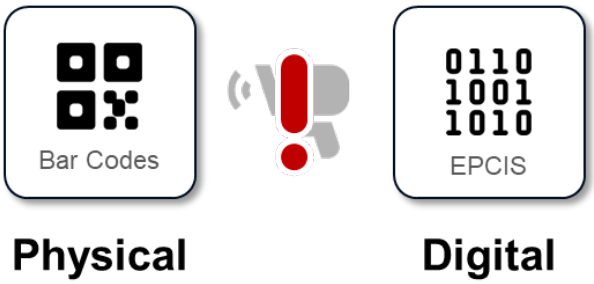
Exception Pilot

Preparing the Industry for the Final Phase

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1. Executive Summary

The annualized serialized data exchange requirements for Drug Supply Chain Security Act (DSCSA) compliance can be described as tracking and tracing trillions of serial numbers over billions of transactions across over one hundred thousand trading partners in near real-time. An error rate of less than one percent of overall transaction volume would require trading partners to deal with more than a million potential issues. This will quickly overwhelm the support and technology platforms required to address transactional exceptions and result in inefficiency, waste, and drug shortages.

This Pilot engagement is an open collaboration across manufacturing, wholesaler, dispenser, and solutions provider participants collaborating on a shared framework for addressing DSCSA exceptions and error corrections. The Pilot team developed a methodology for **Catching** and detecting error conditions for serialized data exchange, **Collaborating** and communicating with trading partners in a clear and concise manner, and **Correcting** transaction data to facilitate further distribution, and eventual use. The Pilot team has also identified the current industry capabilities to correct simple transactional errors and limitations associated with corrections that will require business rule changes.

2. Overview

2.1. Purpose

Exceptions may impact
10%-20%
of receipts...

But will consume
80%-90%
of our time

Missing or incorrect EPCIS data is placing a heavy strain on the DSCSA supply chain. Kaiser Permanente estimates that although exceptions are estimated to impact only 10-20 percent of receipts, it will consume 80-90 percent of their time to correct the issues.

With the guidance of Kaiser, Walgreens, and Option Care, an Exception Pilot was initiated to understand better how exceptions will impact the supply chain. Although the exception use cases start from the point of view of the Dispenser, the Exception Pilot considers the entire DSCSA supply chain since all trading partners must work together.

Many different industry groups have provided guidance and recommendations to help facilitate quick identification and resolution of these errors. The target audience of this pilot initiative includes industry participants utilizing EPCIS data transmissions between solutions providers that represent their trading partner customers. Many of the concepts outlined in this document are also applicable to trading partners utilizing vendor portal-based solutions, but since portals are platform-specific, individual implementations will vary.

The goal of the Exception Pilot is to *enable* readiness to manage exceptions by *accelerating the adoption of industry best practices.* The pilot effort will not define new standards but, instead, will implement standards and recommendations provided by GS1, HDA (Healthcare Distribution Alliance), PDG (Partnership for DSCSA Governance), and NABP (National Association of Board Pharmacy).

Goal of the Exception Pilot

*"**Enable readiness** to manage exceptions by **Accelerating adoption** of industry **best practices**."*

By implementing industry recommendations, the Exception Pilot will help the industry validate the concepts in a real-world environment and serve as a catalyst for the adoption of a common exception-handling process across the industry.

2.2. Exception Conditions

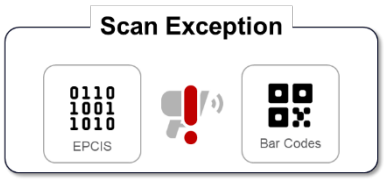
An exception occurs when physical and digital DSCSA information does not match. The industry has classified these exceptions into two categories: 1) Product no Data (PnD) and 2) Data no Product (DnP). Additionally, exceptions can also occur at two different levels, at the file level (File Exception) or *within* the file (Scan Exception).



An exception occurs when the digital EPCIS file does not arrive with the physical shipment/pallet.

This occurs when EPCIS data has not been sent or cannot be ingested. A File Exception is the most critical because it **impacts ALL items** and stops shipment/pallet from being processed.

The industry understands File Exception because it is occurring daily today. It is corrected by sending a valid EPCIS file or returning the shipment/pallet.



An exception occurs when scanned items do not match at the digital and physical level.

This occurs after EPCIS data has been ingested BUT the Digital/Physical serial numbers do not match when scanned. This exception **impacts SOME items** and will be the most difficult to resolve.

There is very limited "real-world" experience with Scan Exceptions. It is corrected by sending valid EPCIS data only for the specific exception items.

File Exceptions are already being addressed by the industry as part of its efforts to meet the November 2023 deadline and are expected to stabilize over time. It is important to note that File Exceptions manifest as missing files in EPCIS data exchange environments, which can be caused by no file transmitted, timing of file transmissions, malformed files, and/or master data errors like GLNs, and GTINs. The current error rate for File Exceptions is between **10-20%** of transmitted data.

The corrective action associated with addressing File Exception issues would normally be addressed by solutions providers collaborating to identify missing and malformed file data issues, correct the root cause, and retransmit the corrected file.

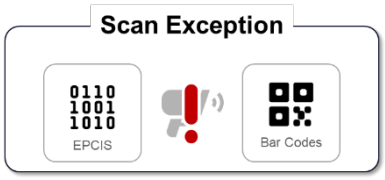
The focus of this pilot is on Digital/Physical Exception because it has not received as much attention as the previous conditions and will be the most difficult to identify and resolve. The Pilot also tested the Data no Product exception, but this creates fewer issues from a legal and commercial perspective given the fact that no product is received without any EPCIS. Enabling a rapid resolution of exceptions regardless of how they occur is important to ensure the continued flow of medicines. It is important to note that the percentage of Scan Exceptions **CANNOT** currently be calculated due to a lack of sufficient real-world serialized data being transmitted between trading partners.

2.3. Three C's

The Exception Pilot is focused on three critical phases of Exceptions (the three Cs):



CATCH the Errors

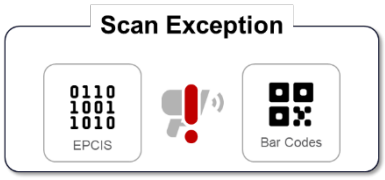


Focus testing on Scan Exceptions with a bias for Product no Data error conditions.

Antares Vision Group has agreed to guide this effort by sharing its internal testing processes and tools for testing Scan Exceptions.



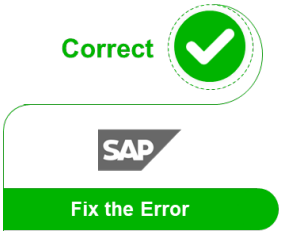
COLLABORATE on Root Cause



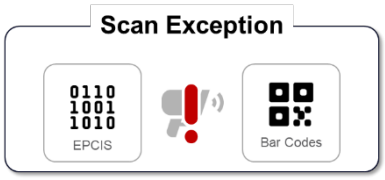


Pilot industry recommendations to improve collaboration for exceptions. This effort benefits both File and Scan Exceptions.

Movilitas.Cloud is integrated with NABP. LedgerDomain led the PDG effort to make JSON a possible standard for collaboration. Both solution providers will lead the exception collaboration effort.



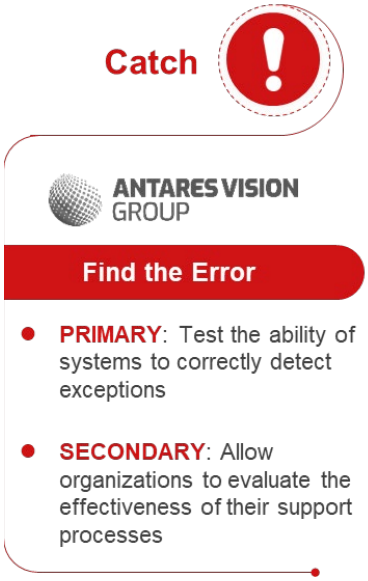
CORRECT the Errors



Pilot using standard EPCIS to correct errors that occur due to Scan Exceptions.

SAP led the effort to use standard EPCIS to correct Scan Exceptions and has agreed to lend their expertise to the Exception Correction effort.

3. Exception Pilot - Catch



The Catch phase of the Exception Pilot is intended to test Scan Exceptions with a focus on testing common conditions that can occur:

- Shortage – Buyer Orders 10; Seller Ships 9
- Overage – Buyer Orders 10; Seller Ships 11
- Invalid Lot – Digital/Physical Lot information does not match
- Returns – Missing EPCIS cannot be sent; Item replaced with a new item
- Invalid Aggregation – Aggregate to wrong case; Possible suspect product

The primary purpose of this phase is to provide processes and tools to enable DSCSA supply chain participants to; create and test exception handling conditions at the lower item level instead of the higher aggregated level.

By enabling this type of testing, the Exception Pilot would meet its secondary objective of allowing DSCA trading partners to evaluate the effectiveness of their support organizations in responding to and assessing the root cause of Product no Data issues.

The Catch/Detection process is the inciting event that kicks off the error correction process (Collaborate and Correction) and it is important to understand that the timeline for a correction is a factor that will ultimately determine if the medication can continue forward in the supply chain or result in a salable or non-salable return. Additionally, current industry guidance requires that products without appropriate product tracing data must be treated as suspect or illegitimate if the transaction is more than ten days old.

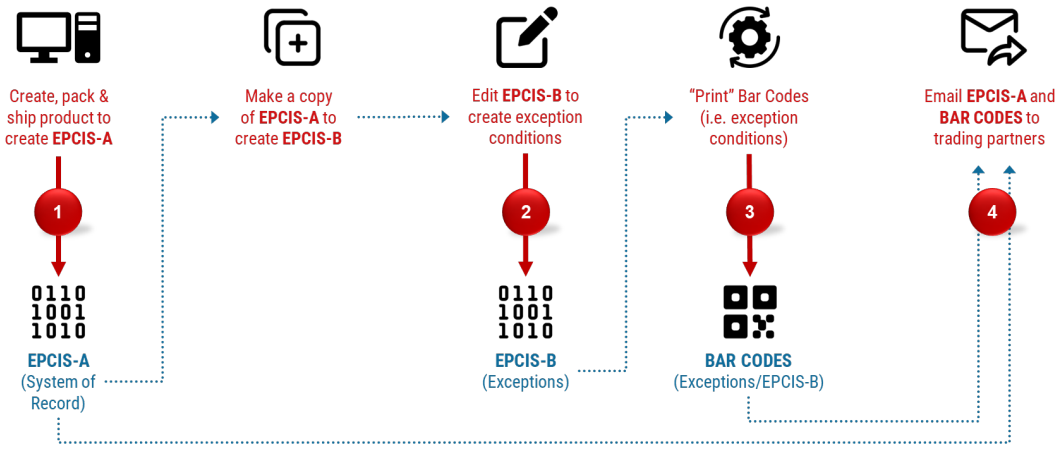
… product without appropriate product tracing data **must be treated as suspect or illegitimate** if the transaction is **more than ten days old**

Catching or detecting an exception error condition will primarily occur in either the receiving process or the outbound shipping process. The shipping process exception detection condition will be the result of trading partners receiving based on inference and discovering that data associated with the product is either missing or incomplete. It is possible that an exception condition that is Caught during the shipping process may be outside of the ten-day regulatory window and will need to be quarantined and investigated as potentially suspect or illegitimate.

3.1. Approach

3.1.1. New Process & Tools

Creating test conditions for Scan Exceptions required new processes and tools for all pilot participants. Scan Exceptions required digital information (i.e. EPCIS files) and a physical representation (i.e. printed bar codes) of the pallets, cases, totes and items that were shipped or received. Antares Vision Group created a test process and tools to enable this. This was shared with the Exception Pilot group.



1 **Create Digital Shipment** – Each participant used their own compliance solution to generate the items, cases and pallets for shipment. The product of this test step was an EPCIS file (i.e. EPCIS-A) that represented the required DSCSA compliance report to be sent to the downstream partner.

2 **Create Exception Condition** – A copy of the EPCIS file is made from the previous step (i.e. EPCIS-B) and edited to create the exception condition. The edits depend on the error condition being tested. This could result in an item or case being removed from the tray or different serial numbers being added to a case or pallet.

3 **Create Physical Shipment** – The file (i.e. EPCIS-B) containing the exceptions is processed by a Bar Code generator tool to create a physical PDF document with all barcodes for the pallet, cases and items. This PDF document allows users to simulate the actual physical products shipped to trading partners.

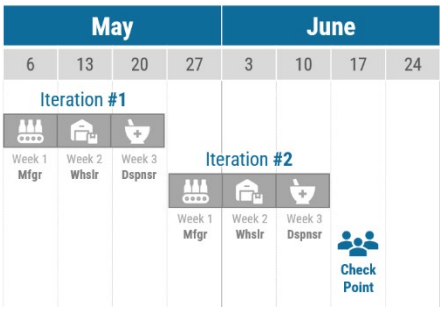


4 **Ship Physical & Digital Pallet** – The DSCSA compliance report (i.e. EPCIS-A) and the PDF document representing the physical pallet, cases and items are emailed to the next trading partner for testing. The physical serial numbers are scanned and compared against the received EPCIS to test the ability of downstream systems to detect various exception conditions.

3.1.2. Timing & Iterations

This phases focused on testing the ability of systems to CATCH exceptions. The pilot team completed two rounds of iteration testing. Each iteration occurred over 3 weeks. Manufacturers tested in Week 1; Distributors tested in Week 2; Dispensers tested in Week 3.

Solution partners in the tests included Antares Vision Group, Movilitas.Cloud, and Gateway Checker.



Iteration #1	Iteration #2
OVERAGE (PnD) – Buyer Returns the Overage Test overage condition where Seller ships more than ordered. Test overage of Aggregated item (e.g., Case) and Single item (e.g., bottle/each). Buyer will RETURN the overage.	**OVERAGE (PnD) – Buyer Returns the Overage** <Repeat OVERAGE test from Iteration #1>
SHORTAGE (DnP) – Seller Sends MISSED ITEM Test shortage condition where Seller ships less than ordered. Test shortage of Aggregated item (e.g., Case) and Single item (e.g., bottle/each). Seller sends item that MATCHES the EPCIS data	**SHORTAGE (DnP) –Sell Sends REPLACEMENT** Test shortage condition where the Seller ships less than ordered. Test shortage of an Aggregate item (e.g., Case) and a Single item (e.g., bottle/each). Seller sends DIFFERENT item that DOES NOT MATCH EPCIS data
INVALID LOT – Invalid Lot; Detect Error and Correct EPCIS Traceability data contains incorrect lot information for the entire shipment:	**Agg Error (PnD/DnP) – Physical & Digital Agg Does Not Match** Test the condition where the Physical contents of the aggregated items do not match the Digital EPCIS information: 1) Valid Item ID but it was aggregated into a DIFFERENT Case 2) Valid Item ID but it was NEVER aggregated into a Case or shipped 3) Incorrect Item ID does not match any manufacturer serial number (i.e. possible suspect product)

3.2. Results

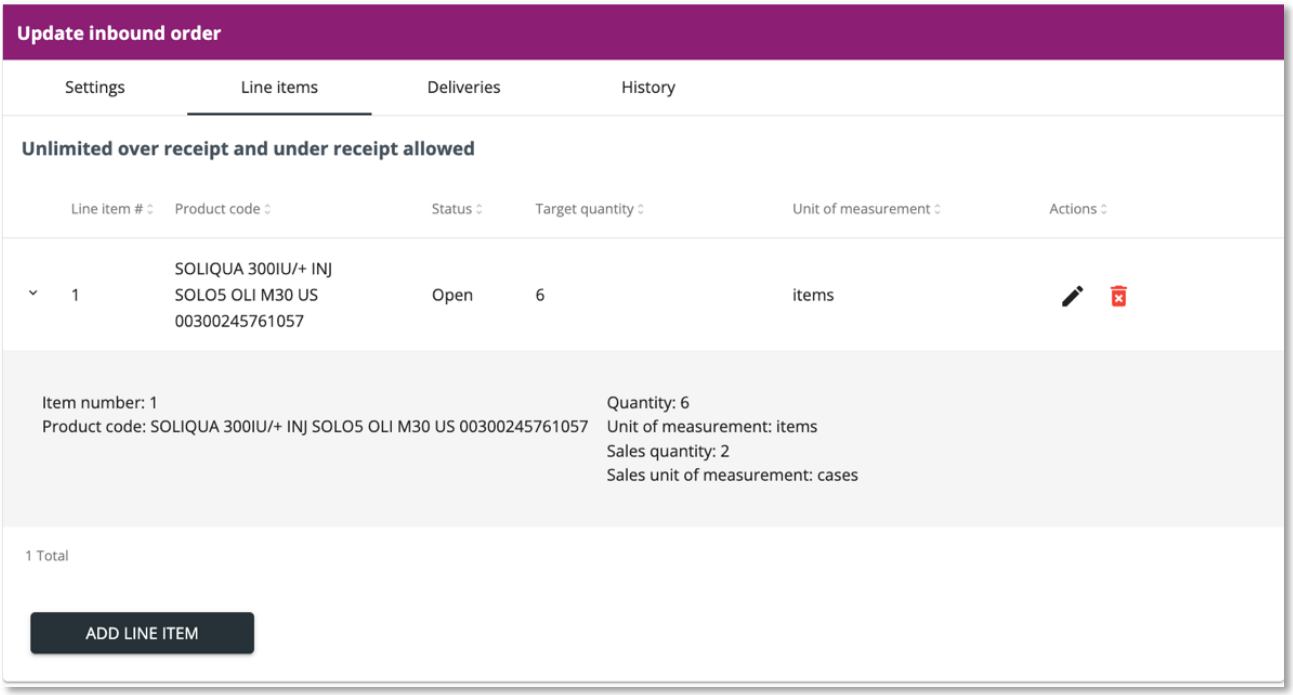
All participants were able to catch the exception conditions outlined in Iteration #1 and #2 of these test cases. How these conditions were detected and managed varied by the solution provider. The most important aspect of the testing, however, was observing how many of the test conditions were indistinguishable from each other. Moreover, the testing approach was critiqued by industry participants who helped to describe real-world outcomes versus structure test outcomes. These learnings are documented in the subsequent "Learnings" section below.

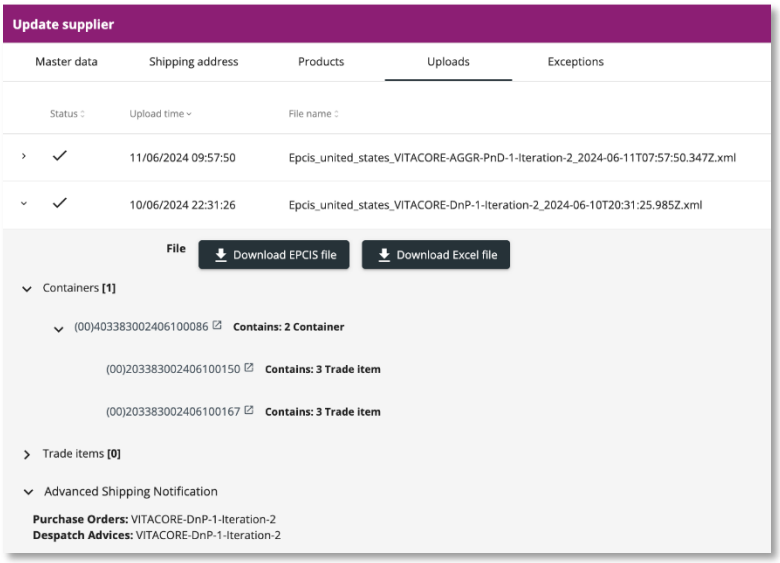
To provide the industry with insight regarding the results of this test, Movilitas.Cloud has outlined a detailed flow of how Exceptions are managed in their system. Movilitas.Cloud used one of its virtual tenants, VitaCore Distribution, to illustrate the testing results.

In these two iterations, VitaCore Distribution received products from two manufacturers: Sanofi and Engineering Industries Excellence (another virtual tenant of Movilitas.Cloud). VitaCore always ordered 6 items: The manufacturers always delivered the products in cases marked with an SSCC, where each case was supposed to contain 3 items, and the cases were always delivered on a pallet marked with an SSCC.

3.2.1. Iteration #1

VitaCore always placed an order for 6 items as described above and because every case contains 3 items, they expect 2 cases (sales unit). For this order, a corresponding inbound order can be created to allow the warehouse to receive the goods:

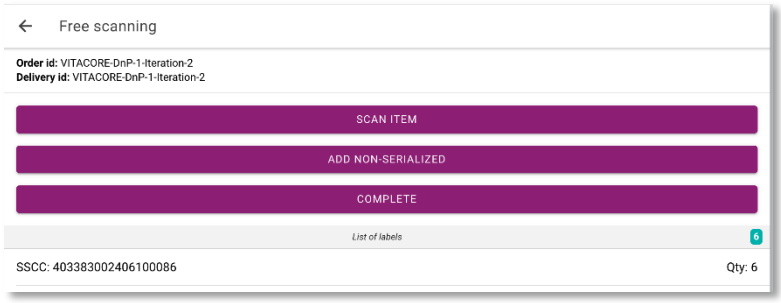


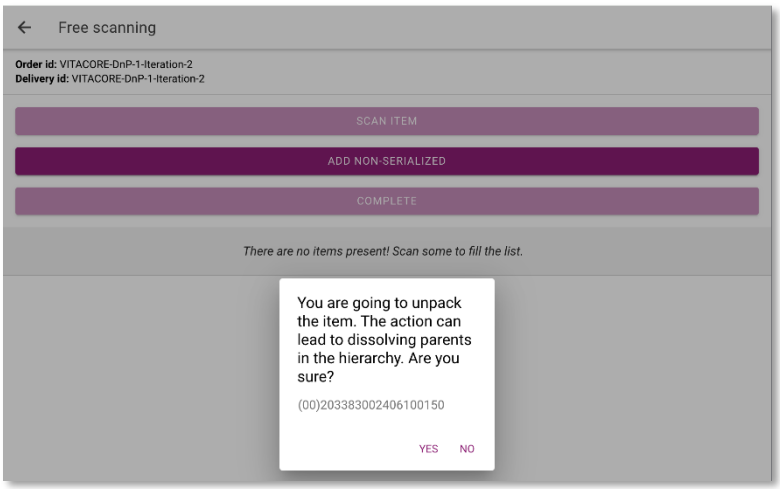


VitaCore should now receive an EPCIS file with the details of the shipment before the goods physically arrive. The format of the file is verified and checked for completeness of data and processed to extract details of the expected shipment.

According to the EPCIS data, the two cases each contain 3 trade items, and they are delivered on a pallet.

However, a pallet with only one case on it (Data no Product condition) was received. If the warehouse would scan the pallet, this error cannot be detected because decisions can only be based on current EPCIS information:



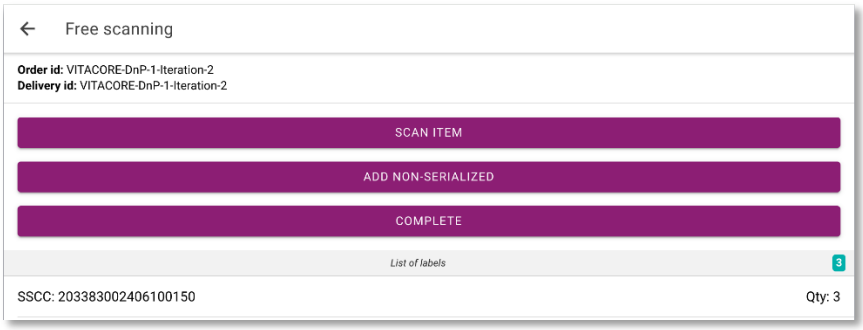


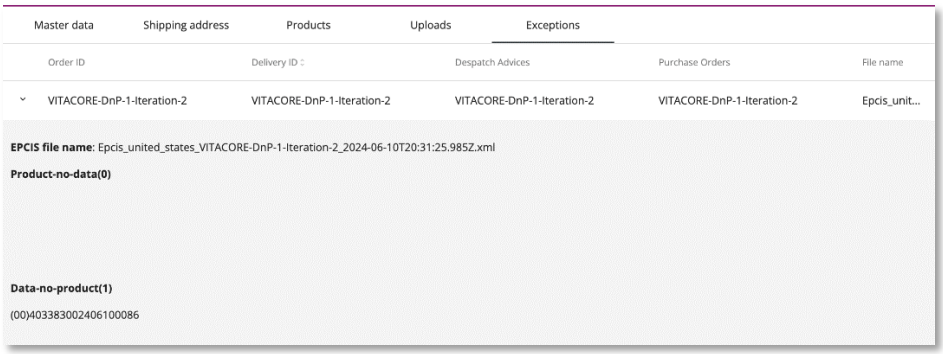
Because the warehouse was expecting two cases instead of one, they decided to scan at a lower level and scan the case.

The scanned case is however linked to a parent container, the pallet. For that reason, a warning is given that the case will be unpacked from the pallet.

Depending on the settings, this can also lead to a decomissioning of the parent.

Now the case is removed from the pallet and the case can be received:



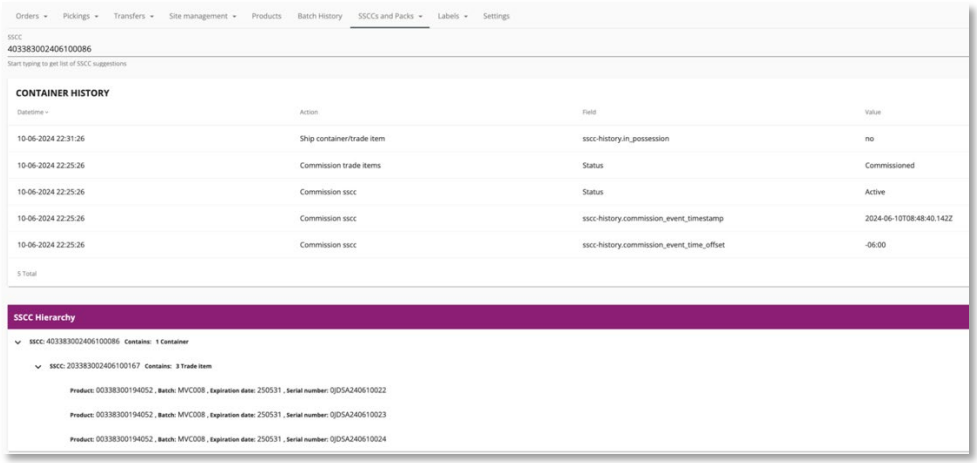


Because there is only one case that was delivered, we should complete the receipt. This causes the system to detect that one case was not part of the delivery and we have a DnP exception.

Two conclusions:

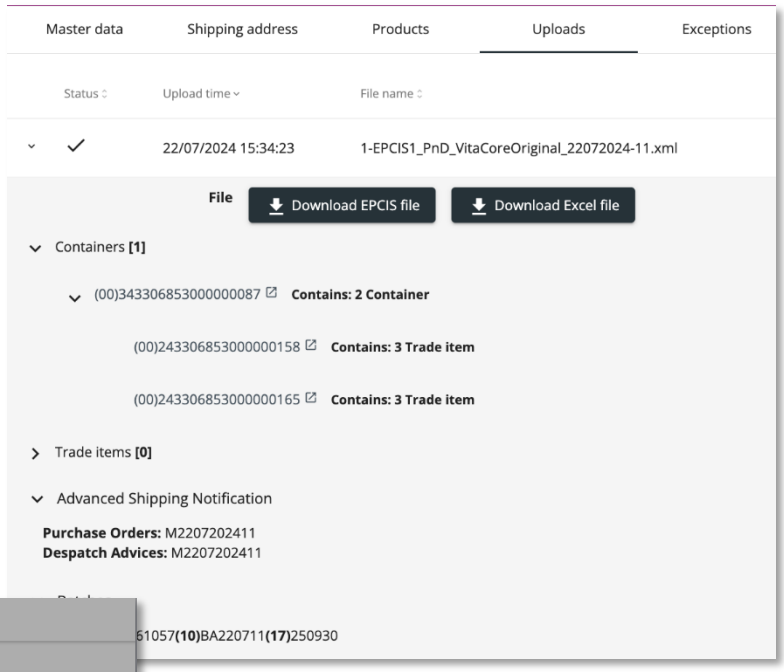
- Scanning at the highest level is the most efficient but can lead to having incorrect data in stock. This can be detected on outbound when aggregations are broken or later in the supply chain when items are unpacked. So having correct EPCIS is of major importance, especially when we are dealing with aggregated trade items.

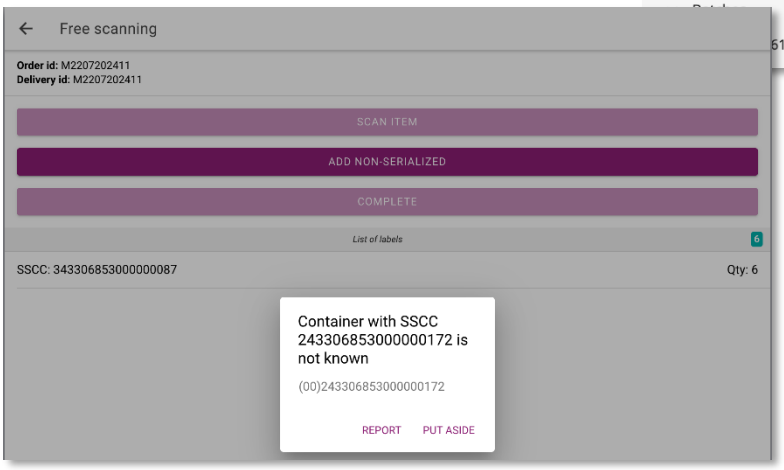
- Even though DnP doesn't give any issues from a DSCSA point of view it might create issues between systems, so it is important to discuss with the supplier how to solve this. In principle, the following was still expected, so the question is if this product left the supplier:



3.2.2. Iteration #2

We placed the same order at Sanofi and received an EPCIS that seems correct again:

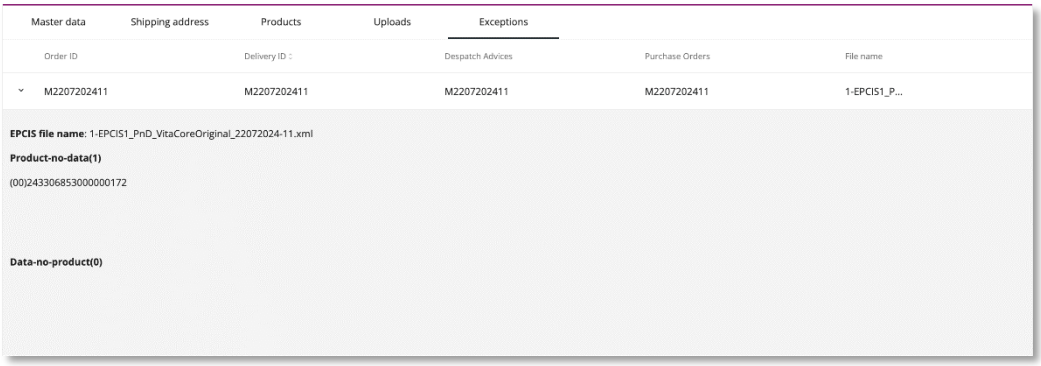




Scanning the Pallete once again doesn't detect the error, but the warehouse noticed three cases on the pallet, while the expectation was only two.

To find the wrong case the operator must scan the cases. If the scanned case is in the EPCIS there is no issue, but if the case scanned is not in the EPCIS the following message gets generated:

The warehouse decided to report this, and we have an exception:



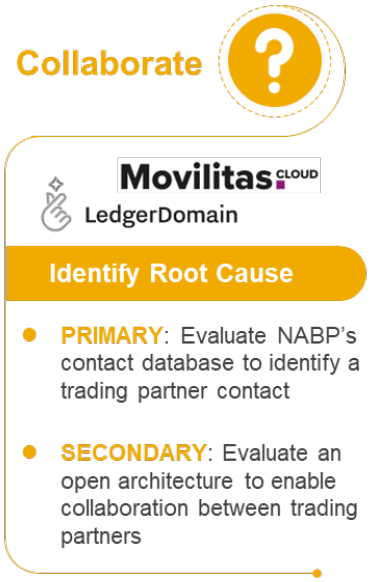
Two conclusions:

- Scanning at the highest level is the most efficient process but can lead to having products in stock that were not allowed to be received. This can be detected on outbound when aggregations are broken or later in the supply chain when items are unpacked. So having correct EPCIS is of major importance, especially when we are dealing with aggregated trade items.
- PnD is an issue from a DSCSA point of view because we have products without an EPCIS, so we are not allowed to accept these products. This needs to be resolved with the supplier.

3.3. Lessons Learned

1.	**Root Cause is Not Obvious**	Detecting the root cause of errors is easy only on paper. During pilot testing, Product no Data issues had multiple root causes that were not easy to discover, especially when errors occurred further up the supply chain
2.	**Higher Returns are Expected**	Dispensers who reviewed the results of the Exception Pilot noted that pharmacists are likely to place a second order for products while awaiting corrections to the digital data. The dispenser will return one of the items depending on which arrives first. This may result in increased products in the supply chain.
3.	**Returned Overages May Deviate From Best Practices**	Although it is not a Product no Data condition, the Pilot tested overage conditions (e.g. Buyer orders 10 items but receives 11 items). In an overage condition, we assumed that the extra item had no matching digital record. The best practice test case is to scan all items to determine and return the item that did not have a matching digital record. Upon review of this test case, dispensers indicated that it is highly likely that users will return any item and may not return the overage item with missing digital data. The impact to the Seller will depend on their processes for managing this condition.
5.	**Receive by Inference**	Receiving and shipping items by inference is mandatory due to the high volume of products in the DSCSA supply chain. At each point of our testing effort, the pilot team paused and asked, “What would a regulator see if he/she asked for a traceability report.” As we traced the Scan Exceptions up the supply chain, it was important to distinguish whether an item was received/shipped based on inference or an actual scan of the item. Discerning how an item was received/shipped added significant insight when communication with a regulator is required.

4. Exception Pilot – Collaborate



Exceptions are triggered by compliance applications when the electronic data does not match the physical receipt. The resolution of the exception, however, always requires some human intervention to determine the root cause and appropriate remediation.

The "Collaborate" phase of this Pilot is focused on clearly communicating exceptions so that human resources can quickly resolve issues and allow the continued movement of DSCSA products through the supply chain.

A foundational step to collaboration is to initiate contact with the sender of the product. This, however, may not be a simple task depending on the number of trading partners in the ecosystem. To support this foundational first step, a primary objective of Collaborate is to evaluate the use of NABP's PULSE contact database for email contacts. NABP's PULSE contact database provides access to user-friendly tools and a comprehensive network of verified relationships, enabling consistent communication with trusted partners across the supply chain. Once the proper contact has been identified, a collaboration with the trading partner can be initiated. A secondary (but very) important goal for this phase is to identify/test a collaboration approach that is accessible to all and will allow both parties to maintain a log of the discussion to support future audit needs.

The Collaborate phase of the Industry Exceptions process is the critical bridge between trading partners and their solutions providers that will unlock success or guarantee failure of the process resulting in product returns. The industry will, unfortunately, utilize **email** communications between trading partners to facilitate the collaboration process, which poses security and standardization risks.

Alternatively, some trading partners utilize portals to facilitate collaboration and correction processes, which pose other issues that potentially further delay the correction process. Trading partners must be clear and specific in their email communications about the scope of the exception and recommended corrective action.

…must be **clear and specific** in their email communications about the scope of the exception and **recommended corrective action**

Additionally trading partners will need to provide supporting technical transaction details, which may include EPCIS, PDF, or Excel attachments. This pilot team has leveraged some of the advanced work developed by Ledger Domain, incorporating JSON into the human-readable messaging components and associated supporting attached data to facilitate technical automation. It is important to note that the JSON work leveraged in this pilot is an OPTIONAL alternative to addressing trading partner collaboration and is not a mandatory standard.

4.1. Approach

When an exception occurs, a collaboration must occur between the Buyer and Seller to determine what has occurred and how it must be corrected. This collaboration must occur between two people. Technology can simplify collaboration or speed-up root cause analysis, but it cannot replace the work required by people. This principle instilled a "keep it simple" approach to this segment of the pilot.

In order for effective collaboration on exceptions, this pilot focused on two key requirements:

4.1.1. Collaboration Contact

When an exception occurs between the Buyer and Seller, the Buyer must contact a person within the Seller organization who is responsible for addressing exceptions. Until recently, finding the contact was not simple since there was no public contacts database for DSCSA.

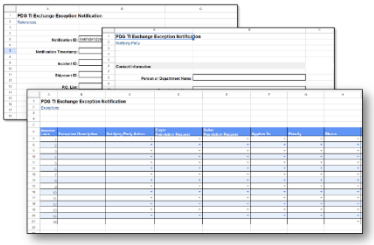
The NABP has offered a self-maintained database for DSCSA trading partners to find other DSCSA contacts. This pilot tested the technology and approach on how to find collaboration contacts.

4.1.2. Collaboration Content

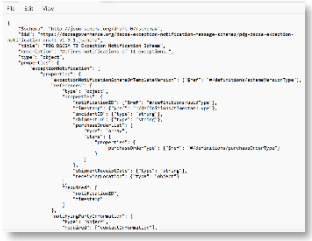
Once a contact has been found, a collaboration can begin determining the cause and resolution of the exception. To enable faster resolution, this pilot is leveraging work done by the PDG (Partnership for DSCSA Governance) to identify common, standard information that should be exchanged between the Buyer and Seller.

Email has been selected as the standard channel for exception collaboration.

1. **Email** is the primary form of communicating exceptions since humans must be involved to determine the resolution.
    a. PDG has drafted Excel templates to use for communicating exceptions. The pilot will use the examples as a starting point to identify the recommended information in the email.



2. **JSON** is an *additional* method of communicating exceptions, not an *alternative* method. It is not a replacement for email.
    a. It offers the opportunity to automate the processing if desired by a trading partner
    b. We are not expecting/requiring any trading partner to send/receive JSON
    c. Our purpose is to confirm that the proposed JSON standard can be implemented if desired



4.2. Results

4.2.1. Contact Lookup

Pulse Status: Movilitas Client	
Ready for TI/TS exchange (EPCIS)	10/31/2024
Contacts	• Type: Trading partner communications: General • Name: DSCSA Inbox • Phone: 5555555555 • Email: DSCSAinbox@Pulsetesting10800.pharmacy • Type: Pulse profile access requests • Name: DSCSA Inbox • Phone: 5555555555 • Email: DSCSAinbox@Pulsetesting10800.pharmacy
GLNs	• GLN: 0000330290262 • GLN: 0000520506414 • GLN: 0000445254679
Business Model	Distributor
Licenses	• Name: Movilitas Client • State: New York • License type description: Wholesaler This is not a proof that license is active or in good standing

NABP provides an automated and manual interface to its Pulse platform. The automated interface allows the system to look up a contact using the trading partner's GLN or (part of) their name. For this whitepaper, we describe how this data can be accessed automatically.

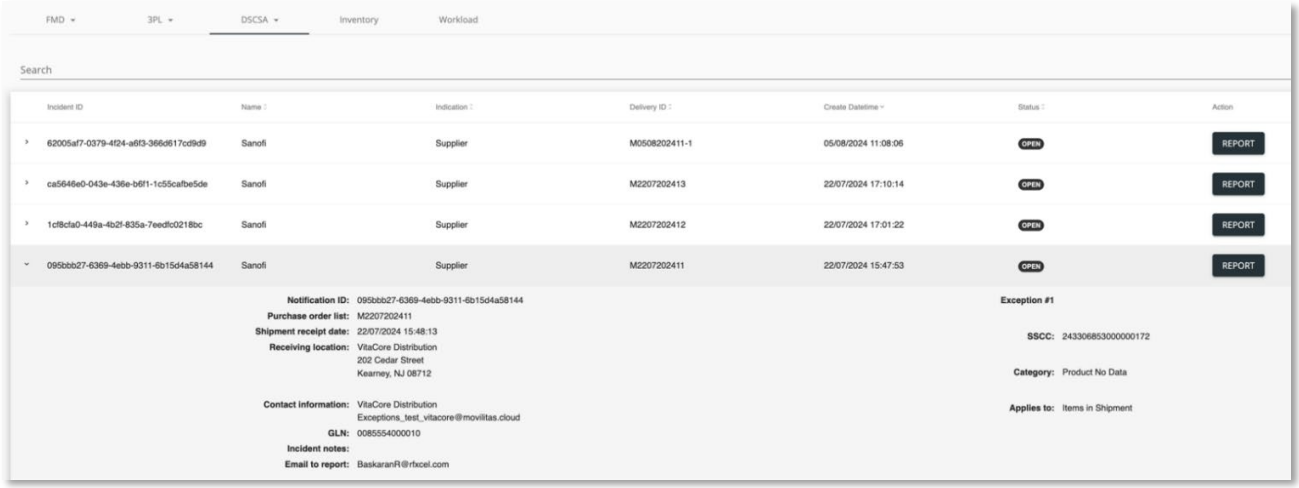
The platform allows searching after entering three letters of an authorized trading partner. This will of course only work well if more and more trading partners claim their profile on Pulse and add data to it.

The image to the left is an example of the Pulse profile of a DSCSA trading partner.

As soon as the e-mail address is known to which exceptions need to be reported, the actual reporting can start.

4.2.2. Exception Reporting

The following example is a list of exceptions of received products and a mismatch between the EPCIS and the physical serial numbers. For one receipt/EPCIS combination, these are grouped into an incident. So, one incident can contain multiple exceptions.

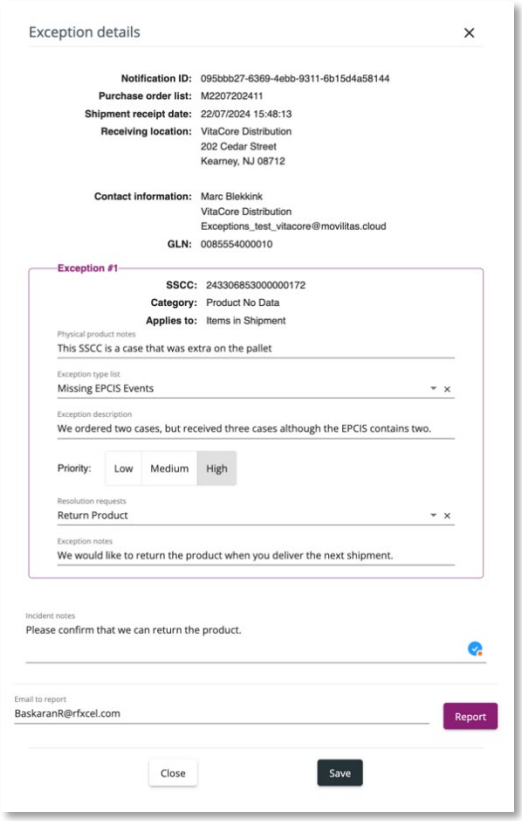


The Collaborate e-mail must include enough information to allow the receiver (the supplier) to understand what the exceptions are and how the receiver suggests how to resolve them.

Standardizing the content of such an e-mail among different solution providers would make the understanding of the e-mails easier and allow for automatic processing for companies that must deal with many exceptions.

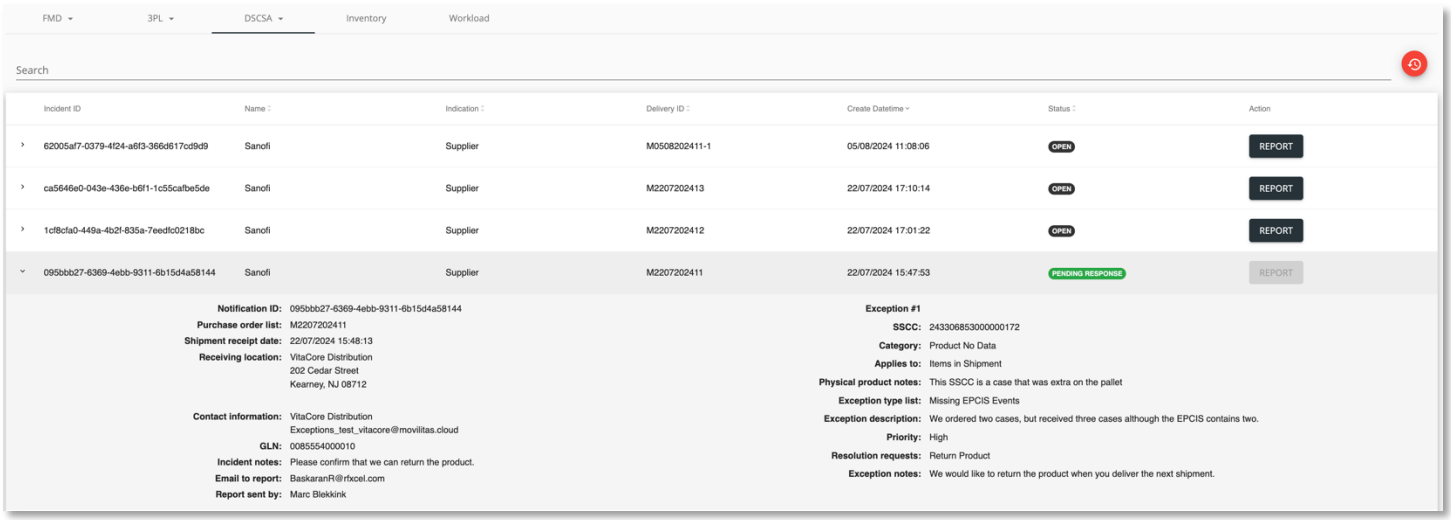
The email sender must consider sending the correspondence in an easy-to-understand human-readable format and an attachment that isolates and describes the error in a machine-readable format including raw EPCIS files, Spreadsheets, and potentially a merging JSON file format. The JSON format being socialized by PDG and developed by Ledger Domain enabled automation of the process and properly accounts for parent-child relationships defined in DSCSA EPCIS files. For that reason, the Pilot team provided optionally the same information in a JSON format attached to the e-mail. This allows an easier exchange of information between systems and keeps the possibility open to allow companies to build API endpoints for secure communication in the future, while still being able to communicate with less advanced companies.

The previously reviewed PnD example can be transformed into an incident incorporating all information based on the current standard defined by PDG.

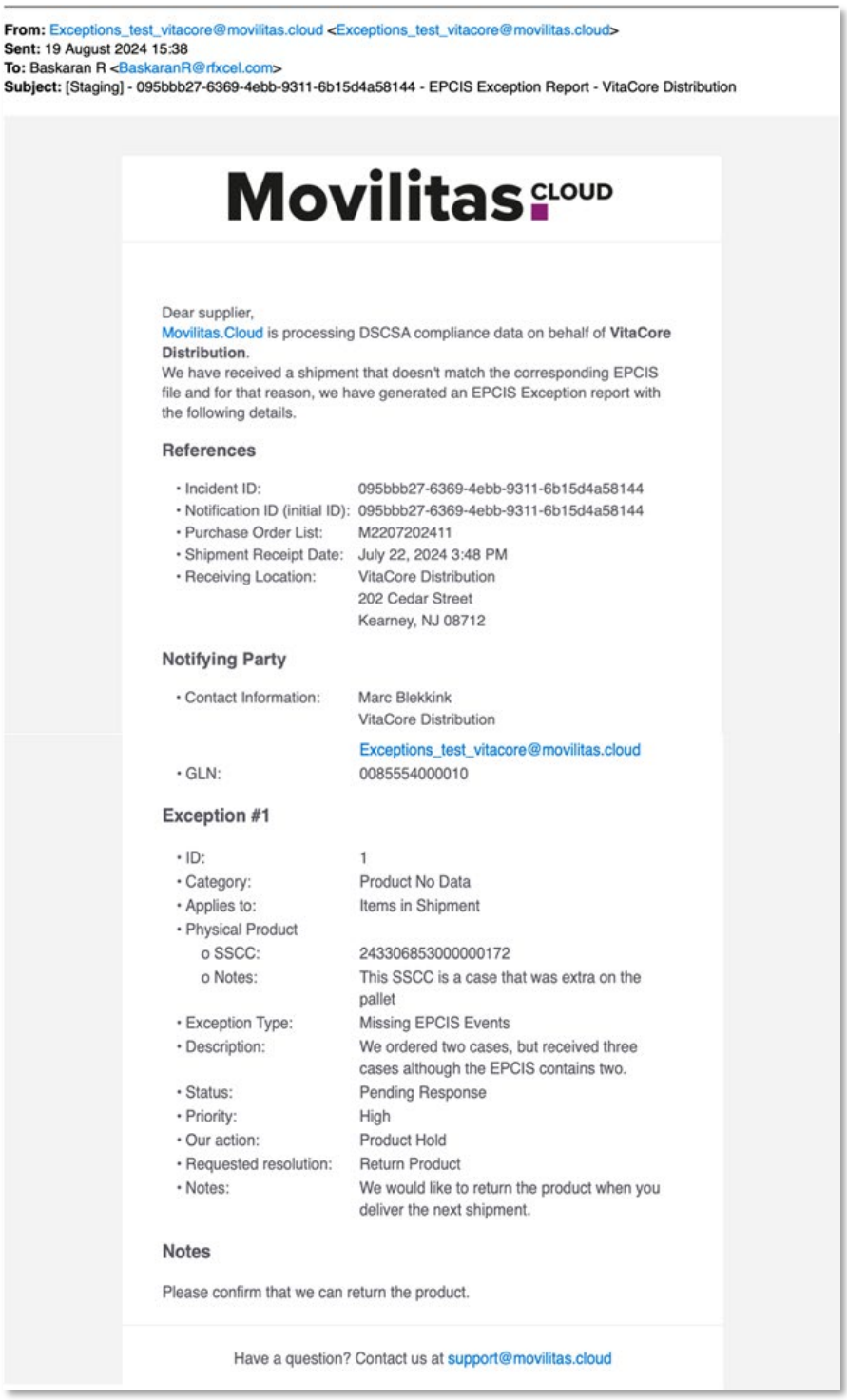


The following example information was incorporated into the report sent to Sanofi.

The information can be formatted into an e-mail and sent to the specified e-mail address and the sender keeps a copy of what was sent:



4.2.3. Email Collaboration



From: Exceptions_test_vitacore@movilitas.cloud <Exceptions_test_vitacore@movilitas.cloud>
Sent: 19 August 2024 15:38
To: Baskaran R <BaskaranR@rfxcel.com>
Subject: [Staging] - 095bbb27-6369-4ebb-9311-6b15d4a58144 - EPCIS Exception Report - VitaCore Distribution

Movilitas CLOUD

Dear supplier,
Movilitas.Cloud is processing DSCSA compliance data on behalf of **VitaCore Distribution**.
We have received a shipment that doesn't match the corresponding EPCIS file and for that reason, we have generated an EPCIS Exception report with the following details.

References

- Incident ID: 095bbb27-6369-4ebb-9311-6b15d4a58144
- Notification ID (initial ID): 095bbb27-6369-4ebb-9311-6b15d4a58144
- Purchase Order List: M2207202411
- Shipment Receipt Date: July 22, 2024 3:48 PM
- Receiving Location: VitaCore Distribution
  202 Cedar Street
  Kearney, NJ 08712

Notifying Party

- Contact Information: Marc Blekkink
  VitaCore Distribution
  Exceptions_test_vitacore@movilitas.cloud
- GLN: 0085554000010

Exception #1

- ID: 1
- Category: Product No Data
- Applies to: Items in Shipment
- Physical Product
  - o SSCC: 243306853000000172
  - o Notes: This SSCC is a case that was extra on the pallet
- Exception Type: Missing EPCIS Events
- Description: We ordered two cases, but received three cases although the EPCIS contains two.
- Status: Pending Response
- Priority: High
- Our action: Product Hold
- Requested resolution: Return Product
- Notes: We would like to return the product when you deliver the next shipment.

Notes

Please confirm that we can return the product.

Have a question? Contact us at support@movilitas.cloud

This e-mail is based on the recommendations from PDG on how to report exceptions in an incident in a JSON format.

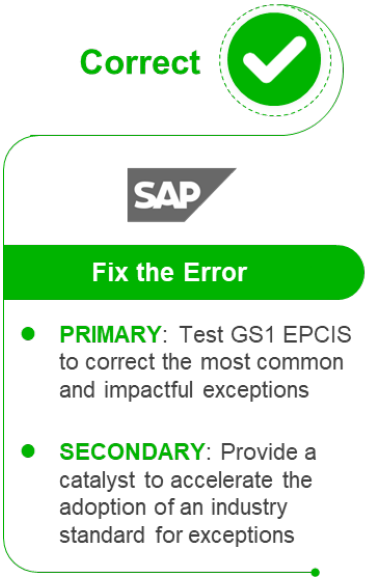
Because JSON is a language for machine-to-machine communication, while the market is using e-mails given the fact that communication is between humans, the JSON from PDG is used as a basis for a structured e-mail.

The JSON is also attached to the e-mail, to facilitate automated systems integration.

4.3. Lessons Learned

1.	**Viable Contacts Directory**	Using the NABP Pulse platform for getting the e-mail addresses for exception notifications is an option if the authorized trading partners publish this data on Pulse. Alternatively direct ATPs, contact information may be sourced from current trading partner repositories
4.	**NABP Pulse Content**	The PULSE platform is still enrolling participants and effectiveness of the Collaborate contact lookup will be limited enrolled trading partners
2.	**Structured Emails**	It is an advantage to have structured e-mails for communicating notifications. That will allow for specifying the minimum information that needs to be exchanged to resolve exceptions. Of course, it is still better to avoid exceptions by providing correct EPCIS files.
3.	**File vs. Scan Exceptions**	The Collaboration phase of this Exception Pilot can add value to both File and Scan based exceptions. Ensuring that all trading partners share the relevant information can reduce the time to address exceptions.

5. Exception Pilot - Correction



The Correct phase of this Pilot is intended to test the use of standard EPCIS correction for Scan Exceptions that were created in prior test scenarios:

- Shortage – Buyer Orders 10; Seller Ships 9
- Overage – Buyer Orders 10; Seller Ships 11
- Invalid Lot – Digital/Physical Lot information does not match
- Returns – Missing EPCIS cannot be sent; Item replaced with a new item
- Invalid Aggregation – Aggregate to wrong case; Possible suspect product

At the time of writing for this white paper, the Exceptions Pilot group had just completed initial tests using standard EPCIS. To simplify the testing, we focused on correcting an Invalid Aggregation error:

1) Aggregation error was isolated to only one shipment;
2) Aggregation error spanned across two different shipments (i.e. 2 cases were inadvertently swapped between 2 buyers.

5.1. Approach

For testing the correction, a new use case has been established. The idea is that a pallet is shipped containing three cases. At the last moment, someone notices that one case is damaged and decides to replace this with another case. This is however not scanned anymore, so we end in a situation of product no data (the replaced case) and data no product (the damaged case that was never shipped).

Sanofi provided this shipment to VitaCore and the solution was to send an additional EPCIS file for the shipped case.

There was however no EPCIS event provided to “void the shipment” because some providers have stated that they would not support this event.

DSCSA Corrections via EPCIS will be sent from supplier to buyer as either a correction of the original file utilizing the original aggregated SSCC license plate or as a new file with just the corrected information utilizing a SYNTHETIC SSCC. It is important to note that if the buyer has already unpacked and decommissioned the original SSCC license plate then a correction can only be implemented utilizing the SYNTHETIC SSCC method.

5.2. Results

Although the solution looks simple, further testing is needed between systems to see how systems react to extra EPCIS files. Additionally, it has become apparent that only the simplest errors can be corrected e.g. missing item-level product information without corresponding data in a timely manner. Most exception conditions beyond this simple missing item use case would require the seller to proactively change business rules governing the data associated with their shipments. Examples of exception conditions requiring business rule changes include but are not limited to: Changing commissioning data, changing aggregations time stamps, and correcting master data elements.

5.3. Lessons Learned

1.	**Corrected EPCIS Files**	Corrected EPCIS files can be generated and sent with either the original SSCC or a SYNTHETIC SSCC…
2.	**Void Shipment**	The Void shipment transaction is problematic and will continue to be inconsistently utilized between solution providers. Not using the "VOID shipment" event seems only possible if the recorded exceptions for an EPCIS are used to analyze the newly sent EPCIS file. In the coming phases, more tests will be executed with more solution providers.
3.	**Synthetic SSCC**	Trading partners and their solutions providers will need to be specific in their communication that the corrected files will utilize the original SSCC or require a SYNTHETICS SSCC be generated.
4.	**Complex Corrections**	Corrections requiring business rule changes and compromises will need to be addressed as they arise may result in unacceptable resolution timelines and returned product
5.	**Allowance for Duplicate SN's**	The industry guidance for correcting Scan Exceptions allows duplicate serial numbers to be sent/resent. This provision allowed for simplifying corrections of items within a shipment/receipt. Duplicate serial number validation, however, is a core feature to ensure the integrity of serialized items. Removing this validation when sending EPCIS corrections can provide an entry point for bad-actors to insert unauthorized products into the DSCSA supply chain.

6. Conclusion

Exceptions and the need for error corrections of Serialized DSCSA will always exist. If trading partners consistently develop systems and processes to Catch, Collaborate, and Correct identified issues it will be possible to minimize the impact of exceptions. The following are several exceptions and error correction points to consider withing your operations:

- The collaboration handoffs between trading partners and solutions providers creates complexity and will increase the time required to potential resolutions
- Trading partners may not have the discipline required to follow the catch collaborate and correct process
- Utilizing email as the communications standard for exceptions management collaboration is not secure, prone to misinterpretation, and inefficient
- There are numerous scenarios where the exception will not be correctable in a timely manner and the only disposition will be the returns process
- Scan Exceptions volume cannot be estimated without real world data evidence
- Receipt via inference may result in exceptions conditions only identifiable upon time of shipment
- Trading partners will need to establish processes for reviewing exception resolving and implementing business rule changes to quickly facilitate exception resolution
- The value of the medications affected by exceptions may result in trading partners making commercial decisions to allow products to be returned versus correcting the exception condition

The Pilot team will continue to evolve the practices developed so far and will publish an update after full implementation of the Act in November of 2024.

7. Acknowledgments

7.1. Authors

Herb Wong

Herb Wong has a strong background in product strategy, development, and customer services. Mr. Wong is responsible for aligning rfxcel's products and services with the needs of the customer. He is also responsible for ensuring that rfxcel contributes back to the industry through active engagement.

Mr. Wong is currently Chief Customer Officer at Antares Vision Group

Marc Blekkink

Entrepreneur with an interest in the automation of business processes within the manufacturing and processing world. A chemical engineering background was combined with a traineeship at General Electric Plastics (GEP). After that companies were successfully started or expanded in the field of production automation, vertical integration, and supply chain integration with a focus on serialization and aggregation based on web and mobile technologies.

Mr. Blekkink is currently Managing Director of Movilitas.Cloud at Engineering Industries eXcellence.

Dwight deVera

The entrepreneurial founder of RxTransparent A drug supply chain security act compliance platform for healthcare providers Since the platform launched it is now used in thousands of healthcare sites and retail pharmacies. Mr. deVera also ran one of the FDA Pilot Programs for DSCSA, and has provided testimony to the agency about drug data standards.

Mr. deVera is currently the Managing Director of RxSupply Chain Advisors a supply chain innovation firm.

7.2. Industry Participants (Alphabetical Order)

Advasur
Antares Vision Group
Axway
Boehringer-ingelheim
Cardinal Health
Cencora
Consorti EX
Dr Reddy
Dyadis
Gateway Checker
GS1
HDA
Inmar
LedgerDomain
Movilitas.Cloud
NABP
Option care
PDG
Publix
rfXcel
Rx Supply Chain Advisors
Sanofi
Tracelink
TrackTraceRx
Walgreens

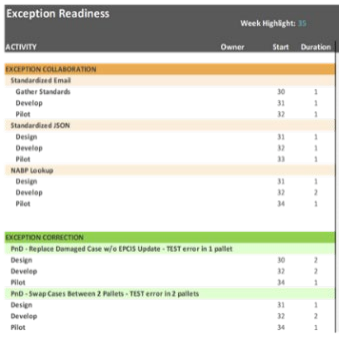
7.3. Midpoint Review & Guidance

We want to acknowledge and thank Kaiser Permanente, Option Care, and Walgreens for serving as an advisory group to this Exception Pilot and providing fresh insight from a dispenser's point of view.

We also want to thank and acknowledge the contributions of participants who joined our June 19th midpoint review of our progress.

The meeting was hosted at Kaiser Permanente's facilities in Washington DC after the "PDG-FDA Joint Public Meeting." The timing of the meeting allowed us to incorporate key feedback from the PDG-FDA meeting as well as learnings from our pilot efforts.





The following people (in alphabetical order) attended the meeting virtually or in person and were instrumental in shaping our approach.

Alex Colgan (Ledger Domain)
Arthi Nagaraj (Sanofi)
Baskaran R. (rfxcel / Antares Vision)
Ben Taylor (Ledger Domain)
David Brown (Walgreens)
David Chook (Option Care)
Dean Bourque (Prodigy Health)
Dwight deVera (Rx Supply Chain Advisors)
Eran Strod (Gateway Checker)
F Carlini (Advasur)
Gary Lerner (Gateway Checker)
Gary Lombard (Option Care)
Herb Wong (rfxcel / Antares Vision)
Jaidalyn Rand (HDA)
Julien Faury (Antares Vision)
Kathryn Uchida (Kaiser Permanente)
Marc Blekkink (Movilitas.Cloud)
Patrick Cassidy (Inmar)
Robin Ward (Option Care)
Roger Sanure (Dyadis)
Sam. Scimeca (Option Care)
Sampath Mucherla (Cencora)
Scott T Hatakeyama (Kaiser Permanente)
Tim Stearns (HDA)

7.4. References

Industry Association	Link
HDA Research and Publications	https://www.hda.org/publications/
PDG Blueprint For Interoperability	https://dscsagovernance.org/blueprint/
GS1 Healthcare	https://www.gs1.org/industries/healthcare

Authored By