end goal of being able to send this data downstream to trading partners during shipments.

*Major® Pharmaceuticals- Repackager (8401 Bearing Dr Ste 100, Indianapolis, IN)*- this business unit within Cardinal Health acts as a private label repackager. We employ in house packaging operations along with using 3 different contracted packagers.

*Cardinal Health Packaging Solutions (CHPS)- CPO/Repackager (LaVergne, TN)*- this is a private label packaging & repackaging unit that works on behalf of manufacturers and Cardinal Health.

Cardinal Health Pharmaceutical Distribution- Wholesaler (Multiple Sites, HQ Dublin, OH) receives files from large variety of manufacturers ahead of 2023 regulatory requirements. To date we have done piloting & on-boarding activity with 15 companies and expect that to increase throughout the pilot.

## Technical Guides

Cardinal Health communicated its requirements for serialization and data exchange to trading partners by publishing three technical guides:

For Cardinal Health Specialty Solutions clients- ***Cardinal Health 3PL Technical Requirements for Serialization version 3.0, July 2018***

For Major® Pharmaceuticals repackagers - ***Major Pharmaceutical Packager Guide for Serialization version 2.0, November 2019***

For Cardinal Health Pharmaceutical Distribution manufacturers/wholesale distributors - ***Cardinal Health EPCIS Onboarding Guide for DSCSA v5.1, November 2019***

We used the requirements specified in these documents as the basis for exception classifications.

# Transmission Exceptions

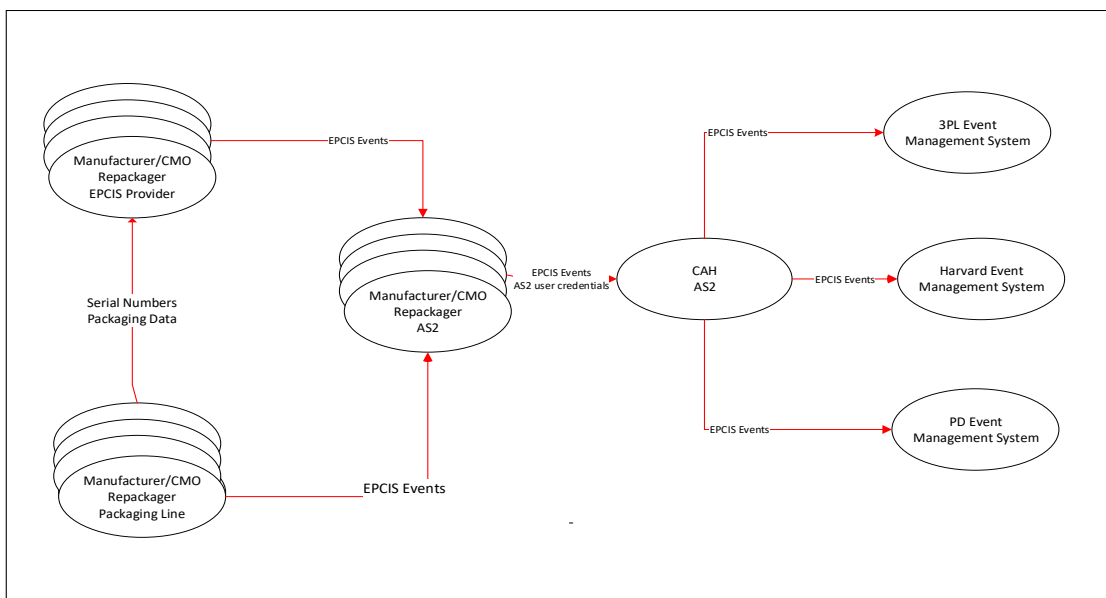
Transmission data samples were collected as a result of vendor/customer onboarding activities. Manufacturers, repackagers and wholesale distributors contacted EPCISsupport@cardinalhealth.com to initiate the exchange of serialized EPCIS data and to provide clarification on master data and to receive feedback on serialized EPCIS data transmitted and processed in Cardinal Health's EPCIS repository to support DSCSA requirements.

## The following is an overview of the vendor onboarding process:

- Conduct kickoff (via meeting or email) to exchange goals and objectives, timelines and assumptions
- Exchange AS2 information, configure and conduct a connectivity test (non-production and production).
- Exchange product and location master data information or agree that master data will be provided in the EPCIS events
- Begin exchanging serialized EPCIS data in non-production environments - we accepted EPCIS 1.1 or EPCIS 1.2.
- After successfully completing testing in a non-production environment, begin the serialized EPCIS data exchange in production.

## Identification of Transmission Exceptions

When we looked at the data transmission path, we were able to identify several points where exceptions could be introduced.



**Figure 1 Data Flow Diagram – Serialization Data**

Ideally, serialization data can be exchanged among trading partners without human intervention. We collected samples representing data exchanged with 150 manufacturers, repackagers, CMOs and wholesale distributors and each of the Cardinal Health business units. The data collection also included interacting with 11 EPCIS providers. This data sample represents about 20% of the overall serialization data exchanged between Cardinal Health and its trading partners from May 2017 to January 2020. We logged samples of successful transmissions only after a trading partner asked for confirmation that a data file had been received and successfully processed. Otherwise, after onboarding activities are completed, any serialization data that was exchange without human intervention or acknowledgement was not include as a data sample.

# of Data Samples Collected	# Exception Records Collected	Percentage of Data Records w/ Exceptions	# Records Collected w/o Exceptions	Percentage of Data Records w/o Exceptions
507	364	72%	143	28%

**Table 1 Summary of Data Samples Collected**

Manufacturers exchanging serialization data with Cardinal Health Specialty Solutions( CHSS 3PL) generated most of the data transmission activity which also resulted in the most the collected data samples. Over 86 manufacturers and nine EPCIS providers have been onboarded to send seriazation data to Cardinal Health Specialty Solutions - 3PL. Ten repackagers/contract manufacturing organizations (CMOs) using three EPCIS providers have been onboarded to send serialization data to Major Pharmaceuticals. Cardinal Health’s wholesale distribution business unit have received serialization data from 22 manufacturers using six EPCIS providers. It is also important to note that nine manufacturers developed their own EPCIS solutions. Since Cardinal Health Packaging Solutions (CHPS) was onboarded as a CMO/repackager for several Cardinal Health Specialty Solutions - 3PL clients and Major Pharmaceuticals, most of their transmission data samples have been included in the results of those business units. All transmission data samples exclusive to Cardinal Health Packaging Solutions involved serial number configuration.

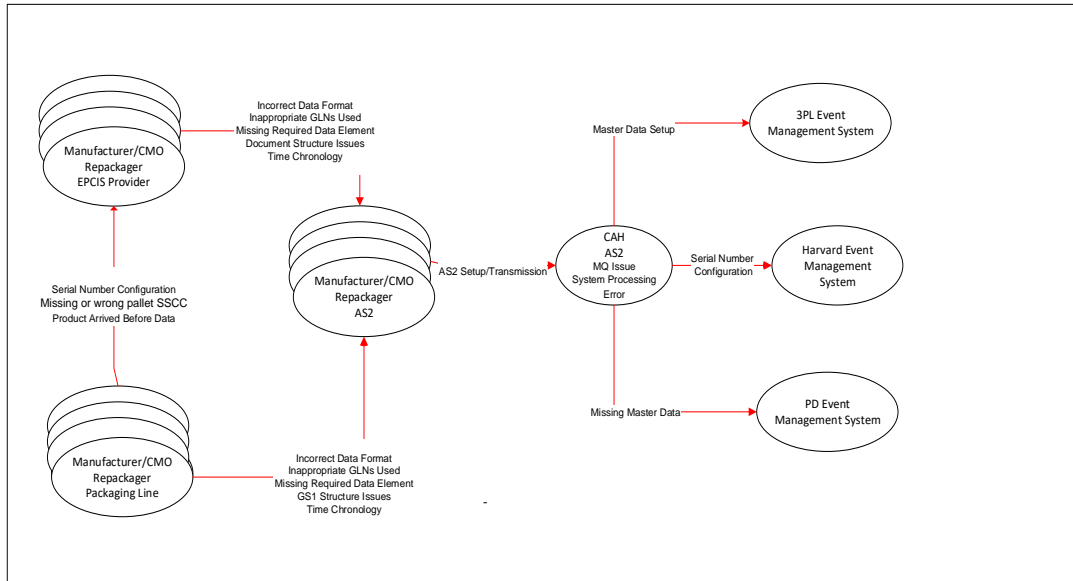
Business Unit	# Data Samples Collected	# of Data Success Samples Collected	# of Data Exception Samples Collected
CHSS 3PL	360	84	276
Major	71	18	53
PD	70	37	33
CHPS	6	3	3

**Table 2 Summary of Data Collected by Cardinal Health Business Unit**



## Analysis of Transmission Exceptions

To analyze the transmission exceptions, we identified the various data exceptions that could occur at each point in the transmission path.



**Figure 2 Data Flow Diagram - Origin of Exceptions**

We identified the transmission exceptions that are defined in the table below:

Error Type	Definition
Event Sequence	Event Times associated with a product are not in expected sequence - commissioning, aggregation, shipping
Inappropriate GLNs Used	EPCIS data file received contained a source owning party/location or destination owning party/location that was inconsistent with master data
Incorrect Data Format	EPCIS data file received contained GS1 syntax violations based on EPCIS version used
Master Data Setup	EPCIS data file received contained was inconsistent with master EPCIS data file setup in event management system
Missing Master EPCIS data	EPCIS data file received contained incorrect or missing master EPCIS data
Missing PO	EPCIS data file received did not contain a purchase order number in the biztransaction data list
Missing Product Identifiers	Barcode on product received was missing product identifier information

Error Type	Definition
No Error	EPCIS data file received contained no exception (SUCCESS)
Product Arrived Before EPCIS data file	Product arrived in the warehouse before the EPCIS data file was received
Serial Number Generation Error	Serial Numbers received in EPCIS data file violated the criteria defined in the serial number policy
Time Chronology	Date/Time recorded for the events received in the EPCIS data file were not in chronology order (commissioning -> packing -> shipping)
XML Structural Issues	EPCIS data file received contained xml data element violations

**Table 3 Glossary of Exception Types**

We were then able to categorize the data sample collected into the defined exception type.

Error Type	# of Data Samples Collected	Percentage of Data Samples Collected
Product Arrived Before Data	114	23%
Time Chronology	44	9%
Missing Master Data	40	8%
GS1 Structure Issues	40	8%
XML Structure Issues	40	8%
AS2 Setup/Transmission	26	5%
Incorrect Data Format	26	5%
Missing Required Data Element	18	4%
Master Data Setup	6	1%
Serial Number Configuration	4	>1%
No Error	3	>1%
MQ Issue	1	>1%
System Processing Error	1	>1%

**Table 4 Summary of Transmission Exceptions**

There were certain exceptions that were common to all business units:

- **AS2 Setup/Transmission** exceptions were common in the initial phase of vendor onboarding but were quickly resolved in order to continue the serialization data exchange. AS2 certificates, URLs and IDs were exchanged and had to be adhered to for the data exchange process to be successful. Cardinal Health provides the AS2 ID and URL in each of its technical guides.

For Cardinal Health Specialty Solutions - -3PL:

- Test Environment: AS2 ID: CARDINAL3PLEPCISTEST  
AS2 URL: <http://stgedigateway.cardinalhealth.com:4080/exchange/CARDINAL3PLEPCISTEST>

- Production Environment: AS2 ID: CARDINAL3PLEPCIS  
AS2 URL: http://edigateway.cardinalhealth.com:4080/exchange/CARDINAL3PLEPCIS

For Cardinal Health Pharmaceutical Distribution- Wholesaler

- Test Environment: AS2 ID: CARDINALEPCISTEST  
AS2 URL: http://stgedigateway.cardinalhealth.com:4080/exchange/CARDINALEPCISTEST
- Production Environment: AS2 ID: CARDINALEPCIS  
AS2 URL: http://edigateway.cardinalhealth.com:4080/exchange/CARDINALEPCIS

For Major Pharmaceuticals:

- Test Environment: AS2 ID: MAJOREPCISTEST  
AS2 URL: http://stgedigateway.cardinalhealth.com:4080/exchange/MAJOREPCISTEST
- Production Environment: AS2 ID: MAJOREPCIS  
AS2 URL: http://edigateway.cardinalhealth.com:4080/exchange/MAJOREPCIS

- **Incorrect Data Format, Missing Required Data Element** and **Time Chronology** exceptions occurred when there were deviations from the **Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability** or use of the **GS1 EPC Information Services (EPCIS) Standard v1.1. Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability** requires using **v1.2**.

Lot #: 678900A

12-09-2019 22:45:07.087	ObjectEvent	RFID21278E: EPC urn:epc:id:sscc: 091091.2143970001 in element epcList is not valid for the IRIS conformance level. RFID04954: Invalid syntax in EPC components "091091.2143970001" RFID04977: Invalid fixed components length 16	urn:ts:capture:ruleFailure	EPC	epcList	urn:epc:id:sscc: 091091.214397000 1
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**Figure 3 Sample Incorrect Data Format Error**

- **Message Queue Issues** exceptions were internal to Cardinal Health's infrastructure. EPCIS events that were sent via an AS2 connection could not be forwarded to the event management system if the Message Queue was inoperable. These exceptions had to be addressed immediately in order to continue to process incoming EPCIS events
- **System Processing Error** exceptions were due to Cardinal Health's event management system inability to process extremely large data files. If incoming EPCIS events contained an OBSERVE event for each serial number  

```
<ObjectEvent>
<eventTime>2019-10-04T13:41:13Z</eventTime>
<eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
<epc>urn:epc:id:sgtin:0355154.096180.40088113485758</epc>
```

```

<action>ADD</action>
<bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
<disposition>urn:epcglobal:cbv:disp:active</disposition>
<bizLocation>
<id>urn:epc:id:sgln:8912345.00004.0</id>
</bizLocation>
<extension>
<ilmd>
<gs1ushc:lotNumber>ASTTST03</gs1ushc:lotNumber>
<gs1ushc:itemExpirationDate>2023-10-31</gs1ushc:itemExpirationDate>
</ilmd>
</extension>
</ObjectEvent>
<ObjectEvent>
<eventTime>2019-10-04T13:41:13Z</eventTime>
<eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
<epc>urn:epc:id:sgtin:0355154.096180.40088113485760</epc>
<action>ADD</action>
<bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
<disposition>urn:epcglobal:cbv:disp:active</disposition>
<bizLocation>
<id>urn:epc:id:sgln:8912345.00004.0</id>
</bizLocation>
<extension>
<ilmd>
<gs1ushc:lotNumber>ASTTST03</gs1ushc:lotNumber>
<gs1ushc:itemExpirationDate>2023-10-31</gs1ushc:itemExpirationDate>
</ilmd>
</extension>
</ObjectEvent>

```

instead of an OBSERVE event that contained a list of serial numbers:

```

<ObjectEvent>
<eventTime>2019-10-04T13:41:13Z</eventTime>
<eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
<epcList>
  <epc>urn:epc:id:sgtin:0355154.096180.40088113485758</epc>
  <epc>urn:epc:id:sgtin:0355154.096180.40098710048660</epc>
</epcList>
<action>ADD</action>
<bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
<disposition>urn:epcglobal:cbv:disp:active</disposition>
<bizLocation>
<id>urn:epc:id:sgln:8912345.00004.0</id>
</bizLocation>
<extension>
<ilmd>
<gs1ushc:lotNumber>ASTTST03</gs1ushc:lotNumber>
<gs1ushc:itemExpirationDate>2023-10-31</gs1ushc:itemExpirationDate>
</ilmd>
</extension>
</ObjectEvent>

```

The size of the data file was enormous causing the Message Queue to timeout before the file finished processing.

- **XML (Extensible Markup Language ) Structure Issues** exceptions occurred when the EPCIS data file received contained xml data element violations

DSCSA00006E: EPCClass vocabulary element urn:epc:idpat:sgtin:\* is not item master or production master: RFID04954: Invalid syntax in EPC components "\*\*\*" RFID04973: Missing component(s) starting at component 2

**Figure 4 Sample XML Error**

There were exceptions that were unique to the individual business units:

- **Master Data Setup** and **Missing Master Data** exceptions were not found in data samples collected from EPCIS events sent to Major Pharmaceutical or to Cardinal Health Pharmaceutical Distribution- Wholesaler. Major Pharmaceutical used an automated data feed to send master data from its enterprise master data repository to its event management system. Due to the high number of manufacturers that wanted to test and send EPCIS data, Cardinal Health Pharmaceutical Distribution- Wholesaler specified in its technical guide (*What You Need Before You Start* , page 3) that: **Cardinal Health requires all vendor and product master data to be specified within the EPCIS file. It is Cardinal Health's interpretation that the master data reside in the electronic file transmission as is done today for lot-level data sent via the ASN.** Since EPCIS events provide a very cryptic view of the product shipped by specifying either an item or case Global Trade Identification Number (GTIN) or the location of where the product was shipped from and shipped to using a Global Location Number, detailed information regarding the product and locations must be available to help warehouse operators and business stakeholders correlate GTINs to NDCs and sglns to manufacturer names and street addresses. Although the Cardinal Health Specialty Solutions – 3PL requested that manufacturers/CMOs send product (NDC, Item GTIN, Case GTIN, Drug Name, Drug Description, Dosage Form and Strength) and location ((S)GLN Type, (S)GLN EPCIS reference, (S)GLN Value, and Company Prefix) master data to initiate the onboarding process, adding the master data to their corporate master data file was a manual process. Cardinal Health Specialty Solutions - 3PL used an automated data feed to send master data from its enterprise master data repository to its event management system. The event management system was dependent on the master data feed from the enterprise master data repository to identify trading partners who were authorized to send EPCIS data to Cardinal Health Specialty Solutions – 3PL. If the event management system could not verify the trading partner using the master data, the EPCIS events failed to process.
- **Serial Number Configuration** exceptions were only found in the data samples collected from Major Pharmaceutical. Major Pharmaceutical defines a serial number policy for each of their GTINs, then assigned the serial numbers to each repackager/CMO. No other Cardinal Health business unit assigns serial numbers to repackagers or CMOs.

The **Product Arrived Before Data** exceptions generated the most attention. Cardinal Health Pharmaceutical Distribution- Wholesaler has not started to reconcile received products with received EPCIS data. Both Cardinal Health Specialty Solutions – 3PL and Major Pharmaceutical reconcile EVERY product received into their warehouse with the EPCIS data received into their event management systems. If there is no EPCIS data found in the event management system, Cardinal Health Specialty Solutions-3PL can receive the product into their inventory, but their manufacturers do not release the products to fulfill customer orders until the product to EPCIS data reconciliation has been completed. Missing EPCIS data will result in the generation of a **Work Order Instruction** to alert the warehouse operations team to notify the manufacturer/CMO that the EPCIS data has not been received.

**WOI (87091 AM ACME Pharmaceuticals INC )Missing EPCIS Data for LOT 678900A  
Figure 5 Sample CHSS – 3PL Work Order Instruction**

Major Pharmaceutical quarantines received products until the EPCIS data is available in the event management system.

## Resolution of Transmission Exceptions

Exceptions that occurred in the non production environment had no impact on operations and occurred during the onboarding process. Upstream trading partners could choose to not resolve an error by correcting existing data or they could send new data with the exception corrected. For exception resolution, we focused on the impact the exception had on warehouse operations.

Error Type	Definition	Impact to Operations
Event Sequence	Event Times associated with a product are not in expected sequence - commissioning, aggregation, shipping	EPCIS document failed to process in CAH event management system
Inappropriate GLNs Used	EPCIS data file received contained a source owning party/location or destination owning party/location that was inconsistent with master data	EPCIS document process in CAH event management system; but serialized product could not be picked because the incorrect GLN provided the wrong business context
Incorrect Data Format	EPCIS data file received contained GS1 syntax violations based on EPCIS version used	EPCIS document failed to process in event management system
Master Data Setup	EPCIS data file received contained was inconsistent with master EPCIS data file setup in event management system	EPCIS document failed to process in event management system

Error Type	Definition	Impact to Operations
Missing Master Data	EPCIS data file received contained incorrect or missing master EPCIS data file	EPCIS document failed to process in event management system
Missing or wrong pallet SSCC	SSCC barcode on the product pallet received was missing or inconsistent with the EPCIS data file received	The scanned barcode will not match EPCIS data stored in event management system Product will not be put into inventory
Missing PO	EPCIS data file received did not contain a purchase order number in the biztransaction data list	EPCIS data will not be visible in internal scanning tool
Missing Product Identifiers	Barcode on product received was missing product identifier information	The scanned barcode will not match EPCIS data stored in event management system. Product will not be put into inventory
No Error	EPCIS data file received contained no exception (SUCCESS)	N/A
Product Arrived Before EPCIS data	Product arrived in the warehouse before the EPCIS data file was received	Product cannot be received and is quarantined until EPCIS data arrives in the Event Management System
Serial Number Generation Error	Serial Numbers received in EPCIS data file violated the criteria defined in the serial number policy	EPCIS document failed to process in event management system
Time Chronology	Date/Time recorded for the events received in the EPCIS data file were not in chronology order (commissioning -> packing -> shipping)	EPCIS document failed to process in event management system
XML Structural Issues	EPCIS data file received contained xml data element violations	EPCIS document failed to process in CAH event management system

**Table 5 Impact of Exceptions**

**Incorrect Data Format, Missing Required Data Element, Time Chronology and XML (Extensible Markup Language ) Structure Issues** exceptions had to be resolved by the Manufacturer IT, CMO IT, Repackager IT or the EPCIS provider. The Cardinal Health IT Support had no control over how long it would take upstream trading partners to resolve an exception and did not alter the contents of any files.

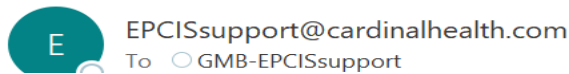
Any exception where the impact was identified as **EPCIS document failed to process in event management system** could result in a **Product Arrived Before Data** exception. The Cardinal Health IT Support team implemented ways to minimize the impact to warehouse operations.

Resolution Location	# of Exceptions Resolved	Percentage of Exceptions Resolved	Elapsed Time until Exception Resolution
UNRESOLVED	113	54%	TBD
CAH IT	62	30%	1 day
EPCIS Provider	24	11%	7 days
Manufacturer	7	3%	6 days
Repackager	3	1%	1 day
CMO IT	1	>1%	5 days

**Table 6 Summary of Exceptions Resolved by Location**

Alerts were implemented to notify the EPCIS support team of a document failure that occurred in the production environment. The alert allowed the IT Support team to try to address the issue, before there was an impact to warehouse operations.

### 3PL EPCIS Alert - PRD



Doc ID	Lot Number	Owning Party	Location	Error Reason
14719	678900A	ACME PHARMACEUTICALS INC	urn:epc:id:sgln:0011111.11000.1	Document failed in EMS

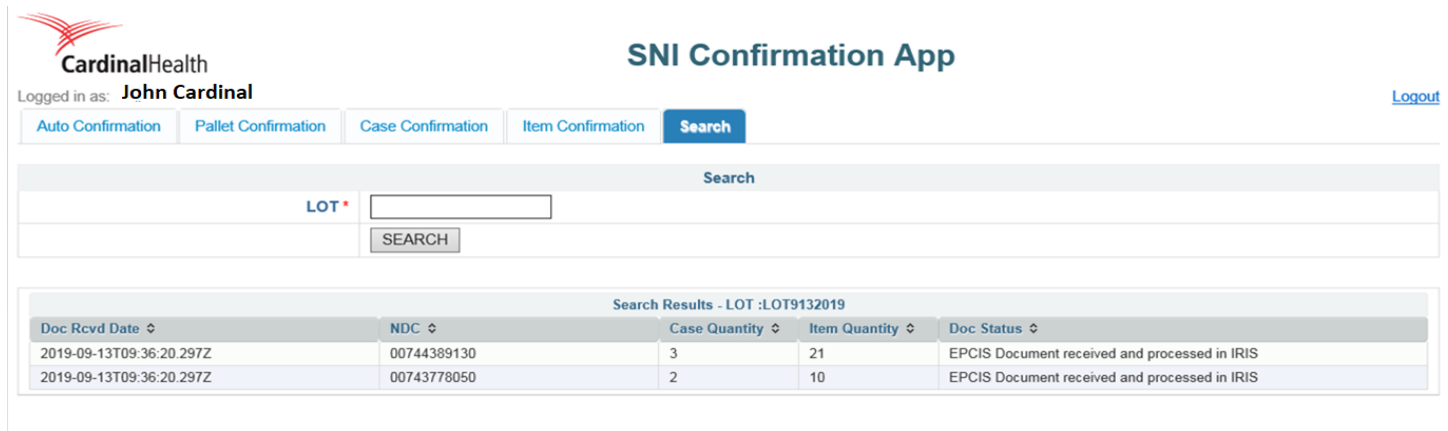
**Figure 6 CAH IT - Document Failure Alert**

Resolutions for the **Product Arrived Before Data** exceptions received the highest priority:

- **Master Data Setup** and **Missing Master Data** exceptions were resolved by CAH IT by manually entering the missing master data into the event management system and reprocessing the EPCIS file. In the case of Cardinal Health Specialty Solutions -3PL, when the inventory management team entered the data in their master data file, the automated data feed would cause an overwrite of the data manually entered in the event management system – this allowed all systems to remain synchronized. Using a master data tool like the Global Data Synchronization Network or HDA Origins would have been ideal, but that solution was deemed out of scope for this pilot.
- **System Processing Error** exceptions were resolved by increasing the size of the message queue and using a preprocessor to compress files before they were pushed to the event management system for processing.



Cardinal Health IT Support also introduced tools that allowed warehouse operations to search for data in the event management system to avoid rework.



**CardinalHealth** **SNI Confirmation App**

Logged in as: **John Cardinal** [Logout](#)

[Auto Confirmation](#)
[Pallet Confirmation](#)
[Case Confirmation](#)
[Item Confirmation](#)
[Search](#)

Search

LOT \*

Search Results - LOT :LOT9132019				
Doc Rcvd Date	NDC	Case Quantity	Item Quantity	Doc Status
2019-09-13T09:36:20.297Z	00744389130	3	21	EPCIS Document received and processed in IRIS
2019-09-13T09:36:20.297Z	00743778050	2	10	EPCIS Document received and processed in IRIS

**Figure 7 Event Management System 'SEARCH' Screen**

## Aggregation Exceptions

Aggregation data samples were collected by scanning barcodes affixed to randomly selected pallets, cases and items of serialized products received in various Cardinal Health warehouses and comparing the scanned barcode data to the aggregated serialized EPCIS events successfully transmitted and processed into the Cardinal Health event management system.

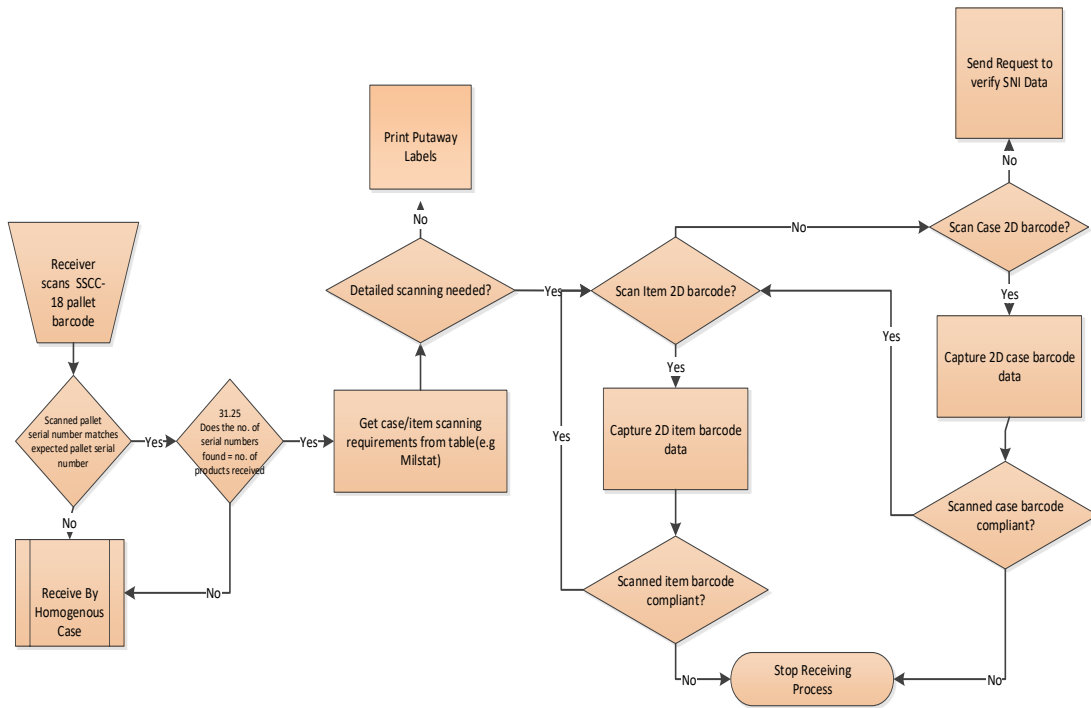
# of Tags Scanned	# of Exception Tags Scanned	Percentage of Total Tags Scanned	# of Successful Tags Scanned	Percentage of Total Tags Scanned
37146	482	1.29%	36664	98.7%

**Table 7 Summary of Aggregation Data Samples Collected**

Cardinal Health Specialty Solutions – 3PL has integrated product/EPCIS event reconciliation into their receiving process. Standard operating procedures state that warehouse operators must scan at the pallet level only. For the purposes of this pilot, Cardinal Health Specialty Solutions – 3PL advised warehouse operators to scan the pallet barcode, then scan multiple case barcodes, open several cases to scan the item barcodes. The additional scanning resulted in 559 data samples representing products from 74 manufacturers/CMOs. The scanned data was then sent to the event management system to verify that EPCIS (packing) aggregation events were accurate. Inaccuracies in the aggregation data will result in the generation of a **Work Order Instruction** to alert the warehouse operations team to notify the manufacturer/CMO that the product and EPCIS data received has reconciliation issues.

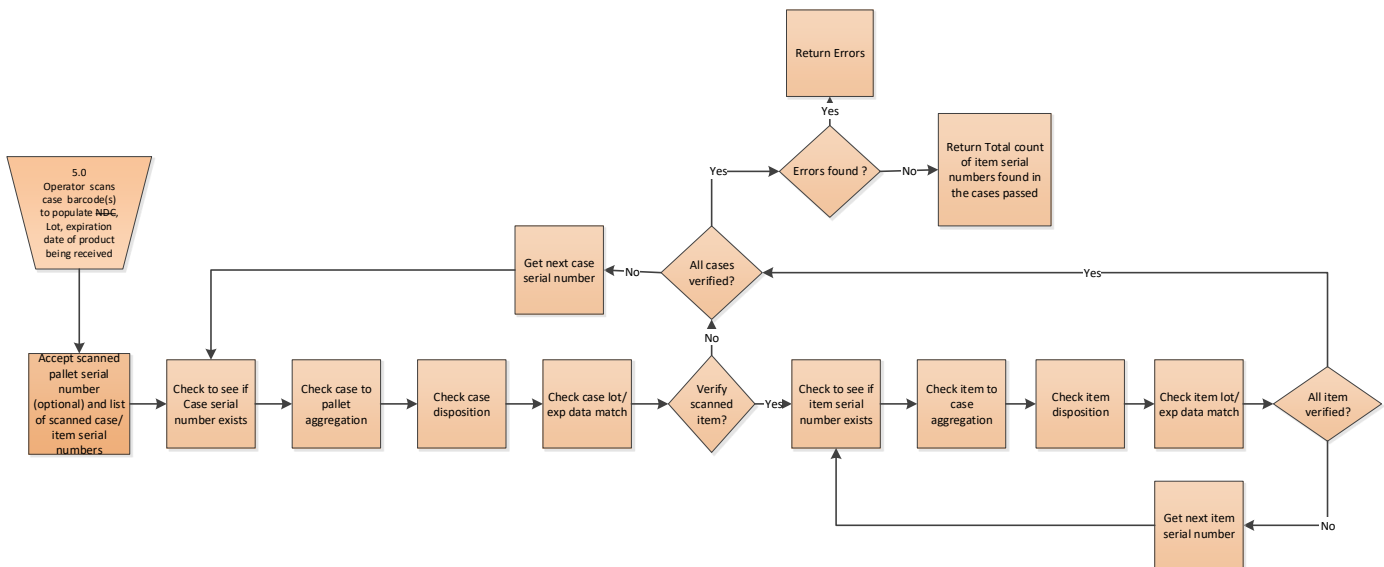
**WOI (87091 AM ACME Pharmaceuticals INC) Serialization Reconciliation  
Figure 8 Sample CHSS – 3PL Work Order Instruction for Reconciliation Issues**

Major® Pharmaceuticals- Repackager has integrated product/EPCIS event reconciliation into their receiving process. Robust “QA Sampling” and “Verify SNI Data” process are also integrated into the receiving process.



**Figure 9 Major Pharmaceutical - QA Sampling Process**

Major Pharmaceutical implemented the QA Sampling process to gather a aggregation verification history that would lead to a “trusted vendor” status for its repackager. The Quality Control sets the scanning sample size per GTIN. During the receiving process, the warehouse operator receives a prompt that additional scanning is required to complete the receiving operation. The scanned barcode data is then sent to the “Verify SNI Data” process to reconcile the barcode data with the EPCIS data stored in the event management system.



**Figure 10 Major Pharmaceutical - Verify SNI Data Process**

The results of the SNI verification process are stored in an exceptions table. The Quality Control team uses the data in the exceptions table to generate an **EPCIS Reliability Report** that will display the results of aggregation verification by NDC or by Repackager.

EPCIS Reliability Report  
Date Range: 12/10/2019  
Repackager: ACME Pharmaceuticals INC

Summary - 91091919900			
Metrics	Pallets	Cases	Items
Total Scanned	4	40	200
Total Scanned - Passed	4	36	152
Total Scanned - Failed	0	4	48

Summary of Failed Events							
Scan Date	Packager	Scanned Serial Number	NDC	Product Name	Lot	Expiration Date	Failure Reason
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:309109.9109199.210	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Case to Item Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.549	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.554	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.571	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.589	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.596	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.571	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.589	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch
12/10/2019	ACME Pharmaceuticals INC	urn:epc:id:sgtin:109109.9109199.596	91091919900	COUGH AND COLD SYRUP	678900A	04/30/2023	Item to Case Aggregation Mismatch

**Figure 11 Sample EPCIS Reliability Report**

Aggregation data samples collected from Major Pharmaceutical were the result of the QA Sampling and Verify SNI Data processes.

Cardinal Health Pharmaceutical Distribution- Wholesaler has not integrated product/EPCIS event reconciliation into their receiving process. Aggregation data samples collected from Cardinal Health Pharmaceutical Distribution- Wholesaler were the result of the product sampling and data verification process very similar to those implemented by Major Pharmaceutical.

All aggregation data samples reflect product barcodes that were actually scanned and reconciled with EPCIS data. No recorded aggregation data samples were the result of inference.

Business Unit	# of Data Samples Collected	Percentage of Data Samples Collected
CHSS - 3PL	0	0%
Major	37046	99.7%
PD	100	0.3%

**Table 8 Summary of Data Collected by Business Unit**

## Identification of Aggregation Exceptions

Error Type	Description
Case to pallet aggregation mismatch	The product identifier data on the scanned case barcode was found in the event management system, but the pallet identified in the packing EPCIS event was not the same as the pallet barcode scanned
EPCIS data not Found	The product identifier data on the scanned barcode was not found in the event management system
Invalid barcode	The scanned barcode does not meet GS1 barcode specifications
Item to case aggregation mismatch	The product identifier data on the scanned item barcode was found in the event management system, but the case identified in the packing EPCIS event was not the same as the case barcode scanned
Scanned Barcode is not an Item	The GTIN extracted from the scanned barcode does not match the item GTIN stored in master data
Scanned Expiration Date does not match the Expiration date found in EPCIS data	The GTIN/Serial Number on the scanned barcode was found in the event management system, but the Expiration Date identified in the commissioning EPCIS event was not the same as the Expiration Date extracted from the scanned barcode
Scanned Lot does not match the Lot found in EPCIS data	The GTIN/Serial Number on the scanned barcode was found in the event management system, but the Lot identified in the commissioning EPCIS event was not the same as the Lot extracted from the scanned barcode
Scanned Serial Number, Lot and Expiration Date does not match with EPCIS data	The product identifier data on the scanned barcode does not match the EPCIS data stored in the event management system
SNI Disposition is invalid but other SNIs belonging to this lot with valid disposition exist	The product identifier data on the scanned barcode was found in the event management system but it was not in the correct disposition to support the current warehouse operation, there were other products found in the event management with the same GTIN, Lot and Exp Date that could be used

SNI Disposition is invalid No other SNIs belonging to this lot with valid disposition exist	The product identifier data on the scanned barcode was found in the event management system but it was not in the correct disposition to support the current warehouse operation, there were no other products found in the event management with the same GTIN, Lot and Exp Date that could be used
SNI Found, but no item to case aggregation found	The product identifier data on the scanned barcode was found in the event management system but no item to case packing event was found
Unacceptable EPCIS Disposition	The status of the scanned barcode data is not in the correct state to complete the current business process

**Table 9 Glossary of Aggregation Exception Types**

## Analysis of Aggregation Exceptions

Packaging Level	# of Tags Scanned	# of Exception Tags Scanned	Percentage of Exceptions Tags Scanned	# of Successful Tags Scanned	Percentage of Successful Tags Scanned
Item	19776	186	0.94%	19589	99.05%
Case	15280	286	1.87%	14994	98.1%
Pallet	2090	10	0.48%	2080	99.5%

**Table 10 Summary of Data Collected By Packaging Level**

Exception Type	# of Data Samples Collected
Item to case aggregation mismatch	170
EPCIS SNI Data Not Found	147
SNI Not Found and No other SNIs belonging to this lot with valid disposition exist	82
SNI Disposition is invalid No other SNIs belonging to this lot with valid disposition exist	20
SNI Disposition is invalid but other SNIs belonging to this lot with valid disposition exist	18
Case to pallet aggregation mismatch	12
Scanned serial number Lot and exp date does not match with SNI Data returned	11
SNI Not found but other SNIs belonging to this lot with valid disposition exist	8
Scanned Lot does not match Lot in EPCIS Data	6
Scanned Expiration date does not match Expiration Date in EPCIS Data	3
Scanned Barcode is not an item	2
SNI Found, but no item to case aggregation found	1

**Table 11 Summary of Data Collected by Exception Type**

## Resolution of Aggregation Exceptions

We focused on resolutions for the **Item to case aggregation mismatch**, **EPCIS SNI Data Not Found** and **Case to pallet aggregation mismatch** exceptions. To address an **Item to case aggregation mismatch**, Major Pharmaceutical sends a request to the event management system to disaggregate the items from the case and to decommission the case serial number. The **EPCIS Reliability Report** provides a basis to regroup with their CMOs on product aggregation/EPCIS events. To minimize the impact of the **EPCIS SNI Data Not Found** exception during the receiving process, Cardinal Health IT Support introduced tools that allowed Major Pharmaceutical and Cardinal Health Pharmaceutical Distribution- Wholesaler warehouse operations to search for data in the event management system before trying to receive products to avoid rework.

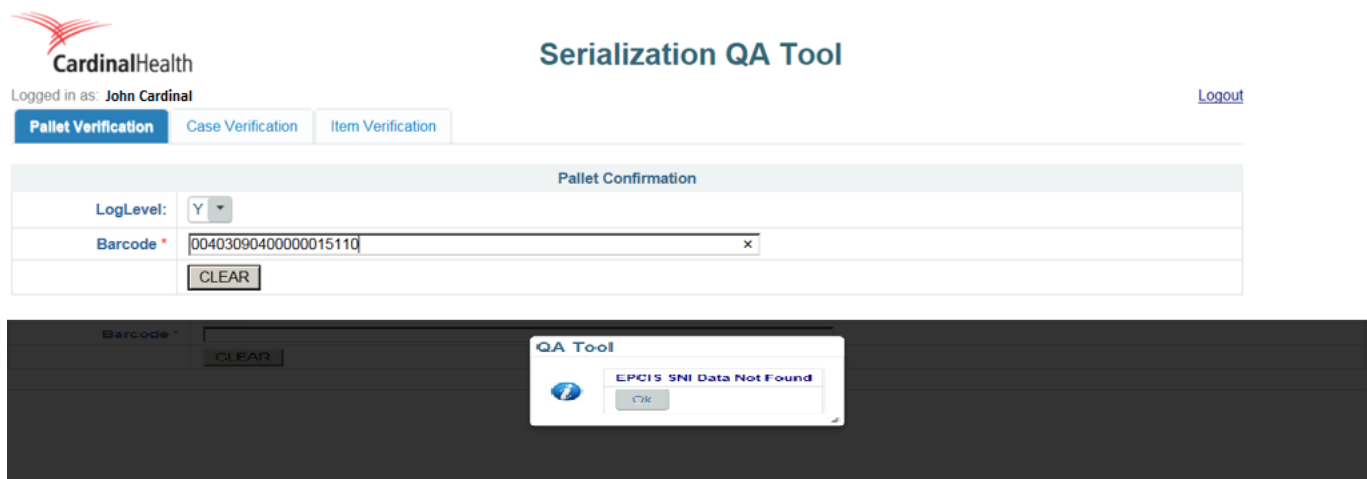
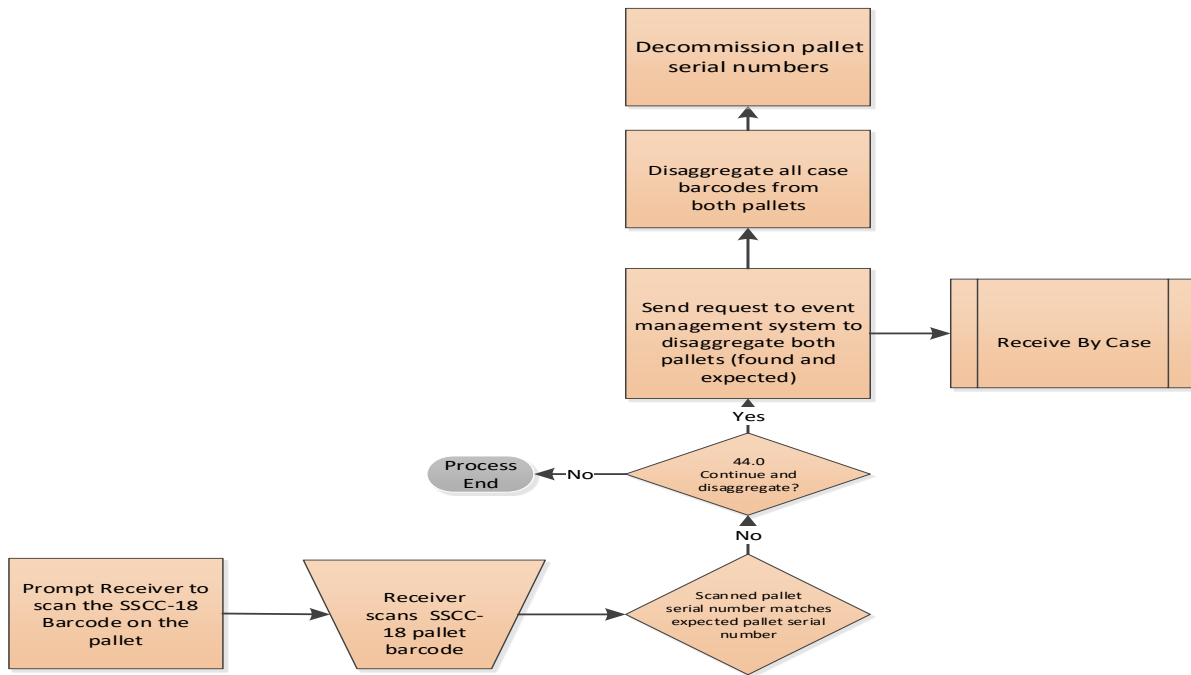


Figure 12 Sample QA Tool Response

To address **Case to pallet aggregation mismatch** exceptions, Major Pharmaceutical has included functionality in its receiving process to disaggregate cases from pallets and to decommission pallet serial numbers when the scanned product barcode does not match the EPCIS data stored in the event management system:



**Figure 13 Major Pharmaceutical - Disaggregation/Decommission Process Segment**

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