IDLogiq FDA Pilot Program Final Report

Contents

1 Background

IDLogiq was accepted by the U.S. Food and Drug Administration to participate in the FDA DSCSA Pilot Project Program to assist in the FDA and members of the pharmaceutical distribution supply chain during this process of determining the development of the electronic, interoperable system that will identify and trace certain prescription drugs at the package-level tracing and verification as they are distributed within the United States. Our pilot program aims at helping the FDA and all the stakeholders to understand the process and evaluate the pilot project, once completed, with the collective hope of optimizing safety and security of the pharmaceutical supply chain ecosystem.

For the first month, we completed end-to-end testing of 200 products through entire product life cycle, beginning from manufacturer issuance, repackaging by repackager and shipping out to pharmacy.

In our second month, we completed end-to-end testing of 200 products from manufacturer issuance, repackaging by repackager and shipping out to pharmacy.

In our third month of the pilot program, we completed end-to-end test of 1000 products from manufacturer issuance, aggregation of products into containers by manufacturer, disaggregation of products at the repackager, repackaging by repackaging, aggregation of products at the repackager, and shipping out to pharmacies.

In our fourth month (Nov 1-30, 2019), we completed end-to-end test of 1100 products through entire product life cycle, beginning from manufacturer issuance, to aggregation of products into containers by manufacturer, to disaggregation of products at the repackager, repackaging by repackager, aggregation of products at the repackager, and shipping out to pharmacies. The above test also included usage of Near-field communication labels to track 100 products through-out its lifecycle.

In our fifth month (Dec 1-30, 2019), we completed end-to-end-test of 2100 products through entire product life cycle, beginning from manufacturer issuance, to aggregation of products into containers by manufacturer, to disaggregation of products at the repackager, repackaging by repackager, aggregation of products at the repackager, and shipping out to pharmacies. Of those total 2100, we performed 1000 pilot test of data-matrix labels with IDLogiq cryptographic authentication. The above test also included usage of Near-field communication labels to track 100 products through-out its lifecycle.

In this final report, we will summarize the activities performed over entire pilot test results for IDLogiq Pilot Program with the help of our partners (mainly Alexso/SA3 and several dispensers).

2 System under Test and Workflow Diagram

The pilot system involves multiple processes, from the manufacturing entity to the dispenser (pharmacy). The system will record precisely all events (aggregation, repackaging, disaggregation, shipping) in the standard EPCIS format using our digital ledger, which includes the “who, what, where, when, how” information of all events related the transfer of goods in the supply chain.

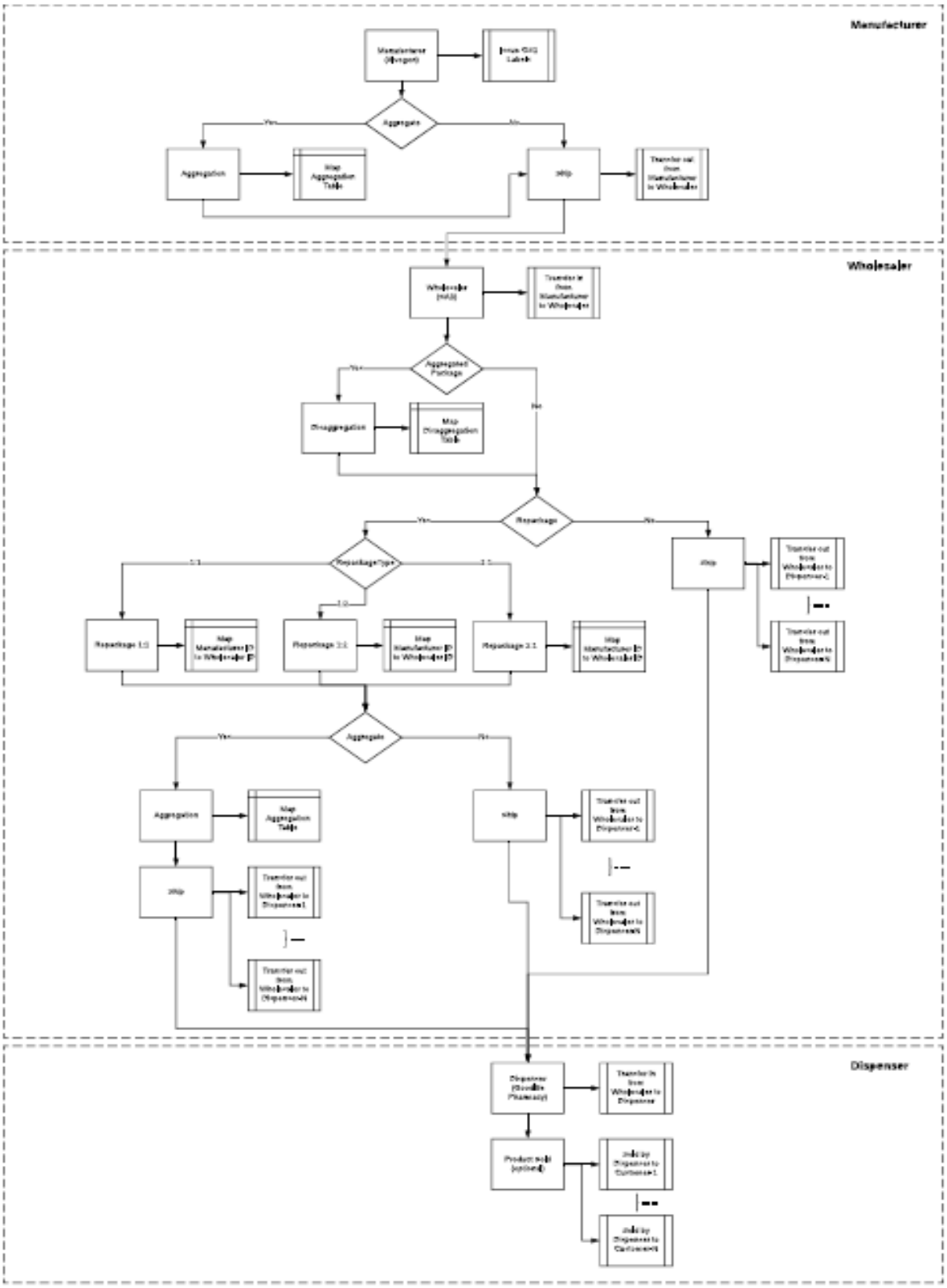


Figure 1. System under Test and Workflow Diagram

2.1 September pilot materials list

- 200 empty and unlabeled prescription medicine bottles
- 200 printed GS1 standard data-matrix labels issued by Alvogen (manufacturer replica)
- 100 printed GS1 standard data-matrix labels issued by SA3 (repackager replica)
- 100 printed GS1 standard data-matrix labels with IDLogiq cryptographic authentication issued by SA3 (repackager replica)

2.2 October pilot materials list

- 1000 empty and unlabeled prescription medicine bottles
- 1000 printed GS1 standard data-matrix labels issued by Alvogen (manufacturer replica)
- 1000 printed GS1 standard data-matrix labels issued by SA3 (repackager replica)
- 15 GS1 standard data-matrix labels to test aggregation into 6-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 12-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 5-pack issued by SA3 (repackager replica)
- 15 GS1 standard data-matrix labels to test aggregation into 10-pack issued by SA3 (repackager replica)

2.3 November pilot materials list

- 1100 empty and unlabeled prescription medicine bottles
- 1100 printed GS1 standard data-matrix labels issued by Alvogen (manufacturer replica)
- 1100 printed GS1 standard data-matrix labels issued by SA3 (repackager replica)
- 15 GS1 standard data-matrix labels to test aggregation into 6-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 12-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 5-pack issued by SA3 (repackager replica)
- 15 GS1 standard data-matrix labels to test aggregation into 10-pack issued by SA3 (repackager replica)
- 100 Near-Field Communication Labels (NFC) to test repackaging using NFC (Hardware data carrier) for robust tamper-resistant measures.

2.4 December pilot materials list

- 2000 empty and unlabeled prescription medicine bottles
- 1000 printed GS1 standard data-matrix labels issued by Alvogen (manufacturer replica)
- 1000 printed GS1 standard data-matrix labels with IDLogiq cryptographic authentication issued by Alvogen (manufacturer replica)
- 1000 printed GS1 standard data-matrix labels issued by SA3 (repackager replica)
- 1000 printed GS1 standard data-matrix labels with IDLogiq cryptographic authentication issued by SA3 (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 6-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 12-pack issued by Alvogen (manufacturer replica)
- 15 GS1 standard data-matrix labels to test aggregation into 5-pack issued by SA3 (repackager replica)
- 15 GS1 standard data-matrix labels to test aggregation into 10-pack issued by SA3 (repackager replica)
- 100 Near-Field Communication Labels (NFC) to test repackaging using NFC (Hardware data carrier) for robust tamper-resistant measures.

Item	August	September	October	November	December	TOTAL
Medicine bottles undergone pilot test	200	200	1000	1100	2000	4500
Labels issued by Manufacturer	200	200	1000	1100	2000	4500
Labels issued by Repackager	200	200	1000	1100	2000	4500
Aggregation containers 6-pack	0	0	15	15	15	45
Aggregation containers 12-pack	0	0	15	15	15	45
GS1 cryptographic labels tested	100	100	0	0	1000	1200
Near-field communication labels tested	0	0	0	100	100	200
Number of EPCIS events registered	418	418	2272	2463	4281	9852
Number of scans	836	836	4544	4926	8562	19704

Table 1. Summary over period of 5 months

3 End-to-End Workflow Under Test

Figures color meaning:

Green is Organization Pink is Saleable Item Blue is Event

3.1 Aggregation and Transfer Out at Manufacturer (Shipping)

Aggregation process using IDLogiq DSCSA Tool begins by allowing Alvogen to scan all items to be aggregated and associate them with a higher-level container item. This allows us to map N-products (6-products / 12-products) to a single aggregated container label.

After completion of aggregation of all products into 6 and 12 packs at manufacturer, we generated EPCIS 1.2 format file representing transfer-out transfer-in event between Alvogen and SA3.

Item	August	September	October	November	December	TOTAL
Aggregation Labels issued for 6-pack	0	0	15	15	15	45
Aggregation Labels issued for 12-pack	0	0	15	15	15	45
Aggregation Labels with IDLogiq Cryptographic Authentication	0	0	0	0	30	30
Number of Child- items aggregated	0	0	270	270	540	1080

Table 2. Aggregated products & labels over period of 5 months

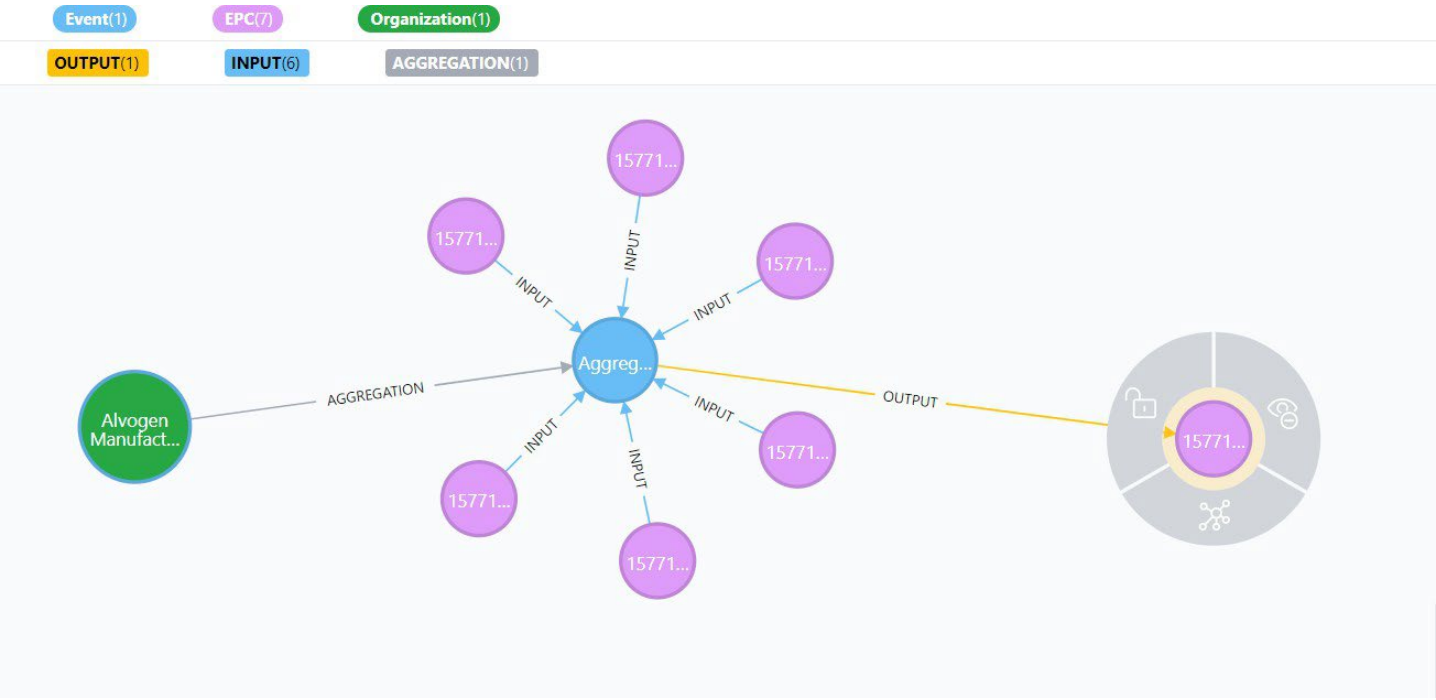


Figure 2. Visualization screen capture of the 6-pack aggregation event at Alvogen recorded in IDLogiq digital ledger.

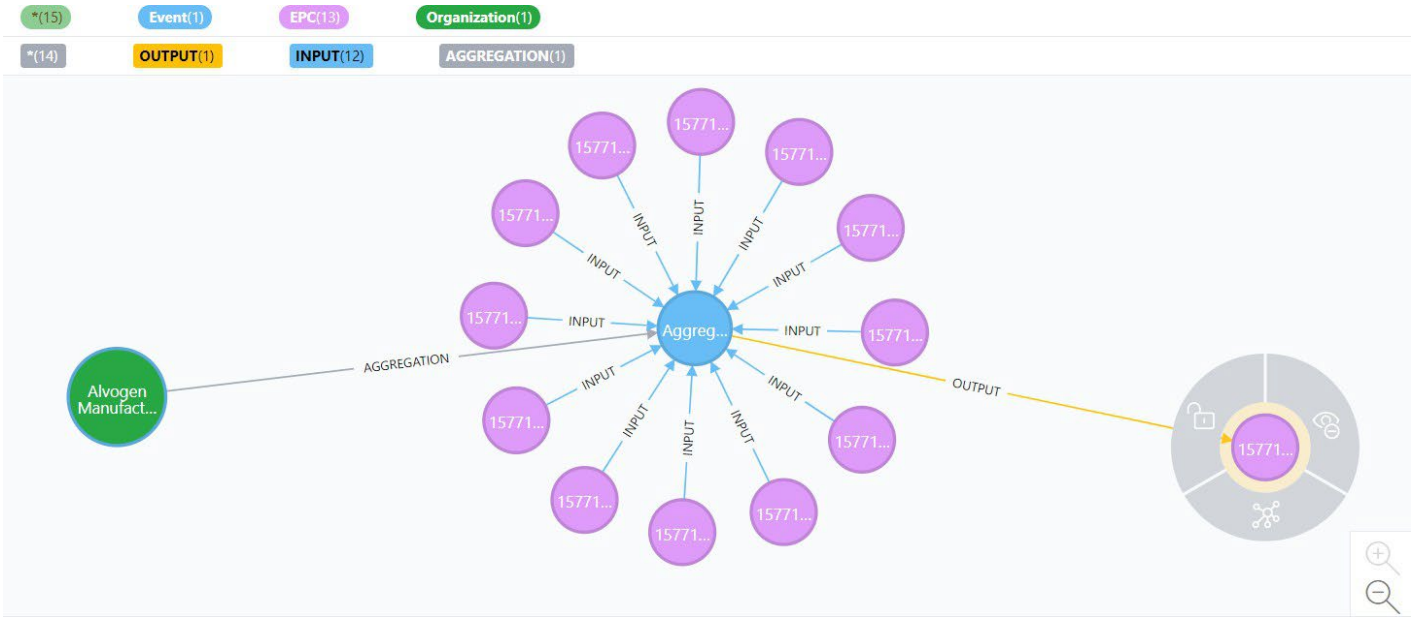


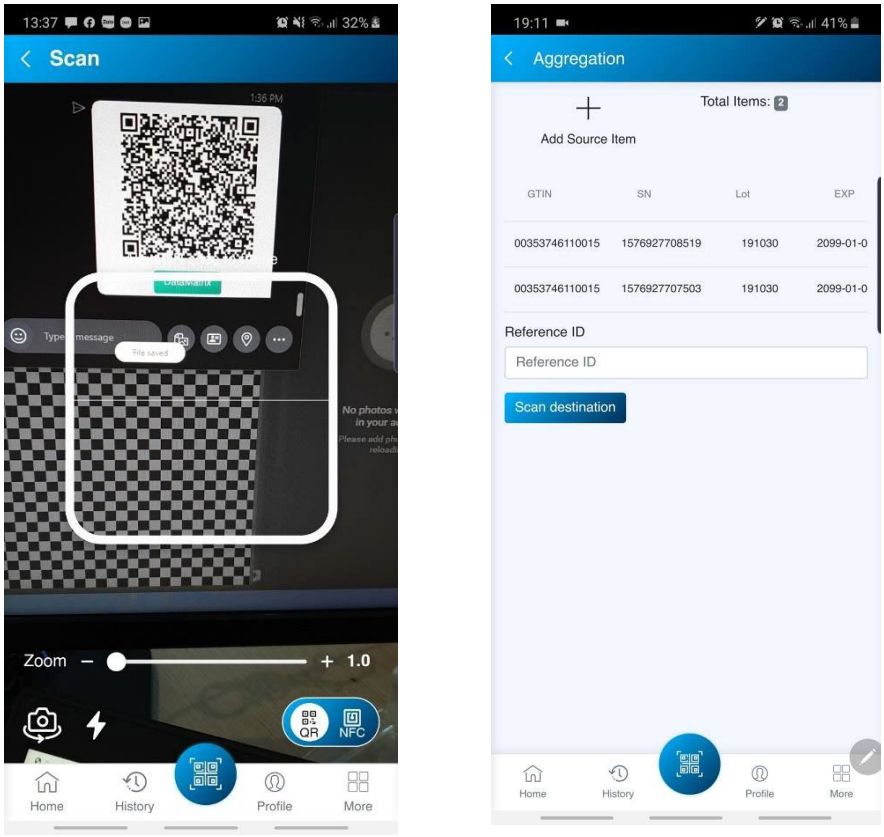
Figure 3. Visualization screen capture of the 12-pack aggregation event at Alvogen recorded in IDLogiq digital ledger.

3.1.1 Aggregation example through IDLogiq application screenshots

Depending on the desirable workflow, the higher-level container item can be scan before or after the items to be included. In this test, we used the “after” method.

3.1.1.1 Scan all child labels via Bar-code scan

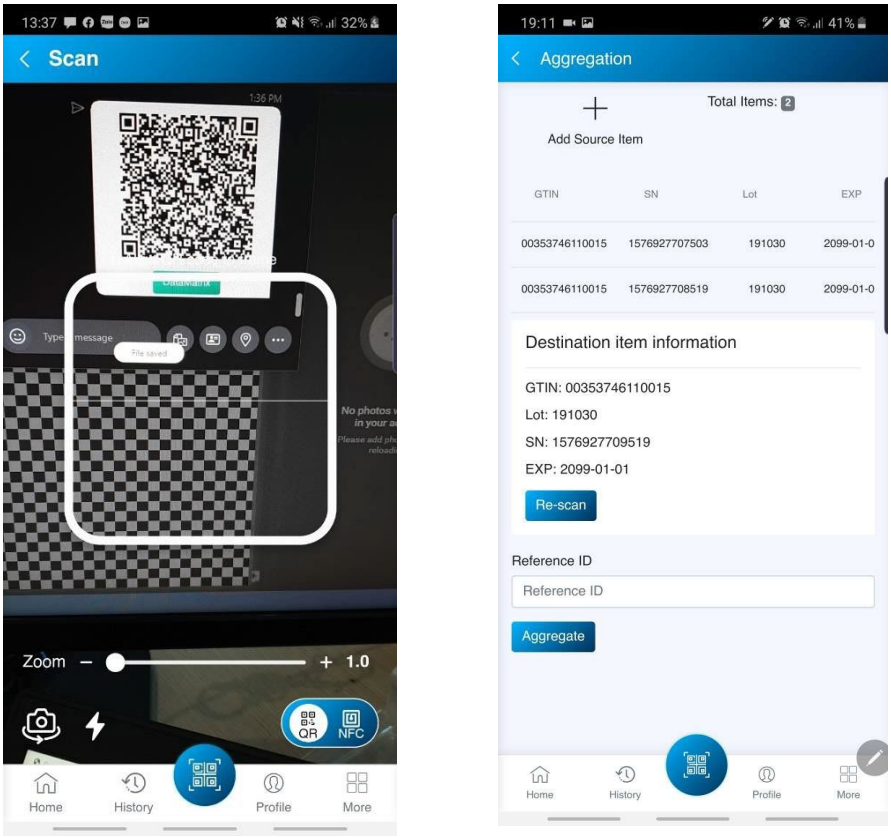
To perform aggregation, we begin by scanning all child items that would be aggregated into a package using IDLogiq app



Screenshot 1. Aggregation UI to scan and list all child items

3.1.1.2 Scan parent label via Bar-code scan

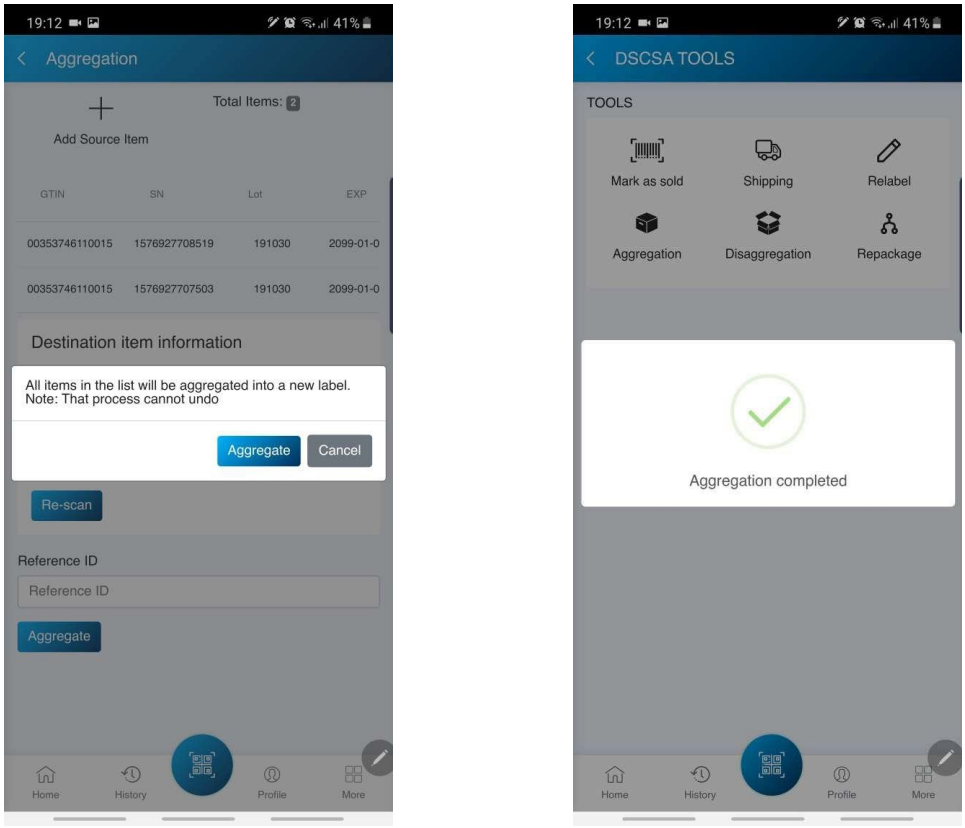
After all child items are scanned, we would scan the parent label as the destination item.



Screenshot 2. Aggregation UI to scan the parent item to complete aggregation

3.1.1.3 Complete aggregation

After all child items are scanned, and their destination parent label is mapped, we execute complete aggregation to register an aggregation event which would be saved in IDLogiq digital ledger.



Screenshot 3. Aggregation submission UI

3.2 Transfer In (Receiving)

SA3 receives prescription drugs from the drug manufacturer (Alvogen) GS1 label, together with a file describing shipping events either in EPCIS 1.2 or ASN EDI 856 standard. The file includes all electronic product codes (EPC), lot number and source/destination information of the transfer event. IDLogiq software allows SA3 to directly import these file and parse necessary data required to extract details about the shipment. A shipment received event will be generated under SA3 in our digital ledger. SA3 can cross-check whether the transfer event is registered correctly by searching shipment using filters such as GTIN, lot number, serial number. The EPCIS 1.2 also specifies the aggregation events performed at the manufacturer and the list of all electronic product codes (EPC) in the aggregated package.

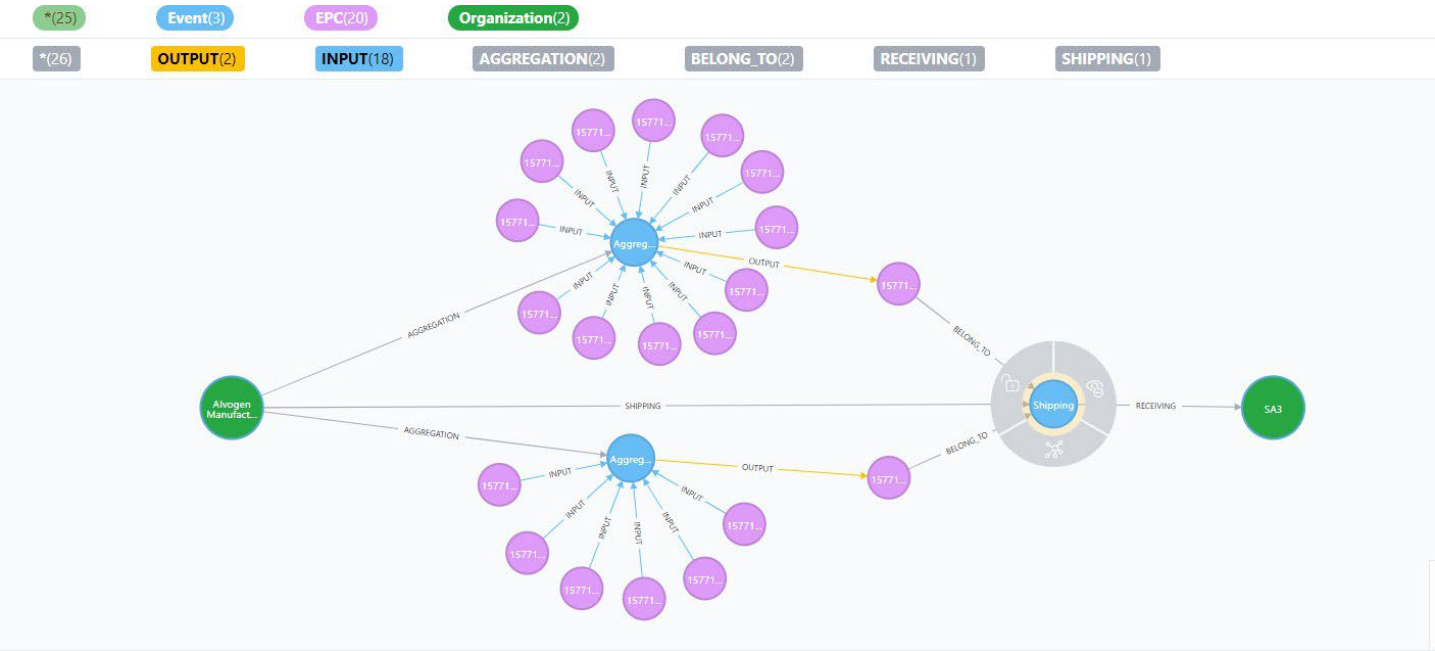


Figure 4. Visualization screen capture of the transfer-in event between Alvogen manufacturer and SA3 in IDLogiq digital ledger system.

3.3 Disaggregation

Before performing repackaging in Step 4, we disaggregated all the aggregated packages into individual products to prepare them for repackaging. Tracking disaggregation step allows us to accurately track and trace individual EPCs during their entire lifecycle from issuance, aggregation, disaggregation, repackaging and shipping.

Track and trace records of the disaggregation process is automated with the IDLogiq DSCSA tool as follows:

- Scan the GS1 label of the top-level (parent) container to be disaggregated, then
- After opening the package, all the products inside the package are scanned and verified. *IDLogiq responsive UI performs real-time verification, error detection, and cross-checking whether the items aggregated at the manufacturer are the same as the ones received through shipment documentation while performing disaggregation.* We can notify on the repackager about missing items or additional items added into the package while shipping due to human error through the IDLogiq responsive UI.

After completion of disaggregation of all products from 6 and 12 packs at repackager, we would begin repackaging simulation at SA3 in Step 4.

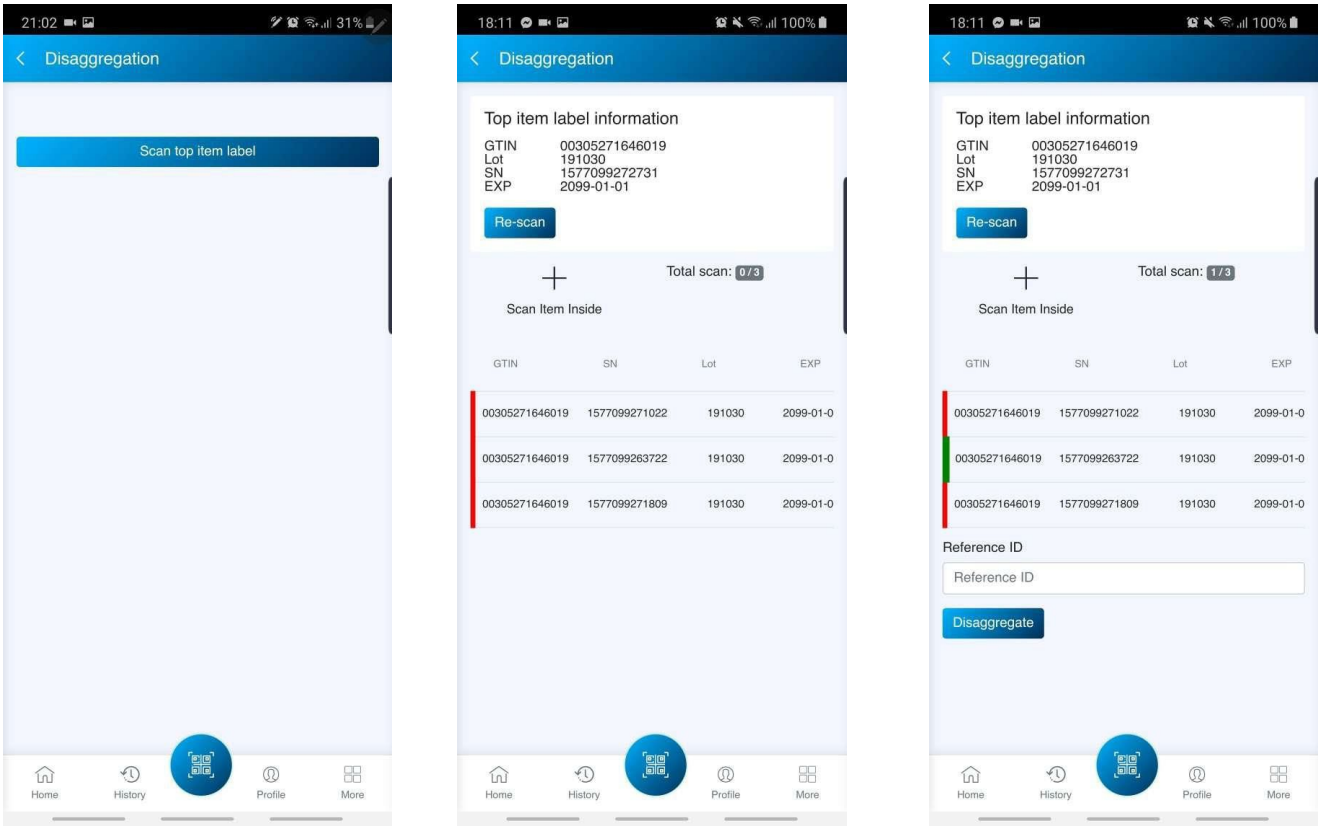
Item	August	September	October	November	December	TOTAL
Number of Child-items aggregated	0	0	270	270	540	1080

Table 3. Disaggregated products during the DSCSA Pilot Program

3.3.1 Disaggregation example through IDLogiq application screenshots

3.3.1.1 Scan parent item of the package to disaggregate

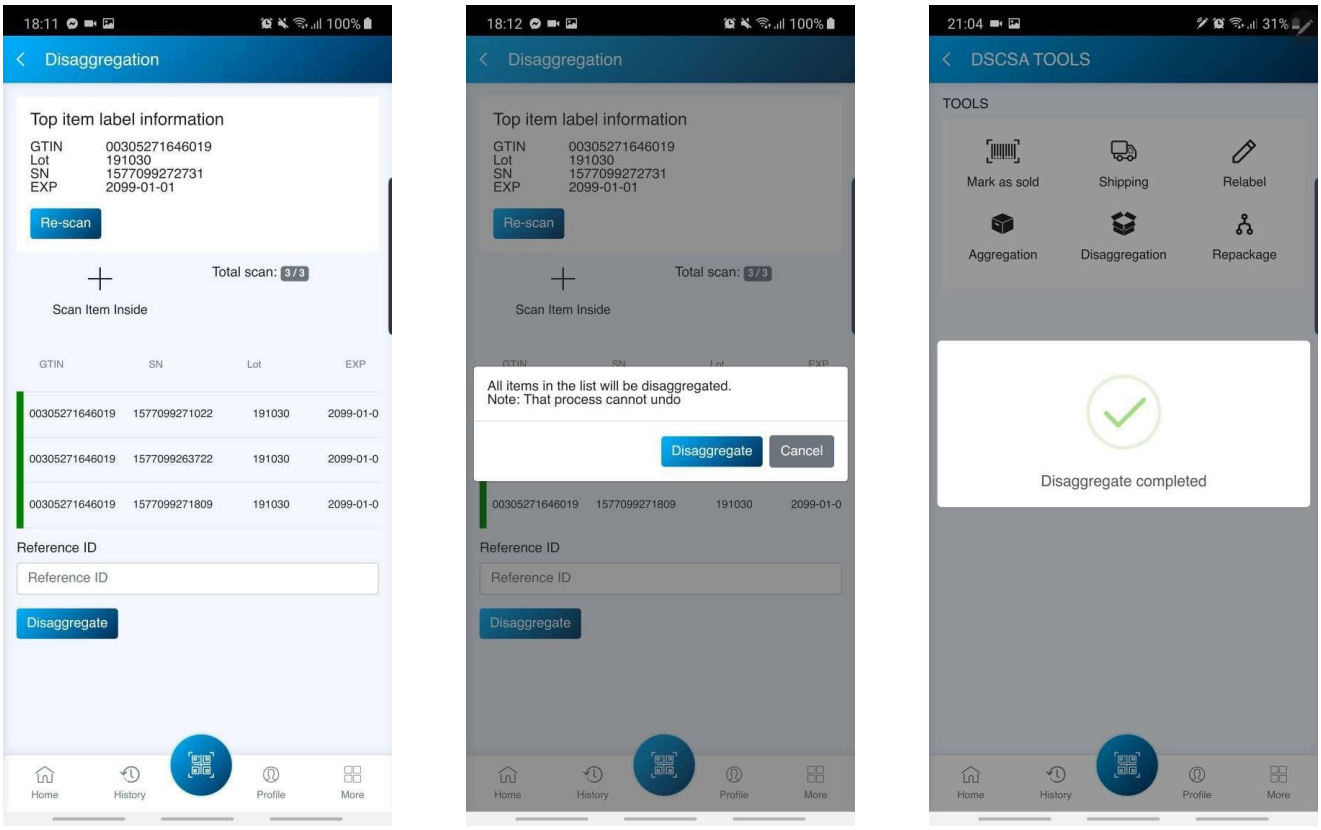
After the parent label is scanned, IDLogiq application will display the list of child items the package must contain. At the beginning, all items are marked with red indicator to indicate that they are in the disaggregation but have not been scanned and verified, as we scan the individual child items, the indicator is updated to green. Any remaining items with red labels after child items scanning is complete are mismatch or missing items due to human error. *If an item is not in the list, it will be flagged as a CRITICAL error to warn that an unexpected (undocumented) items has been received.*



Screenshot 4. Disaggregation UI with color-coded (red: missing, green: received) indicator to identify missing items during aggregation and disaggregation

3.3.1.2 Complete Disaggregation

After all child items are scanned, and their source parent label is mapped, we execute complete aggregation to register a disaggregation event which would be saved in IDLogiq digital ledger.



Screenshot 5. Dis-aggregation submission UI

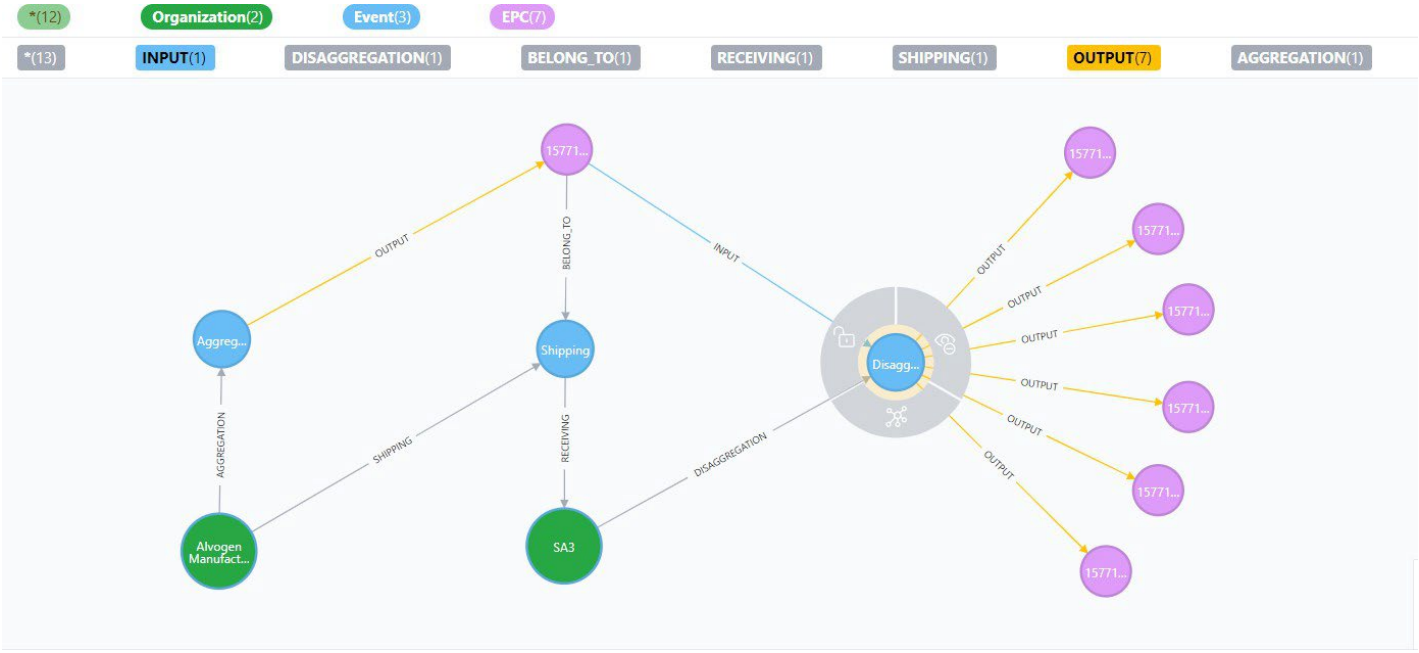


Figure 5. Visualization screen capture of the 6-pack disaggregation event at SA3 recorded in IDLogiq digital ledger.

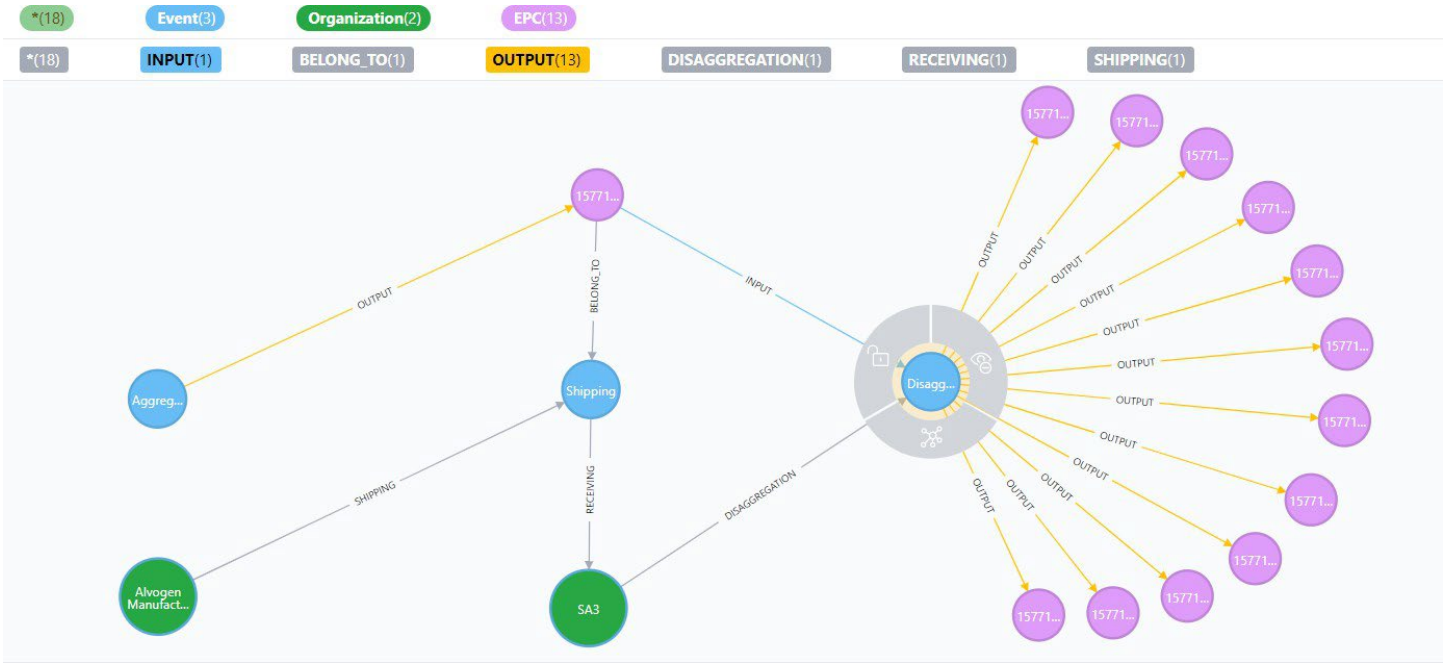


Figure 6. Visualization screen capture of the 12-pack disaggregation event at SA3 recorded in IDLogiq digital ledger.

3.4 Repackaging

After successful disaggregation event, SA3 will begin repackaging the products with the MFG labels from the shipment to the new SA3 GS1 labels (generated from IDLogiq built-in SW).

Item	August	September	October	November	December	TOTAL
Number of items repackaged	100	100	1000	1100	2000	4500

Table 4. Products repackaged during the DSCSA Pilot Program

We performed three different scenarios of repackaging:

a) Repackage One to One (1:1)
b) Repackage Many to One (N:1)
c) Repackage One to Many (1:N)

3.4.1 Repackaging One-to-One (1:1)

One-to-one scenario involves repackaging contents from an old label (Manufacturer) pharmaceutical product into repackager, i.e., SA3 labelled product.

We used our IDLogiq application to perform repackaging 1:1 using GS1 standard labels as follow:

2) Select “Scan old label” on IDLogiq application
3) Scan Alvogen label on the bottle, scan would display the label information (GTIN, Lot number, Exp, Serial Number) on IDLogiq application to cross-check information
4) Select “Scan new label” on IDLogiq application
5) Scan SA3 issued GS1 data matrix standard label
6) Attach the SA3 new label to the bottle thereby successfully repackage the old Alvogen label
7) Repeat the procedure

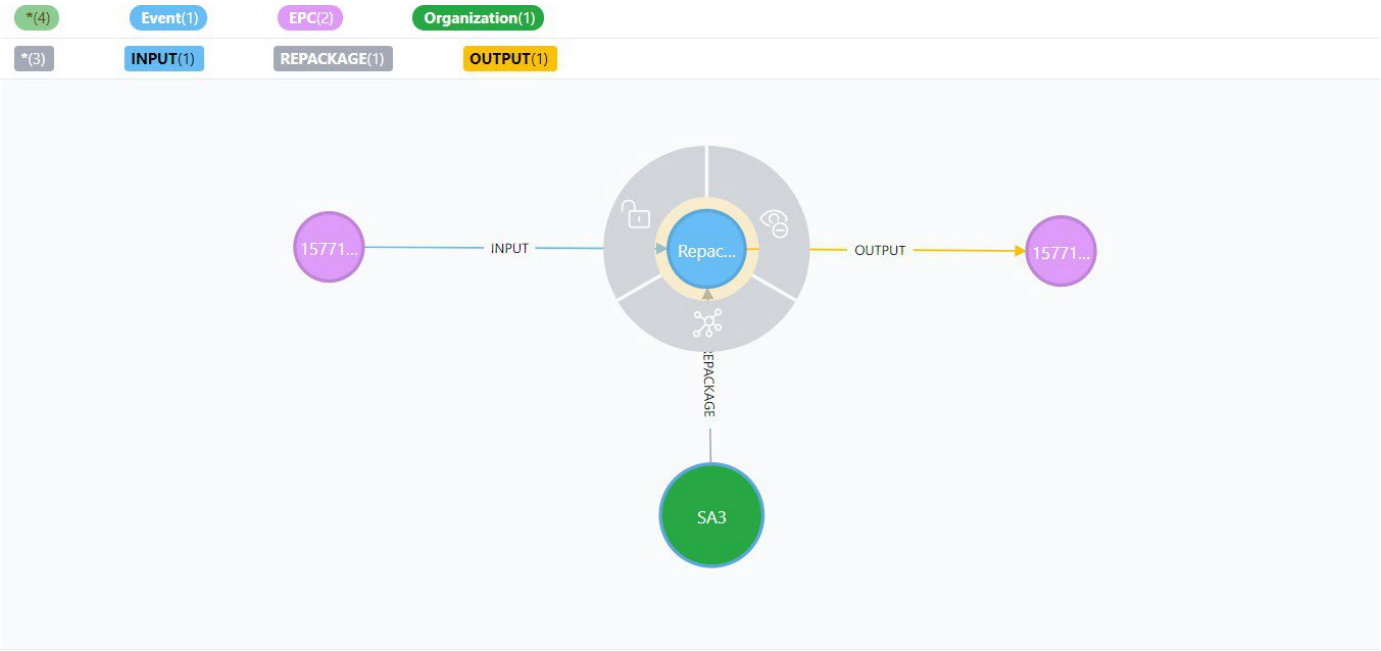


Figure 7. Graphical screen capture depicting connection between old and new label after SA3 repackaging

After SA3 completed the repackaging process, a data map<old_label,new_label> is created that maintains the connection from the new label to the old label of a particular item, subsequently registering a repackaging event under SA3 in IDLogiq digital ledger.

3.4.2 Repackaging Many to One (2:1)

Many-to-one scenario involves repackaging contents from n-homogenous pharmaceutical products into a single product. For our pilot, we performed repackaging for two homogenous pharmaceutical products from manufacturer into a single product of repackager.

We used our IDLogiq application to perform repackaging 2:1 using GS1 standard labels as follow:

8) Select “Scan old label” on IDLogiq application
   a) Scan Alvogen label on the bottle, scan would display the label information (GTIN, Lot number, Exp, Serial Number) on IDLogiq application to cross-check information
   b) Repeat step 1a. Since this is a 2:1 repackaging, we only need to repeat once.
9) Select “Scan new label” on IDLogiq application
   a) Scan SA3 issued GS1 data matrix standard label.
10) Attach the SA3 new label to the bottle thereby successfully repackage the old Alvogen label

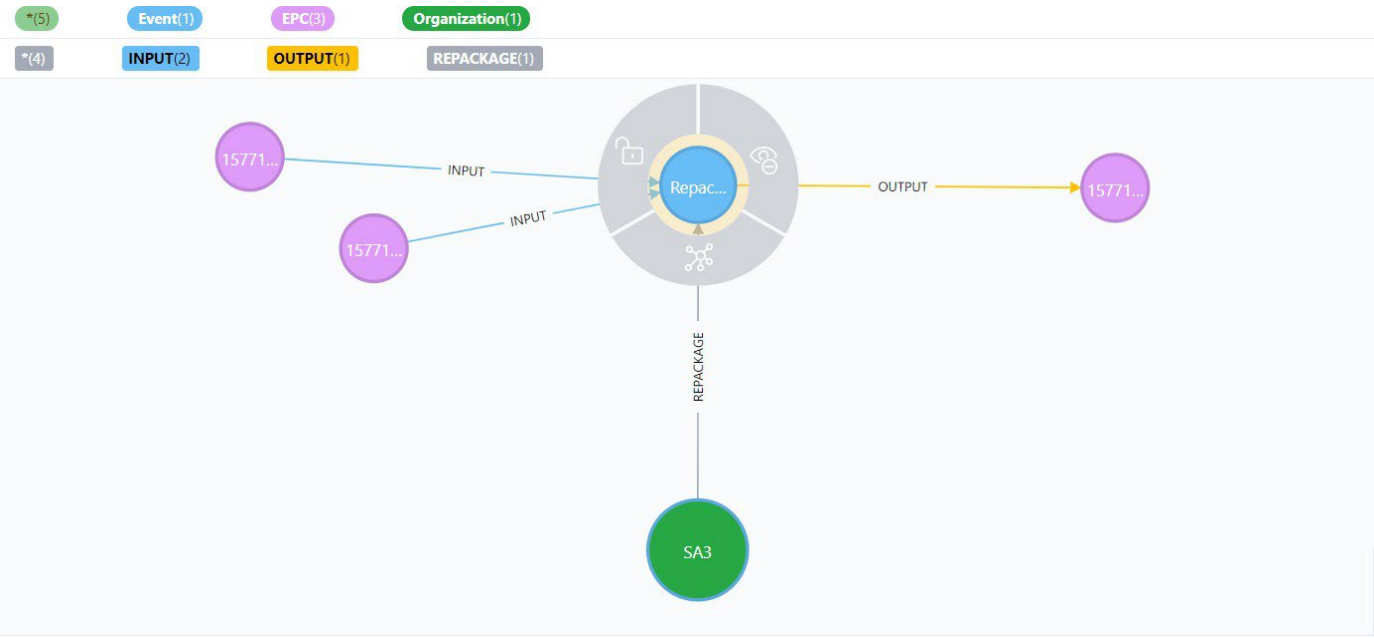


Figure 8. Graphical screen capture depicting connection between old and new label after SA3 repackaging

Once SA3 completed the repackaging process, a data map <{old_label1, old_label2, ..}, new_label> is created that maintains the connection from the new label to all old labels, subsequently registering a repackaging event under SA3 in IDLogiq digital ledger.

3.4.3 Repackaging One to Many (1:2)

One-to-Many scenario involves repackaging contents from a single product into n-homogenous products. For our pilot tests, we performed repackaging for single product from the manufacturer into 2 different products of the repackager.

We used our IDLogiq application to perform repackaging 1:2 using GS1 standard labels as follow:

1) Select “Scan old label” on IDLogiq application
   a) Scan Alvogen label on the bottle, scan would display the label information (GTIN, Lot number, Exp, Serial Number) on IDLogiq application to cross-check information
2) Select “Scan new label” on IDLogiq application
   a) Scan SA3 issued GS1 data matrix standard label.
   b) Repeat step 2a. Since this is a 1:2 repackaging, we only need to repeat once.
3) Attach both the SA3 new label to the bottles thereby successfully repackage the old Alvogen label.

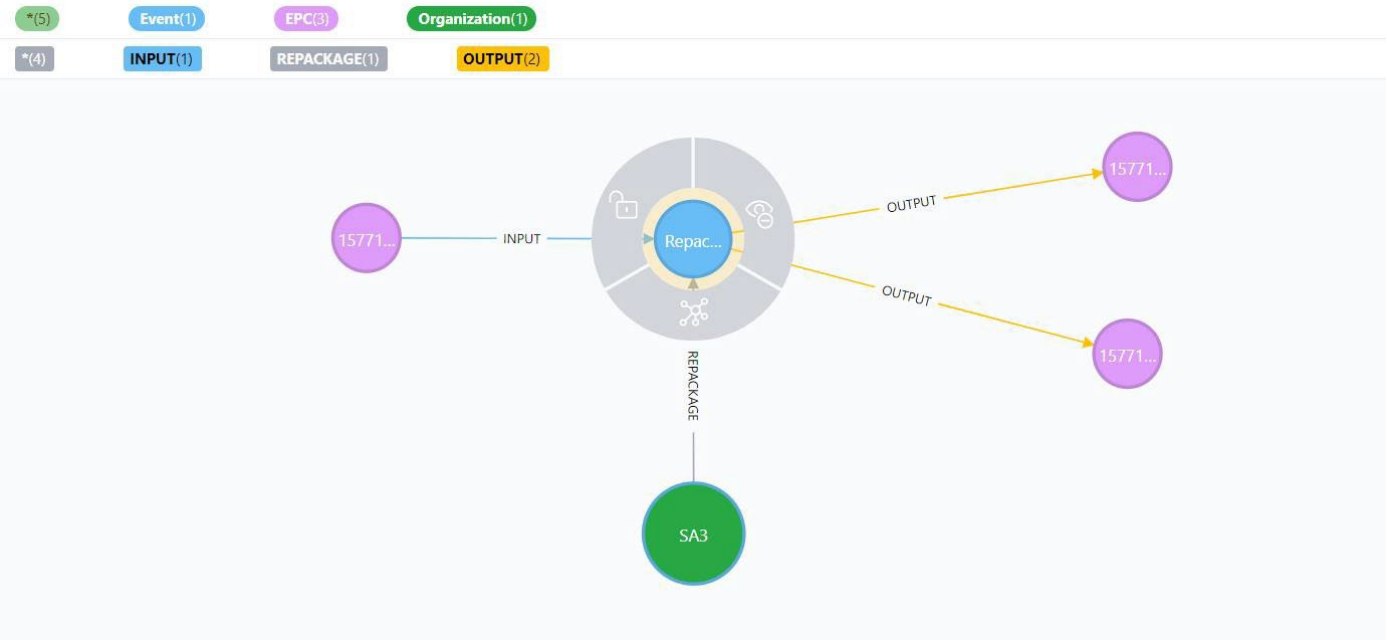


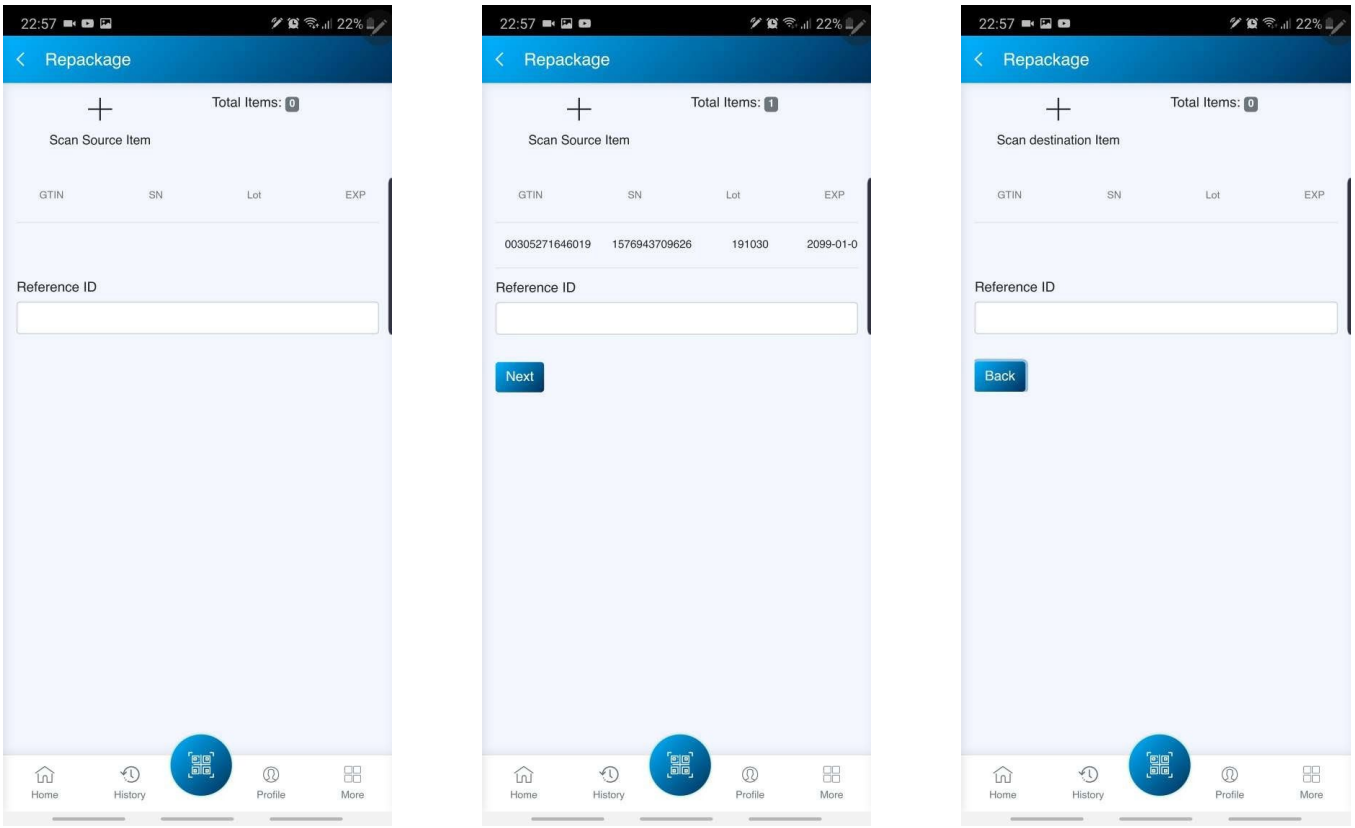
Figure 9. Graphical screen capture depicting connection between old and new label after SA3 repackaging

After SA3 completed the repackaging 1:2 process, a data map<old_label,{new_label1, new_label2 ..> is created that maintains the connection from the new labels to the old label of a particular item, subsequently registering a repackaging event under SA3 in IDLogiq digital ledger.

3.5 Repackaging example through IDLogiq application screenshots

3.5.1 Scan barcode of the source items to be repackaged

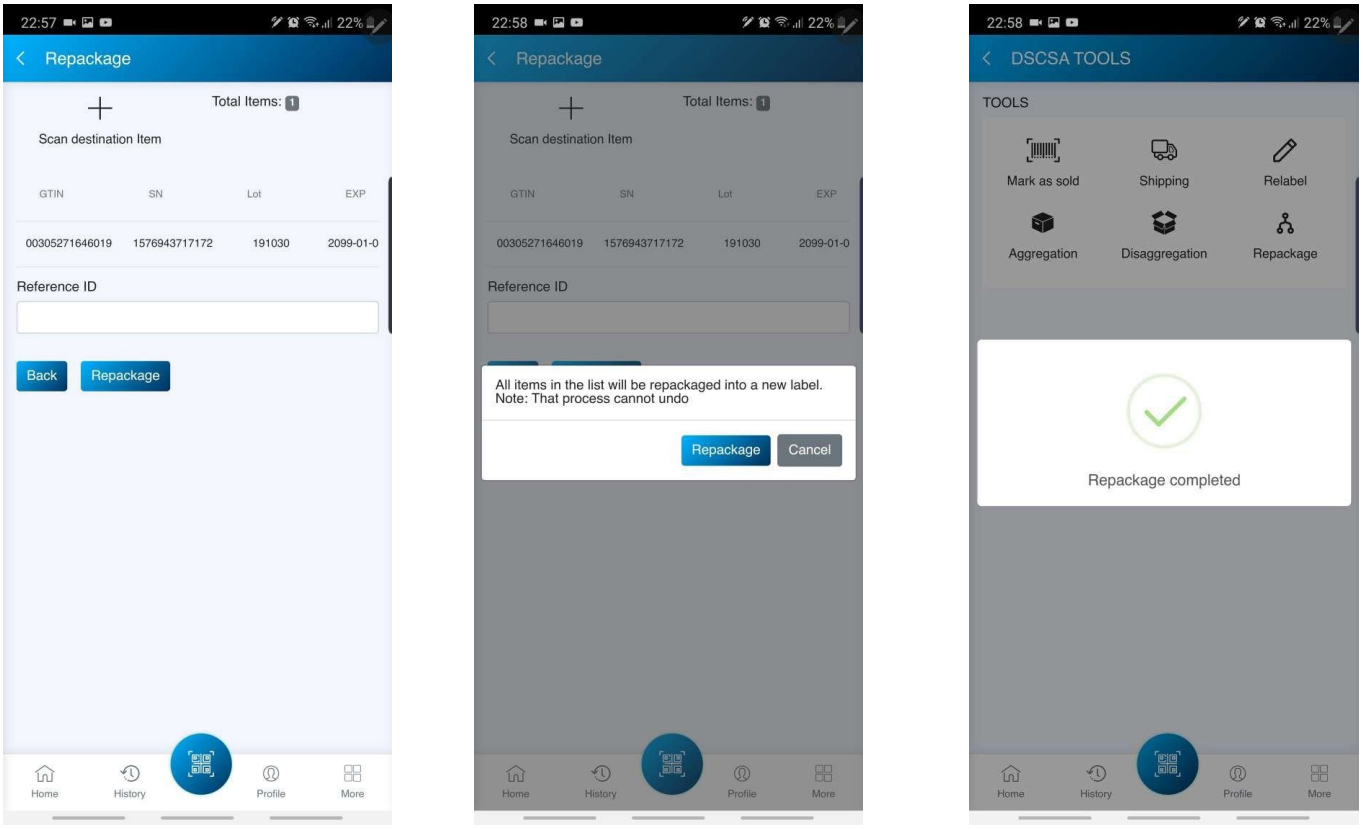
The user of IDLogiq application will scan all the source items required for repackaging. For 1:1, 2:1, 1:2 repackaging the number of source items are respectively one, two, and one.



Screenshot 6. Repackaging UI to scan source items

3.5.2 Scan barcode of the destination items to be repackaged

The user of IDLogiq application will scan all the repackaged destination items for respective source items. For 1:1, 2:1, 1:2 repackaging the number of destination items are respectively one, one, and two.



Screenshot 7. Repackaging UI to scan destination item and complete repackaging

3.6 Aggregation at Repackager (SA3)

In some cases, repackagers ship packages to different pharmacies and have to aggregate individual items into different homogenous or heterogenous packages. SA3 can scan the new labels of necessary items and aggregate them into different high-level packages to be shipped to different pharmacies. IDLogiq software records the aggregation event creating an aggregation table mapping parent package to its concealing child items. We record the aggregation events in our digital ledger to allow tracking parent packages as well as complete, detail track and trace history of each individual items with-in such homogenous or heterogenous parent packages.

Item	September	October	November	December	TOTAL
Aggregation Labels issued for 5-pack	0	15	15	15	45
Aggregation Labels issued for 10-pack	0	15	15	15	45
Aggregation Labels with IDLogiq crypto-authentication	0	0	0	30	30
Number of Child-items aggregated	0	225	225	450	900

Table 5. Aggregated products at SA3 over period of 5 months

The above items are aggregated using the IDLogiq DSCSA tool similar to Step 1. Aggregation at manufacturer by allowing SA3 to scan list of products to be aggregated. After finishing scanning of list of products to be aggregated, the container or package label would be scanned. This allows us to map N-products (5-products / 10-products) to a single aggregated container label.

After completed aggregation of all products into 5 and 10 packs at the repackager, we generate EPCIS 1.2 format file representing transfer-out transfer-in event between SA3 and other pharmacies where products must be shipped to.

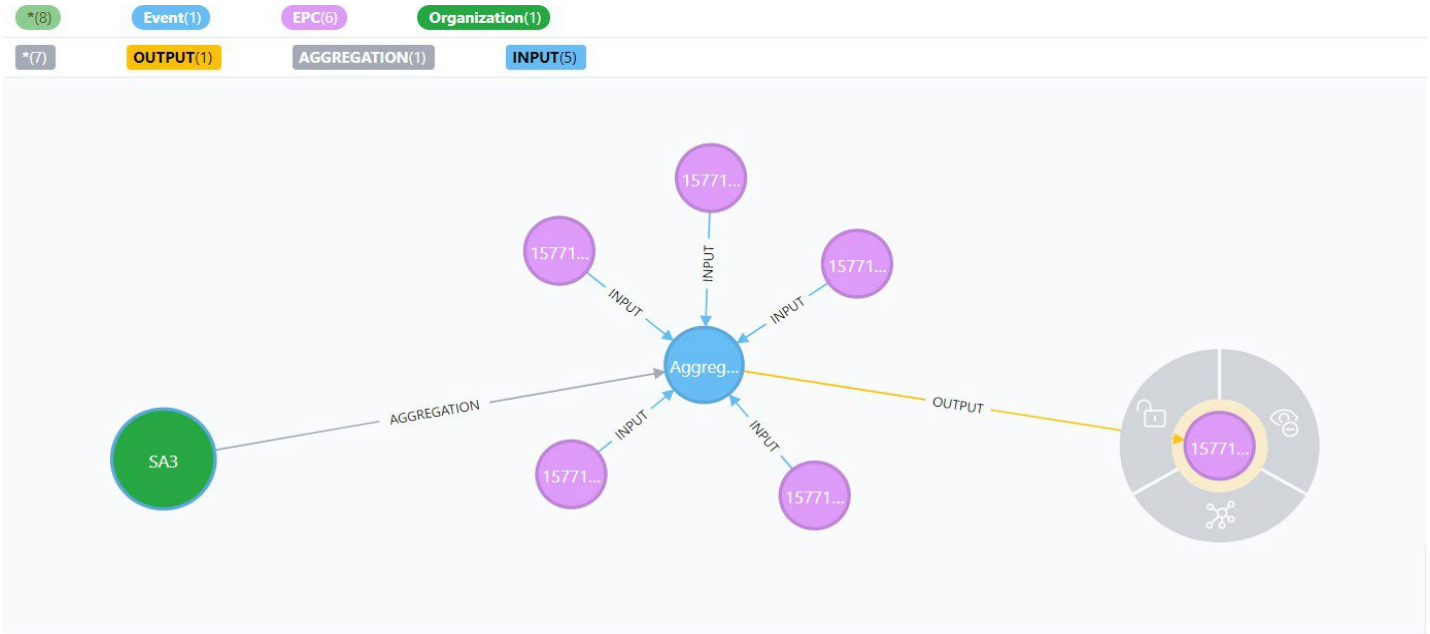


Figure 10. Visualization screen capture of the 5-pack aggregation event at SA3 recorded in IDLogiq digital ledger.

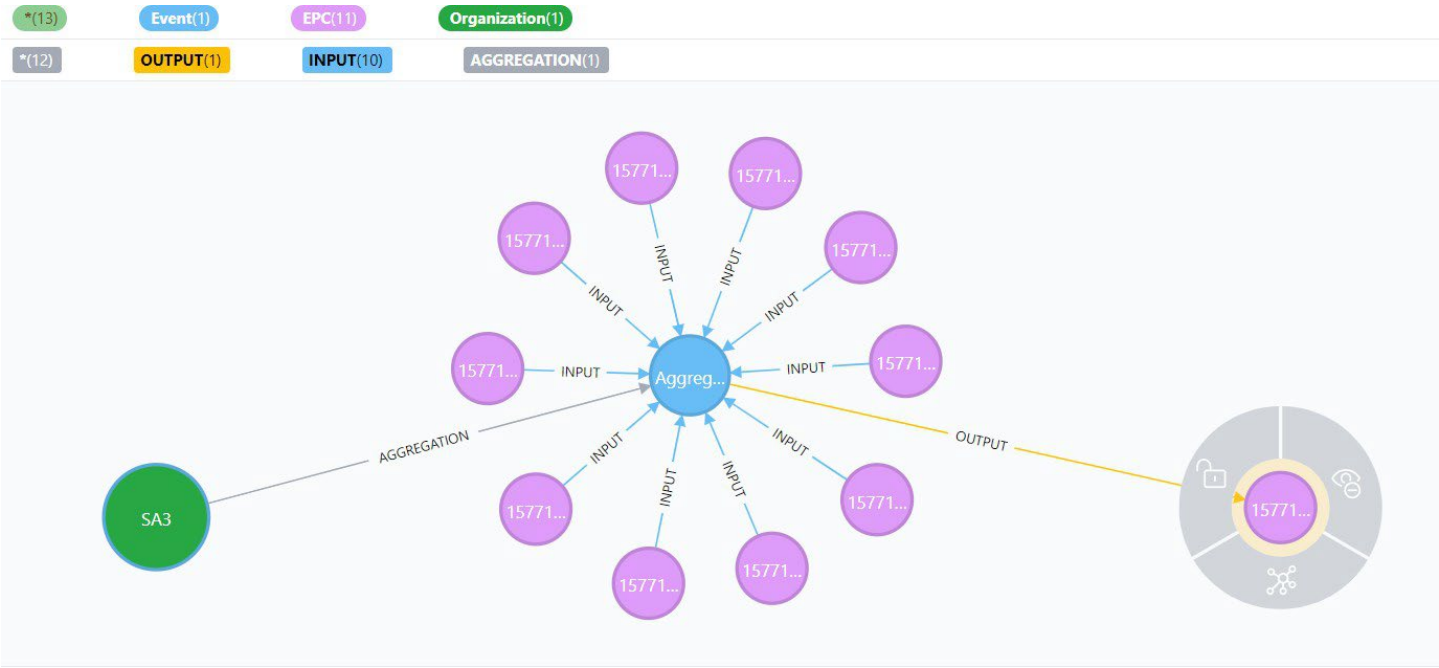


Figure 11. Visualization screen capture of the 10-pack aggregation event at SA3 recorded in IDLogiq digital ledger.

3.7 Transfer Out (Shipping)

SA3 ships the package to Good Life Pharmacy and Alpha Pharmacy (3 different pharmacy locations).

Shipment procedure using IDLogiq application is straightforward. Once logged in, open the DSCSA tool on the application and follow these steps:

1) Select “Shipping”.
2) Press “Add new item”.
   a) Scan the SA3 on the bottle.
   b) Repeat step 2a until all items for the shipment are scanned.
   c) Press “next”.
3) Select “Transfer To” and select Alpha Medical or Good Life Pharmacy.
4) Add note “Shipping to Pharmacy”.
5) Press “Submit”. Our system would create a shipping event with details of the parent package, EPC of all child elements in that parent package, lot number, source and destination details of the transfer shipping event, thus allowing SA3 to track the entire supply chain from receiving the package, transformation by repackaging and to the final shipment to the pharmacy.

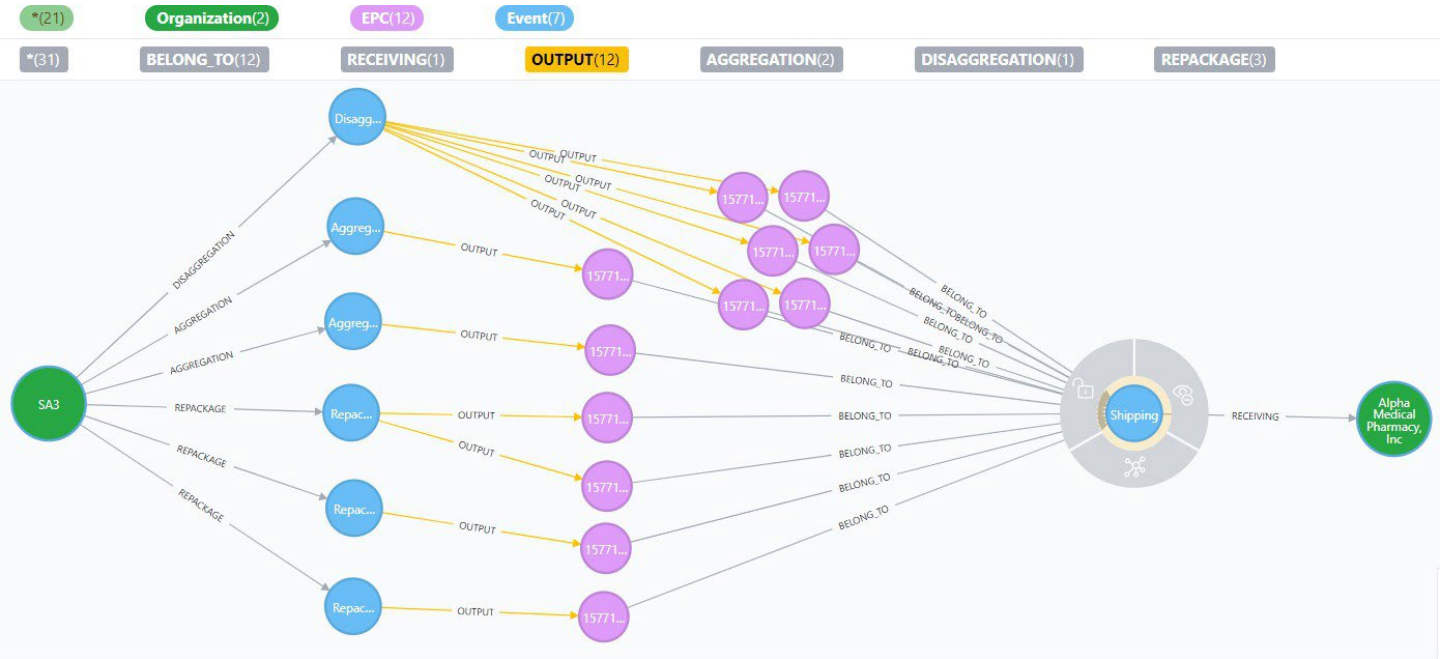
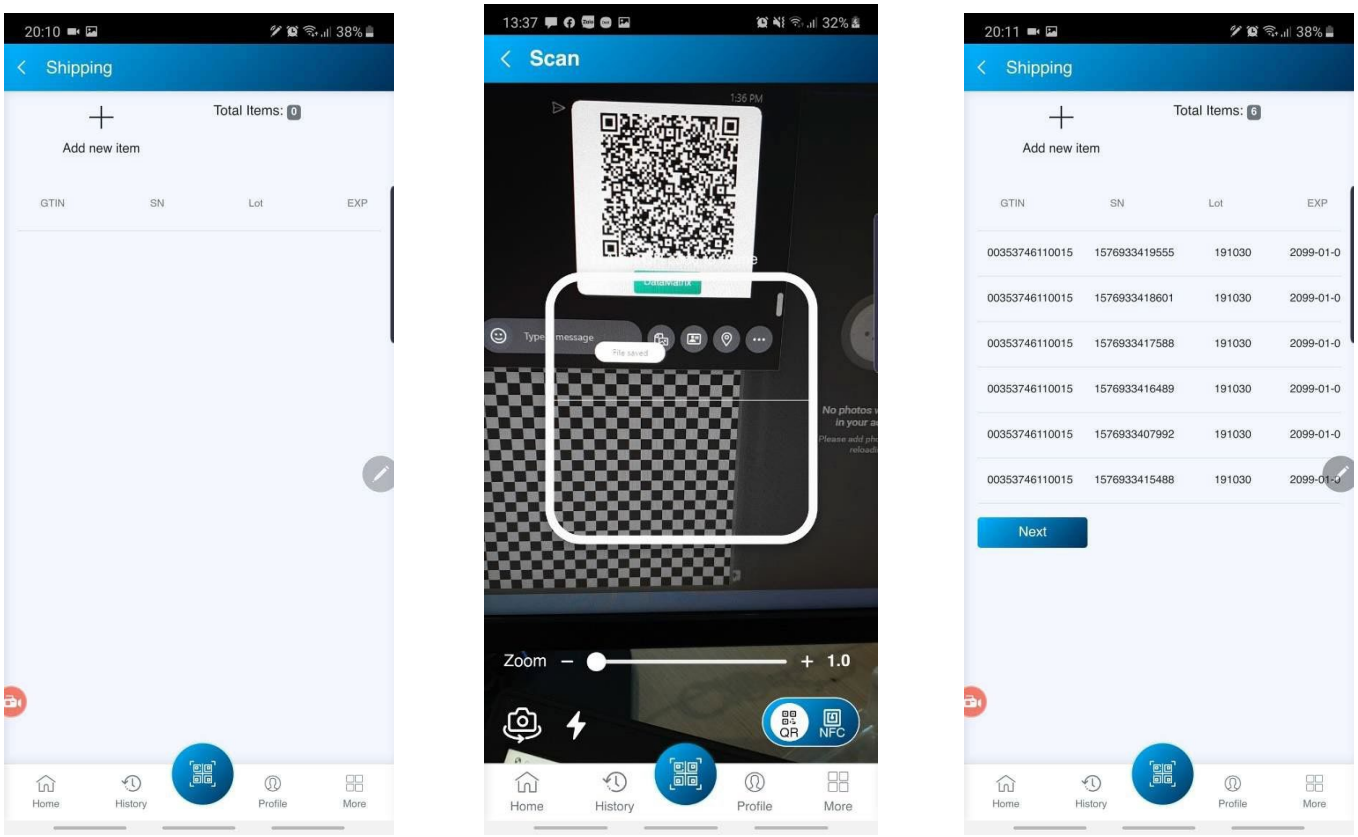


Figure 12. Screen capture depicting SA3 shipment event to Alpha Medical pharmacy

3.7.1 Shipping example through Screenshots

3.7.1.1 Add all source items to be shipped using barcode scanner

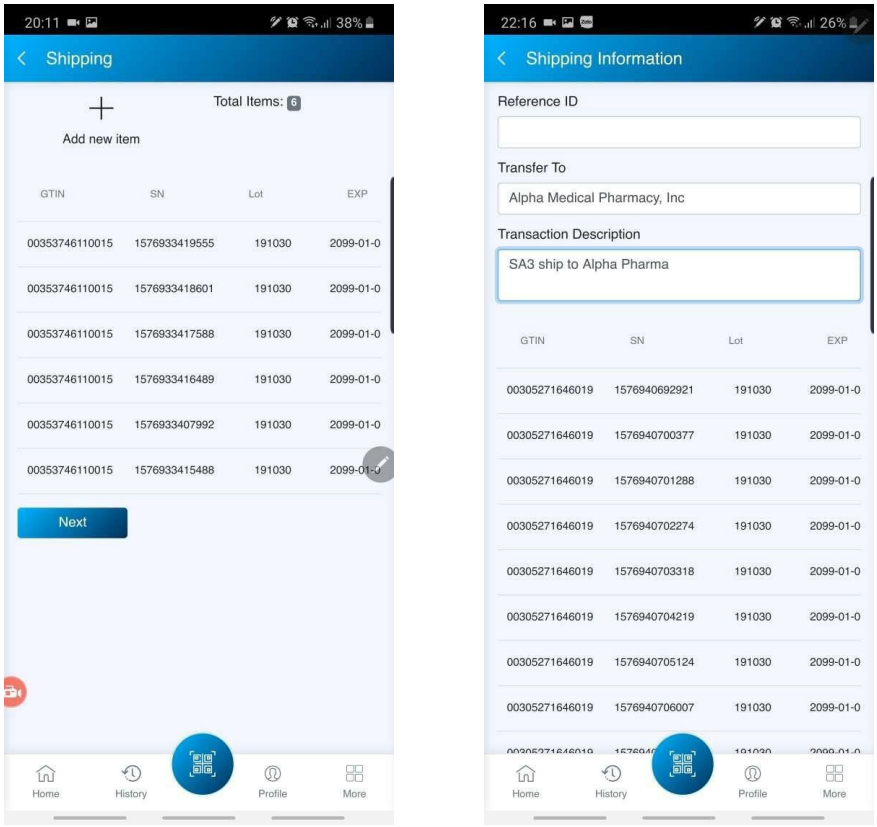
The user of the IDLogiq app clicks on “Add source item” button. A barcode scanner is opened by the application, which the user can use to scan all source labels. After an item is scanned all information about the item such as GTIN, Lot number, Expiration, etc. appears on screen.



Screenshot 8. Shipping UI to scan all items to be shipped

3.7.1.2 Enter the shipping information of the destination

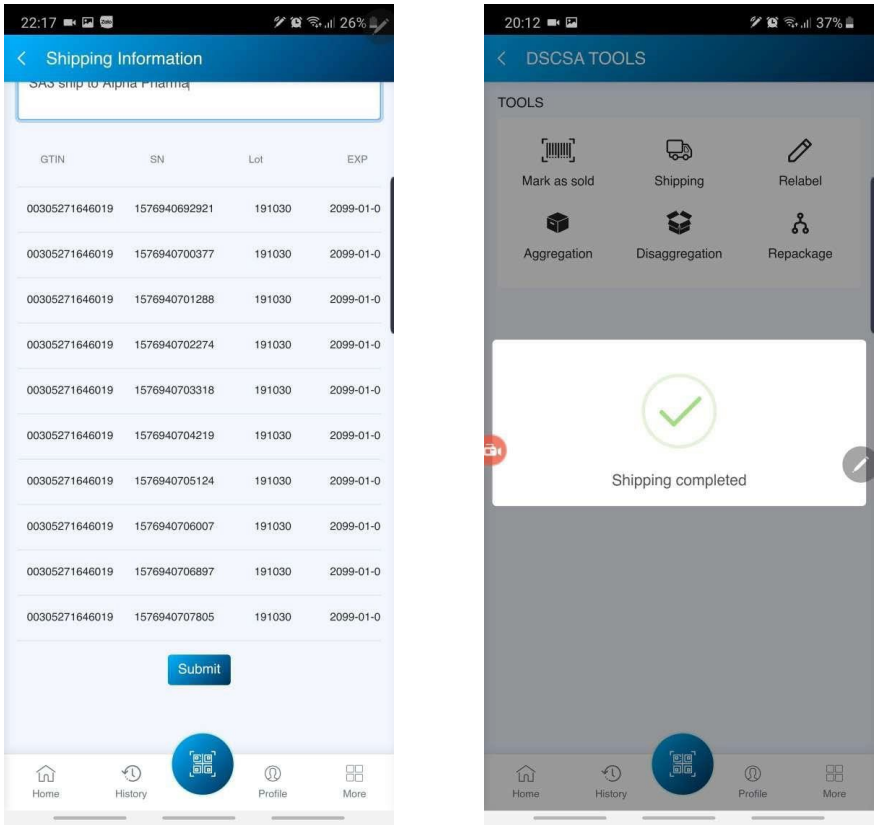
The user of IDLogiq would enter the destination information for all the items ready to be shipped. IDLogiq app already has a drop-down list of all trading partners that the repackager has relationship with or regularly ship to.



Screenshot 9. Shipping UI to enter destination details

3.7.1.3 Complete the shipping event

After all information of the destination is filled, shipping event is trigger. Every shipping event trigger through the UI is recorded in IDLogiq digital ledger with all the information attached to the event, such as items listed in shipping, source, destination, timestamp.



Screenshot 10. Shipping UI to complete shipping process

3.8 Track and Trace, Report Generator

We allow SA3 to generate a report of the entire lifecycle of an item using our dashboard containing all detail information of each EPCIS format event recorded. SA3 then can export EPCIS file from IDLogiq dashboard containing the information of the shipment (EPCs, GTIN, SGTIN, LGTIN, Source, Destination). For this reporting period, we also added support for track-and-trace of individual products from its issuance, repackaging, process through aggregation and disaggregation, to final shipment. We allow exporting all the event details of a product lifecycle in .csv, pdf and EPCIS 1.2 xml file format.

SA3 or any governing entity using digital ledger can track and trace all recordings during the lifecycle of a package or group of packages from creation to its final shipment. We allow clients to examine detailed graph providing “what, where, when, how, who” of each event and powerful filtering engine to customize search based on location, lot number, GTIN, source/destination of transaction, parent container id, etc. Further updates include geo-location and dynamic query syntax to enable understanding and retrieving contextual data.

3.9 Near-Field Communication (NFC) Labels Test

The following table describes the number of Near-Field Communication Labels test, IDLogiq performed at SA3 during every period of our pilot tests.

Item	September	October	November	December	TOTAL
NFC labels tested	0	0	100	100	200

Table 6. NFC labels tested during DSCSA Pilot Program

3.9.1 Issuance of NFC labels at the manufacturer

We used our IDLogiq application to perform issuance of NFC with GS1 standard barcode information as payload on the label,

6) Select “Issuer Tool” on IDLogiq application
7) Scan Alvogen 2D Datamatrix label on the bottle, scan would display the label information (GTIN, Lot number, Exp, Serial Number) on IDLogiq application to cross-check information
8) Select “Write NFC”
9) The GS1 standard barcode information would be written as payload on the NFC label along with IDLogiq cryptographic authentication ensure tamper-resistant labels
10) Repeat steps 2 to 4 for each label.

3.9.2 Issuance of NFC labels at the repackager

We used our IDLogiq application to perform issuance of NFC with GS1 standard barcode information as payload on the label,

1) Select “Issuer Tool” on IDLogiq application
2) Scan SA3 2D Datamatrix label on the bottle, scan would display the label information (GTIN, Lot number, Exp, Serial Number) on IDLogiq application to cross-check information
3) Select “Write NFC”
4) The GS1 standard barcode information would be written as payload on the NFC label along with IDLogiq cryptographic authentication ensure tamper-resistant labels
5) Repeat steps 2 to 4 for each label.

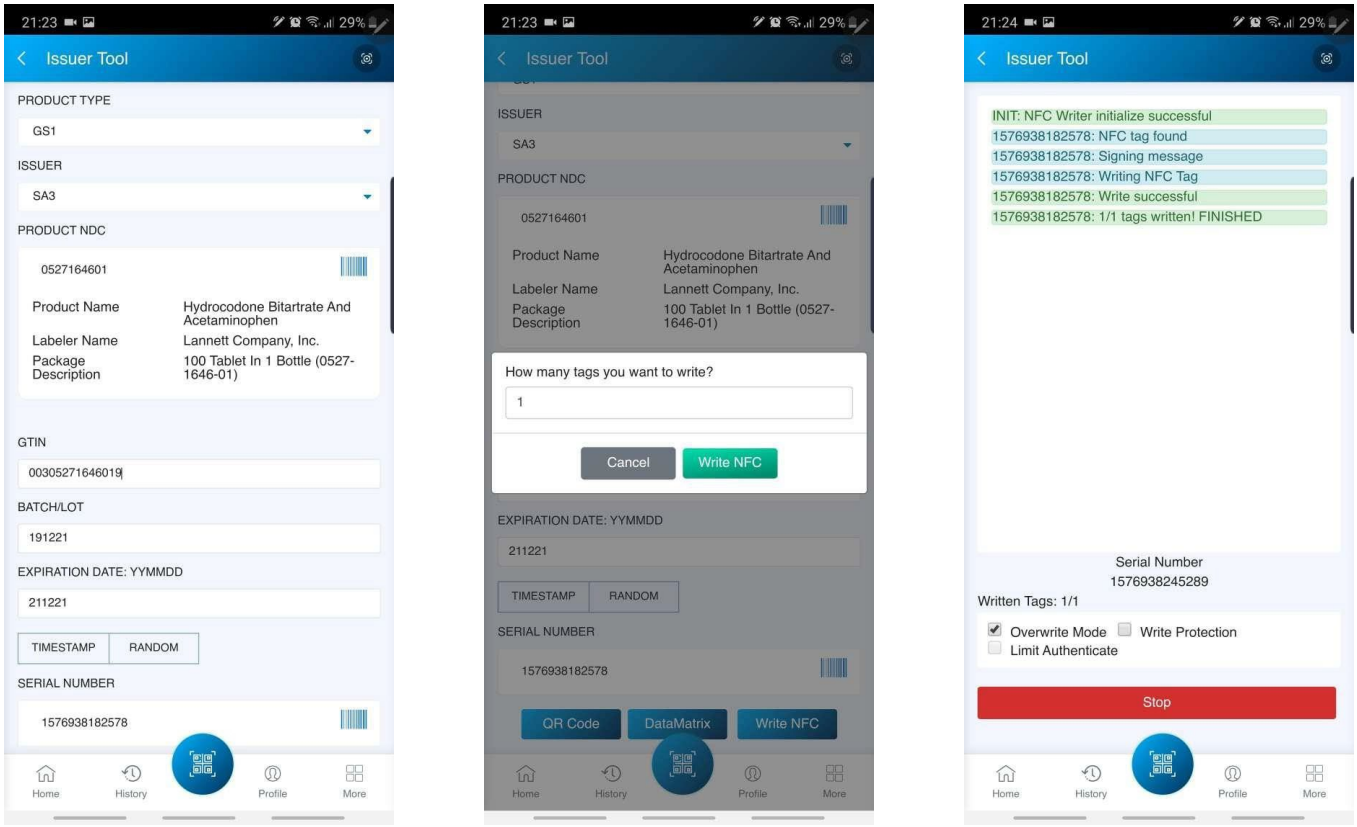
Issuance of NFC labels with SA3 GS1 standard barcode information payload along with IDLogiq cryptographic authentication ensure repackaging of NFC labels from manufacturer to repackager.

Usage of NFC labels enable us to have much more robust tamper-resistance measures than a normal Data-matrix due to the nature of NFC hardware labels and IDLogiq cryptographic authentication.

3.9.3 Near-field communication labels issuance example through screenshots

3.9.3.1 Issuing a Near-field communication label using the Issuer tool

The user of IDLogiq would access the issuer tool and scan the barcode information. After the barcode is scanned all necessary data according to GS1 standard is extracted from the barcode such as GTIN, NDC, lot number, expiration date.



Screenshot 11. NFC Issuance UI

3.9.4 Why Near-field communication label instead of Data-matrix

3.9.4.1 Anticloning

The issuer payload on the Near Field Communication label using IDLogiq application is equivalent to the GS1 data matrix. Usage of Near Field Communication labels instead of Data Matrix barcode allows user to have better and more responsive scanning. During scanning, the user of the mobile application can register the NFC label scan directly on the home screen of the mobile phone thereby opening the appropriate application in our case IDLogiq application to handle the NFC scan, enabling a user-friendly experience.

Near-Field Communication label bolsters anti-cloning properties with usage of IDLogiq Cryptographic Identity Authentication technology. Each labeled bottle can now be uniquely authenticated, and any tampering to the label or replace of label can be detected.

The IDLogiq authentication enabled label contains self-contained authentication, once the label is programmed at manufacturer it can be independently authenticated without the need of track and trace history. When IDLogiq authentication enabled label is coupled with IDLogiq track and trace system, we can ensure the authenticity of the product as well as accurate tracking of the product throughout the supply chain system to establish a robust chain-of-ownership and product authentication system.

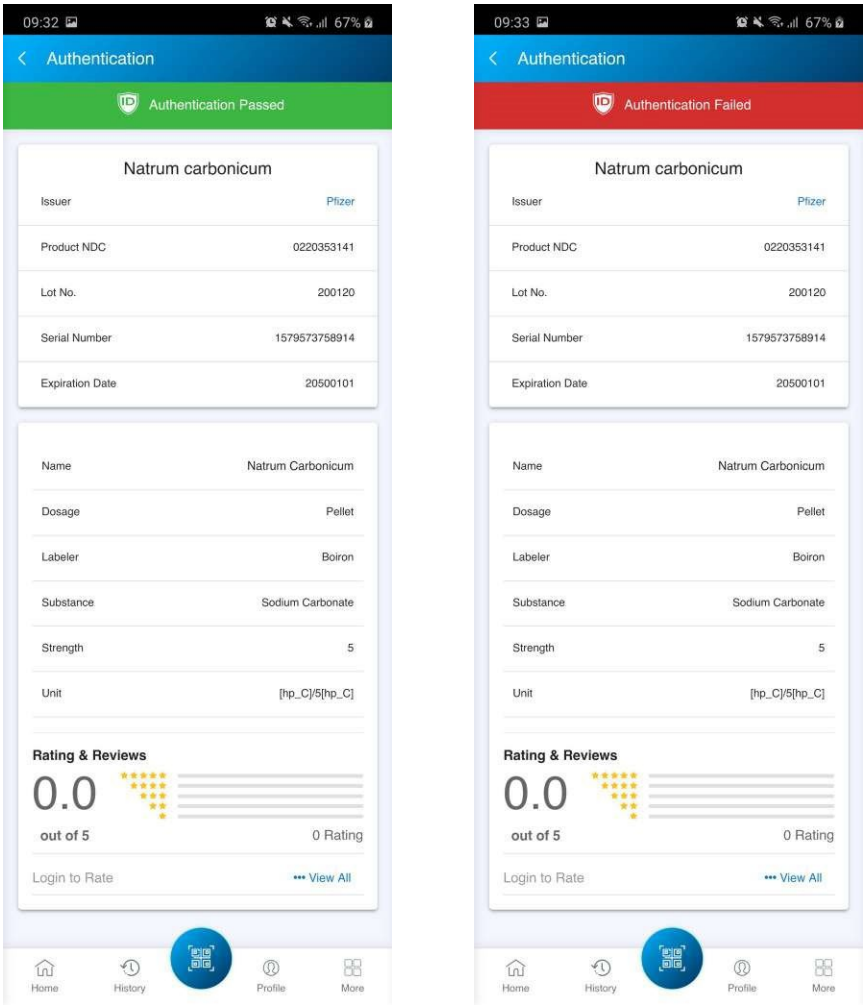
3.9.4.2 Cryptographic Authentication vs Chain of Custody

For a product with GS1 data matrix to prove authenticity requires details of its chain-of-custody to ensure that the product is not comprised with or tampered with. The Near-Field Communication label with help of IDLogiq authentication is self-contained and the data on the label is sufficient to prove its authenticity and original provenance. The customer who purchases a product such a drug, can check the whether a product is counterfeit using the product itself and doesn't require to know the Chain-of-custody of the product. Such self-contained product authentication is critical in situations where the entire Chain-of-custody cannot be exposed to the supply-chain participants or customer of product. Any detection of counterfeit product scanning would send notification to the issuer of Near-Field communication label with all necessary information about the scan.

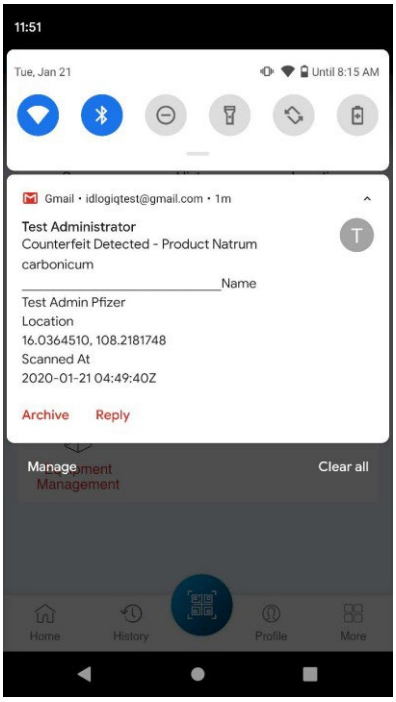
3.9.5 NFC labels end-user examples

3.9.5.1 User taps the NFC label near NFC reader of his phone

Once a user requires a product with IDLogiq secured Near-field communication label attached. The user would tap on the NFC label near his NFC reader of mobile device. The user would be notified the authenticity of the product, along with marketing information, product educational information, product side-effects. User can also open the application to perform the scanning of NFC. User accesses the NFC scan screen by using the Scan button and choose NFC option. After user completes his NFC tag scan, he would view the Authentication screen, that details whether the product pass authentication test, the product GS1 information (Drug), the Product description, reviews, and other details such as side-effects.



Screenshot 12. End User NFC Scan Screen After Product Scan. It shows two examples, one drug authentication was successful and for other the authentication was failed.



Screenshot 13. Issuer of the product receives an email notification whenever a counterfeit is detected by user.

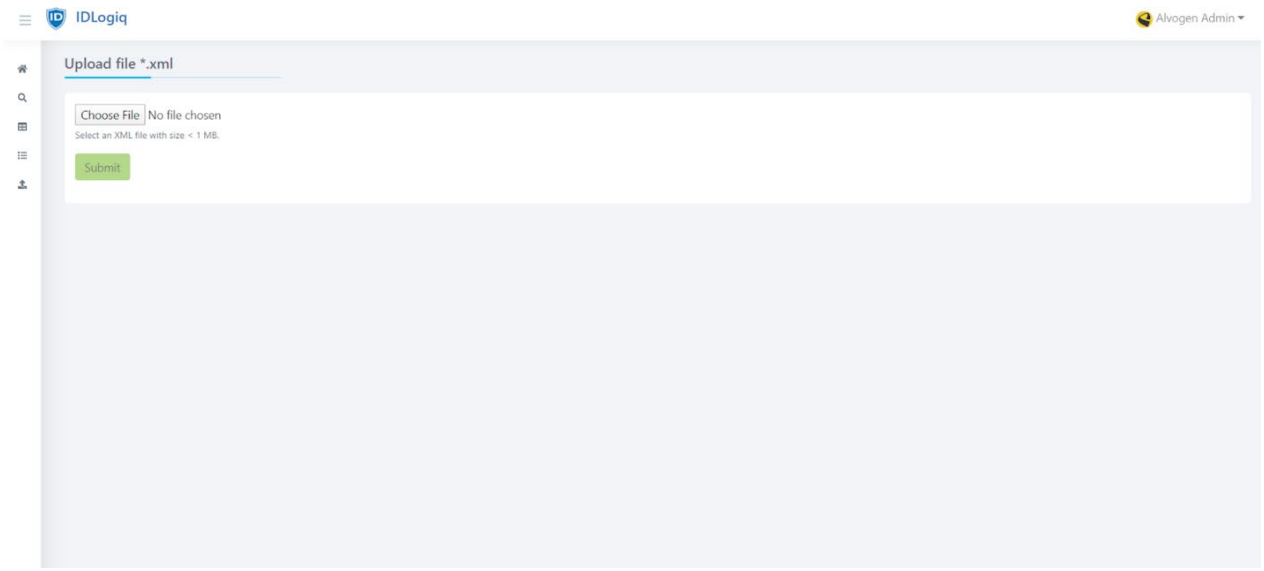
3.10Import/Export EPCIS files

IDLogiq dashboard allows manufacturers, repackagers, and pharmacies to easily import the shipment notice files received in EPCIS 1.1 format. Once the EPCIS files are imported by organizations all recorded shipments will be correctly added to reflect the their IDLogiq digital ledger.

3.10.1 EPCIS Import/Export example through screenshots

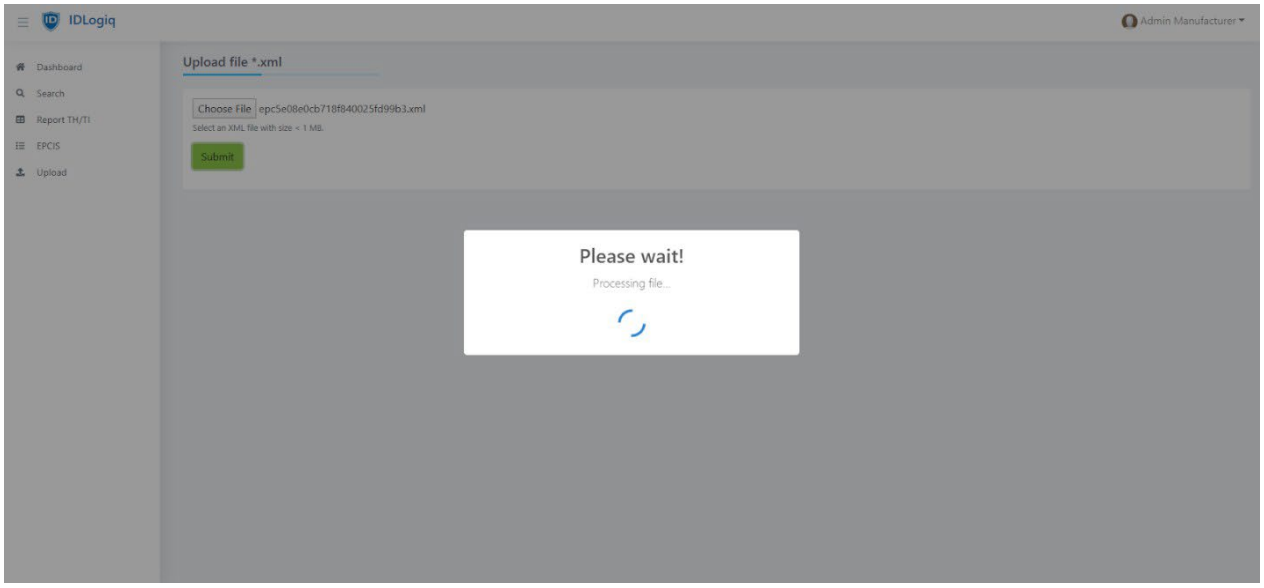
3.10.1.1 Import EPCIS file from IDLogiq dashboard

After successfully authenticating with IDLogiq dashboard, an organization employee can select **“Upload”** section from the menu on dashboard and would see the below screen.

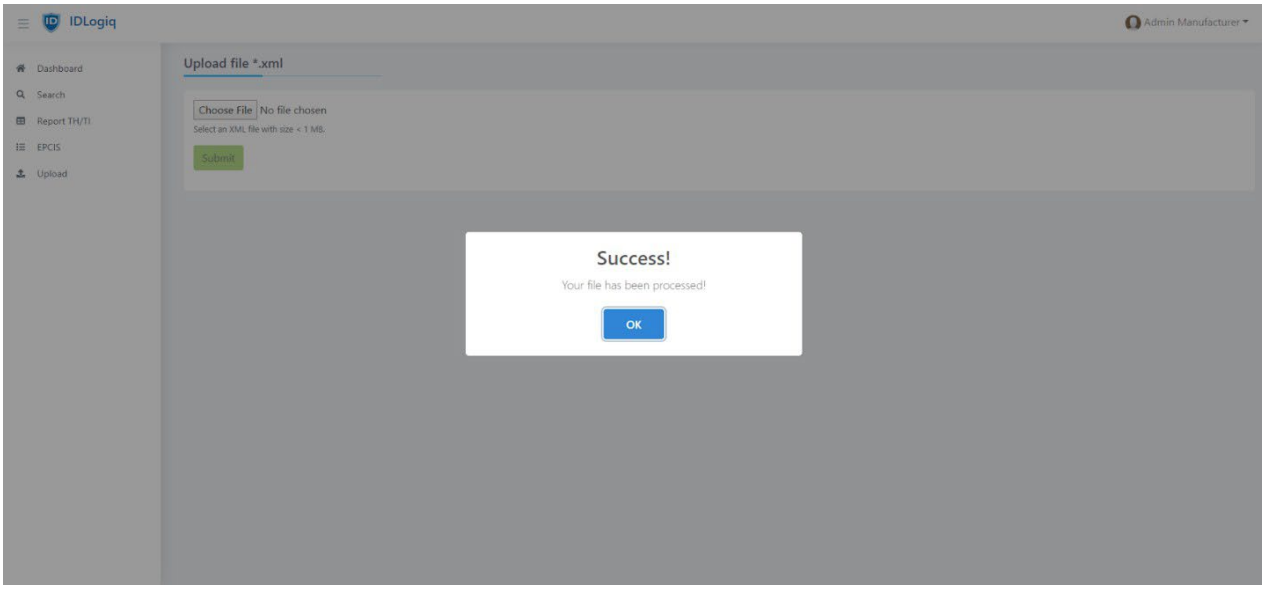


Screenshot 14. Choose file to import

Choose the necessary EPCIS file in xml format to upload to the IDLogiq dashboard.



Screenshot 15. Once the file is imported please wait till it is parsed correctly

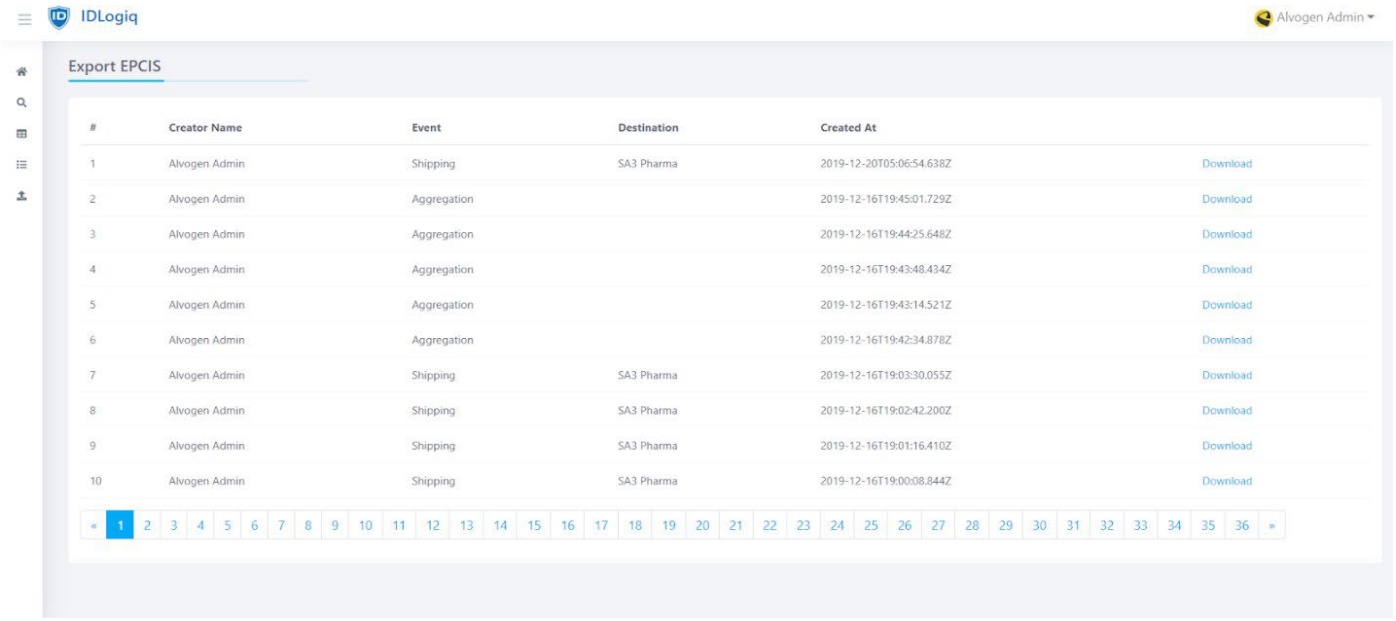


Screenshot 16. Prompt notifying that the epcis parsing was successfully

Importing of EPCIS file is successfully completed and IDLogiq graph ledger would be updated. After a successful import the employee for the organization can visit the Search section to cross-verify if the items shipped are successfully added under his/her organization.

3.10.1.2 Export EPCIS file from IDLogiq dashboard

After authenticating with IDLogiq dashboard, we can find all the EPCIS files to be exported by the organization under the EPCIS section.



Screenshot 17. Export EPCIS file by using Download option on the right

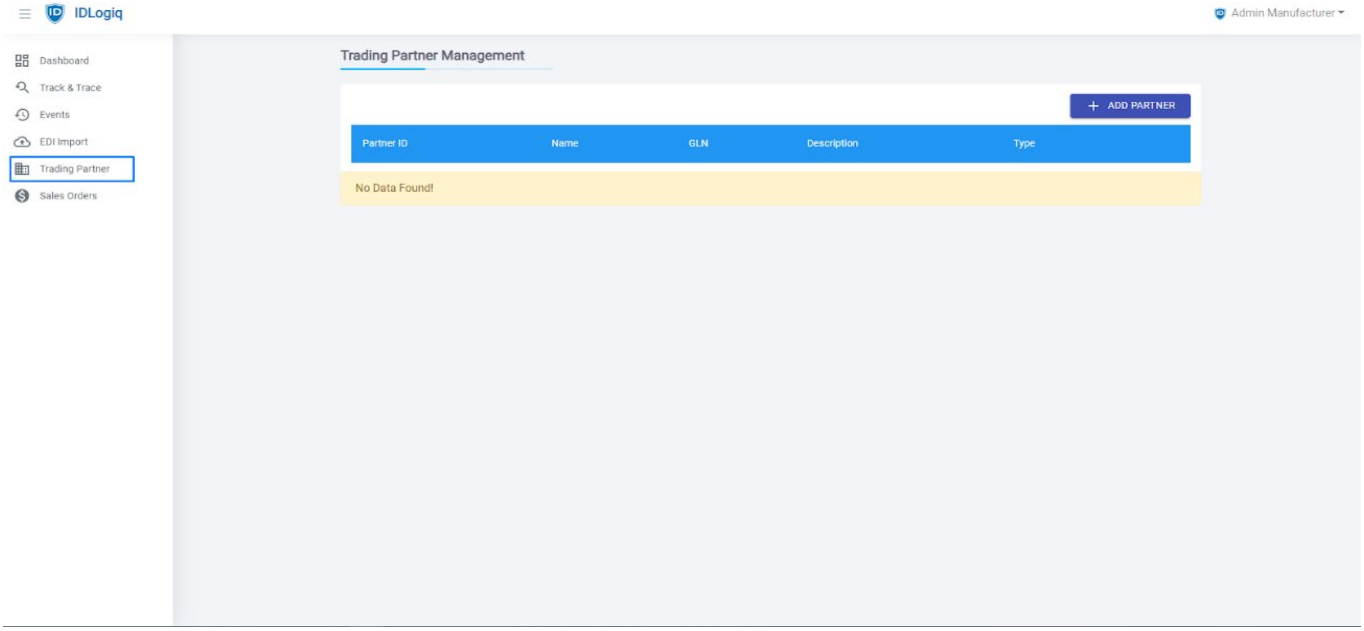
3.11 Trading Partner Management

Management of Trading Partner is critical while operating together with different manufacturers, repackagers and dispensers. We allow every company using IDLogiq software to manage their trading partners through IDLogiq dashboard. Each company creates, access and manages their trading partner list in their private container to ensure privacy of data.

3.11.1 Trading Partner Management example through screenshots

3.11.1.1 Access to trading partner list using IDLogiq dashboard

User access trading partner list through the IDLogiq dashboard menu.

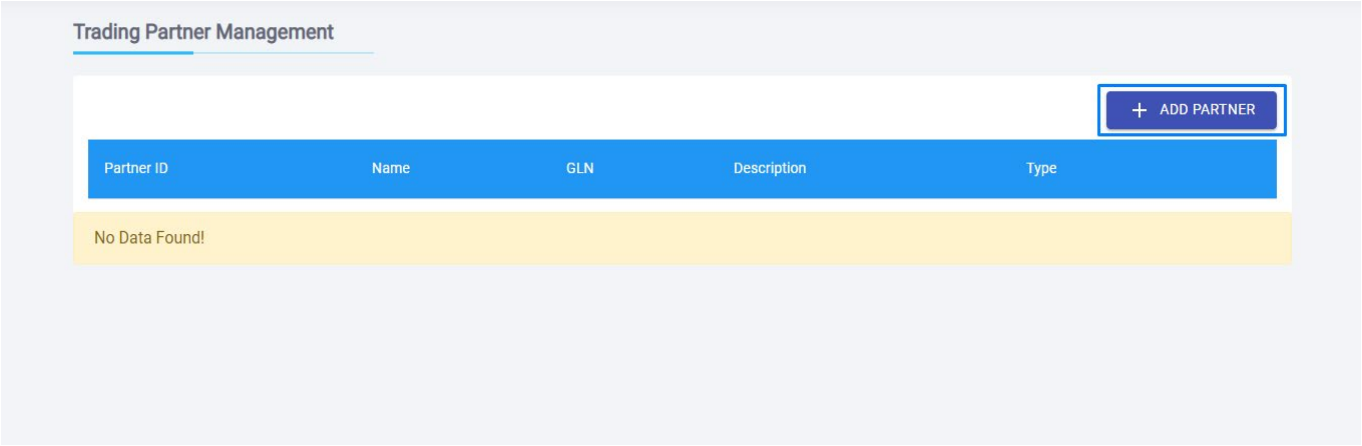


Screenshot 18. Trading partner list dashboard view

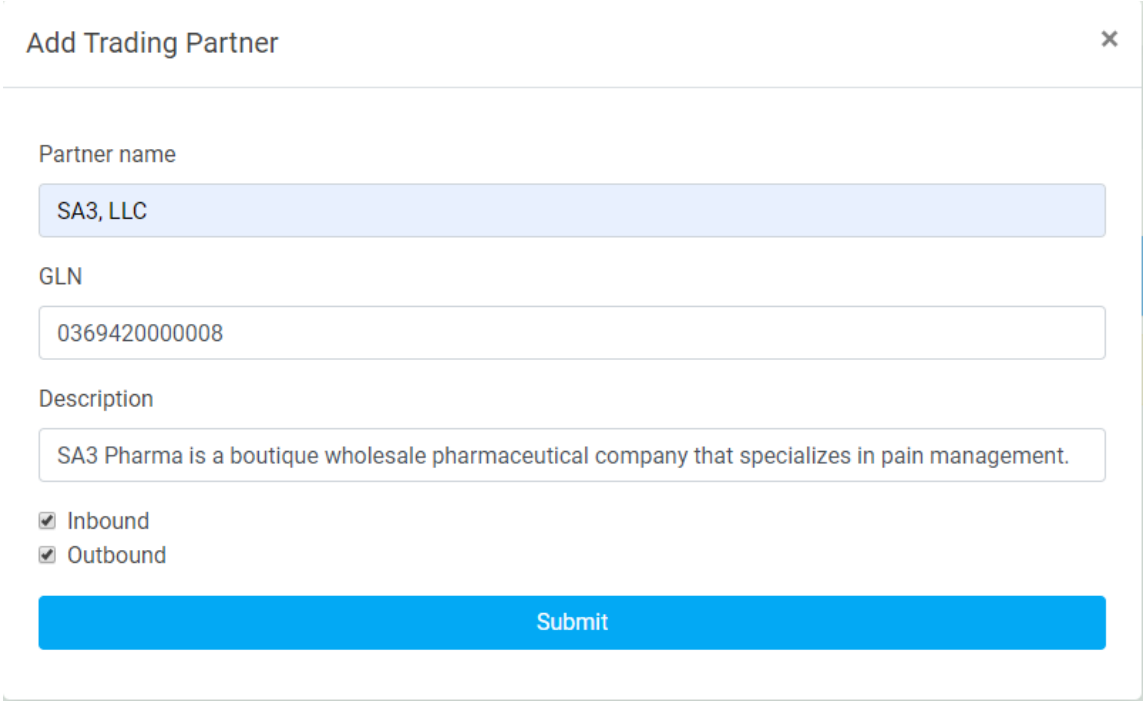
3.11.1.2 Adding Trading partner using IDLogiq dashboard

At first the trading partner list would be empty, each company adds the list of trading partner it would participate with during transfer of products.

In order to add a new trading partner, every company administrator would add a partner using the “Add Partner” and using Partner’s GLN along with name to uniquely identify their partner.



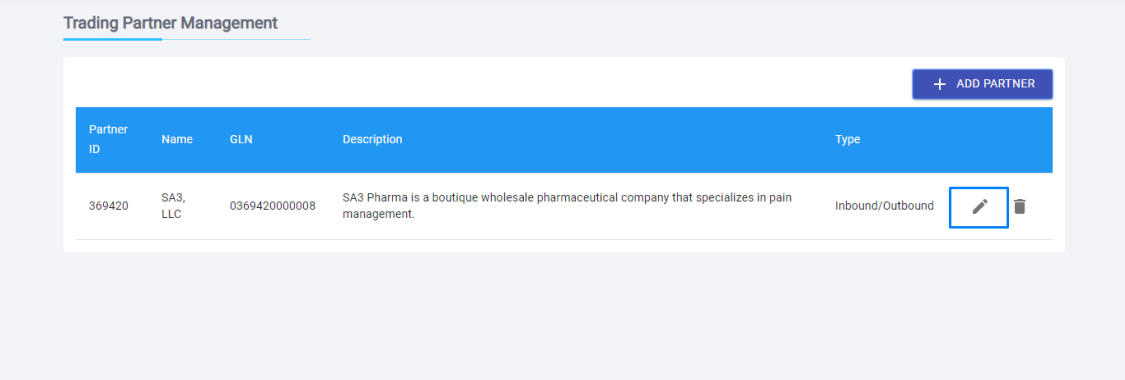
Screenshot 19. Add partner button



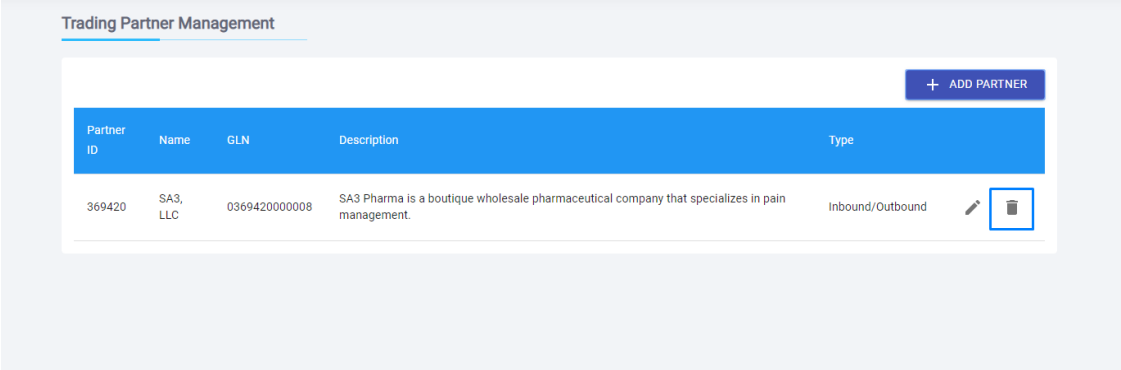
Screenshot 20. Example of adding Trading Partner for manufacturer Alvogen

3.11.1.3 Update or Remove Trading Partners

IDLogiq dashboard allows update and removal of trading partners, through the “Update” and “Delete” icons.



Screenshot 21. Example of trading partner edit



Screenshot 22. Example of trading partner deletion

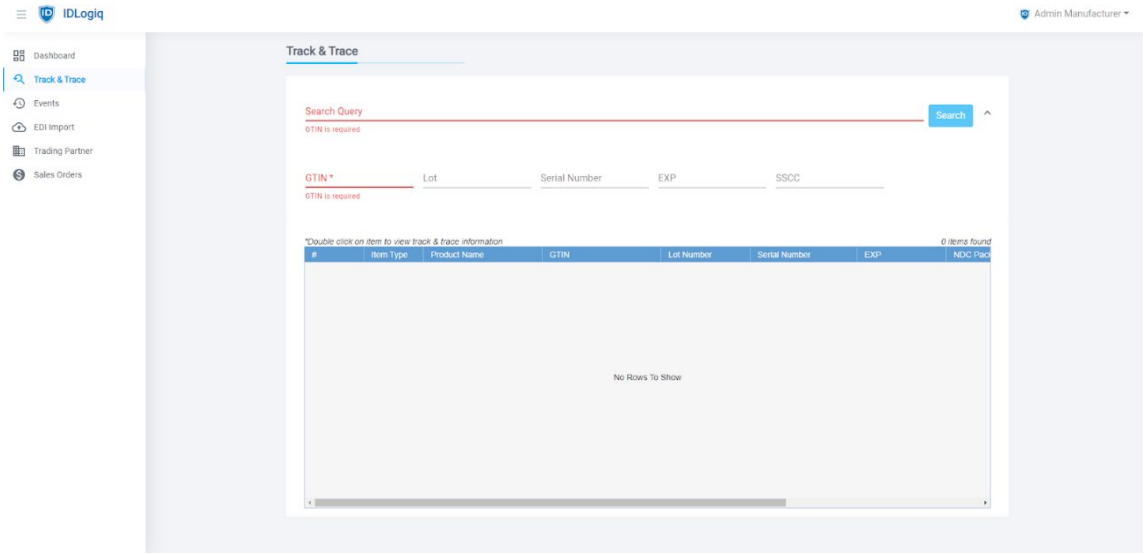
3.12 Search and Visualization using IDLogiq track-and-trace dashboard

IDLogiq track-and-trace dashboard allows organizations to search and visualize the product chain of custody history. IDLogiq provides filtering depending upon Serial number, expiration date, lot number, SCCC, etc.

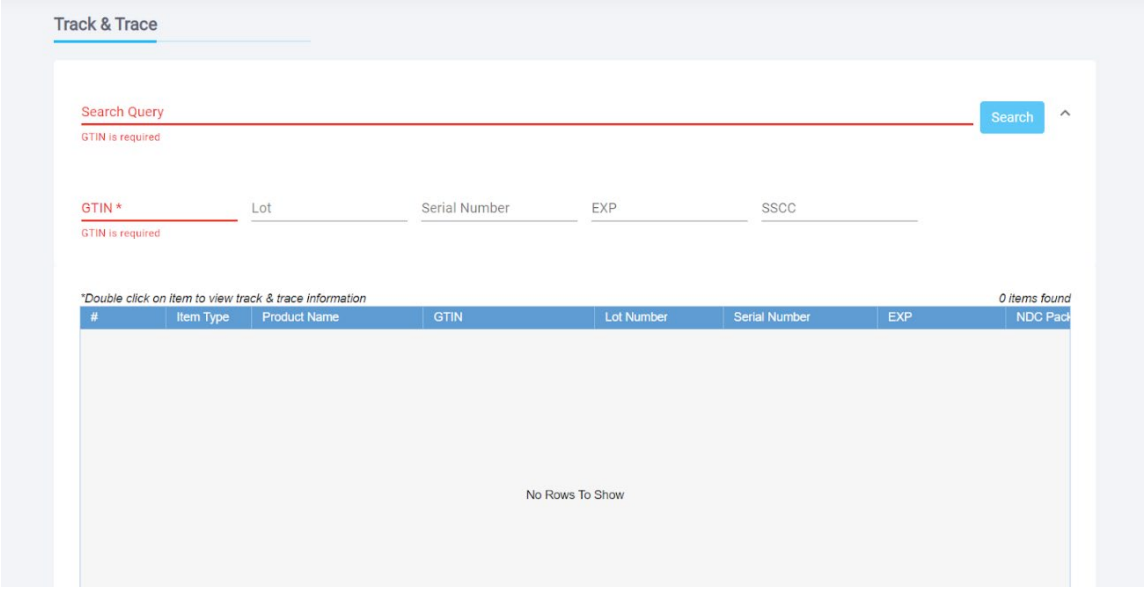
3.12.1 Search and Visualization example through screenshots

3.12.1.1 Track & Trace Query View

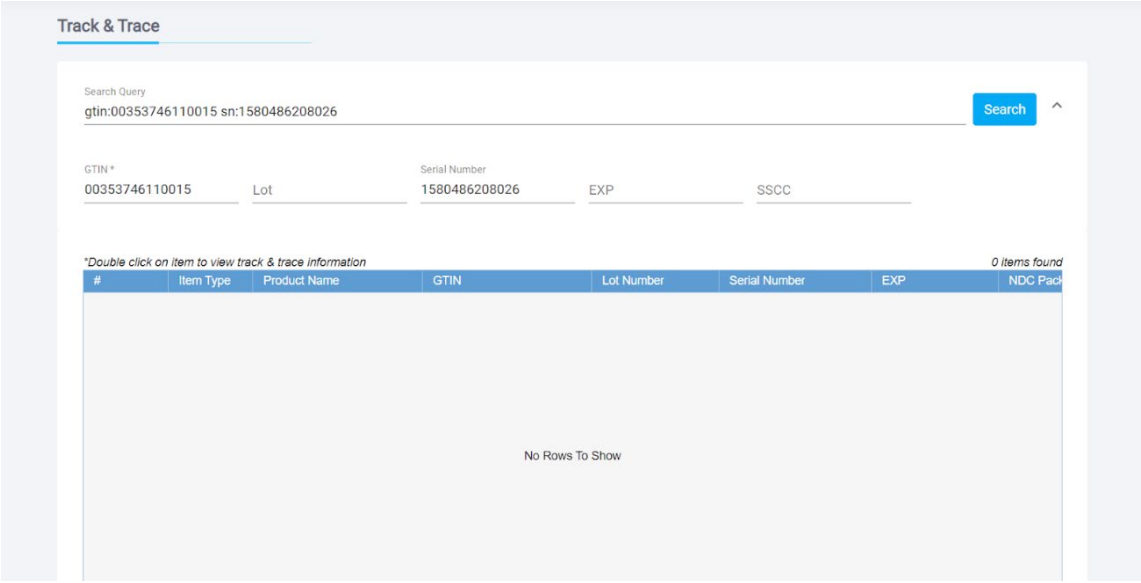
The Track & Trace query view can be located under the vertical menu of IDLogiq Report Dashboard.



Screenshot 23. Example of Track & Trace Menu Icon on the left of IDLogiq dashboard



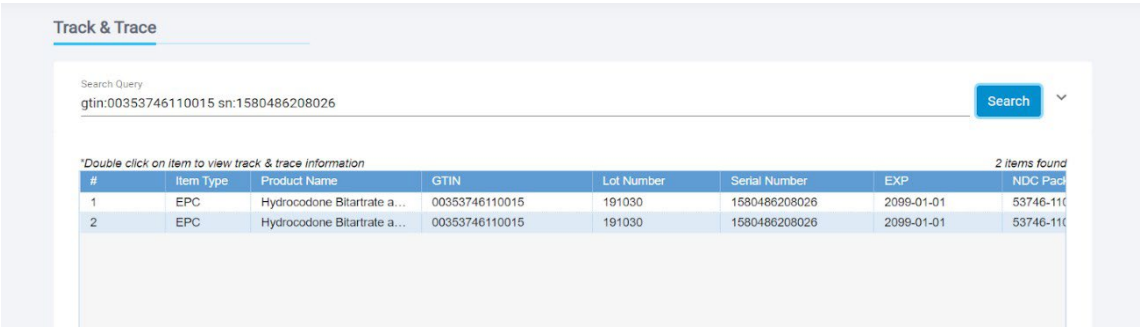
Screenshot 24. Example of Trace & Trace Query View



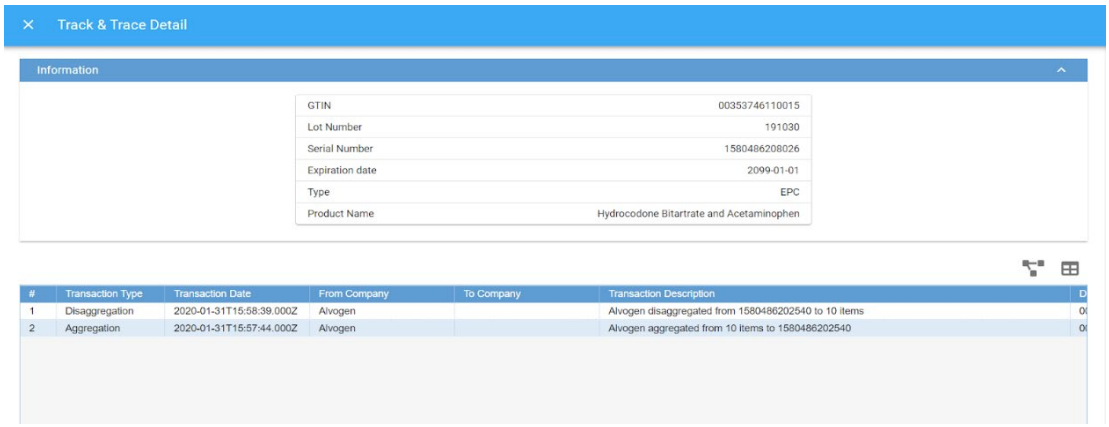
Screenshot 25. Example Trace & Trace query input

3.12.2 Query Result Information Display in Tabular Form

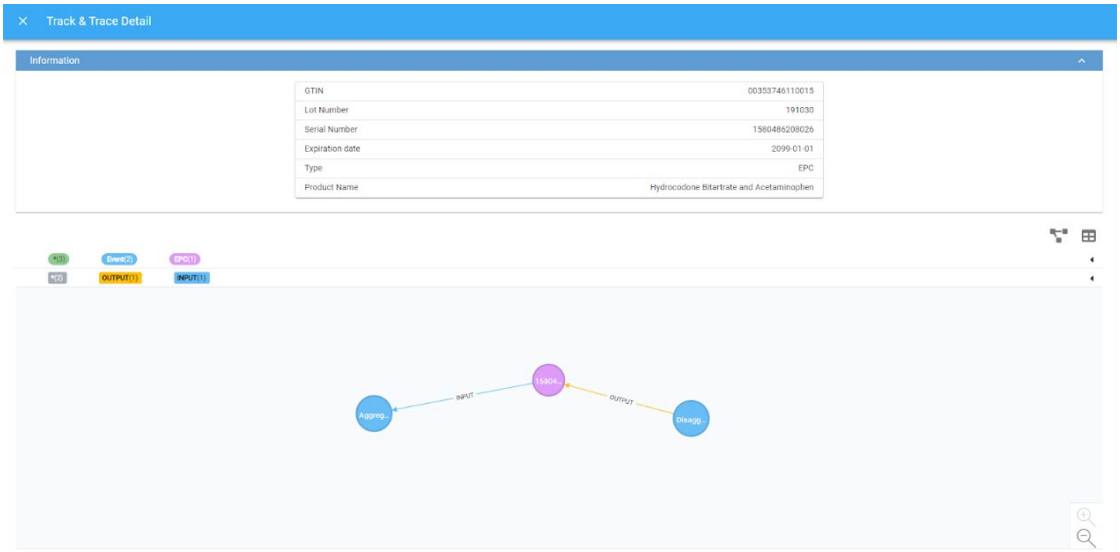
The result of queries would be displayed in a tabular format as follow



Screenshot 26. Example of Tabular Format Result



Screenshot 27. Example of Detail View through Tabular Format



Screenshot 28. Example of Graphical View

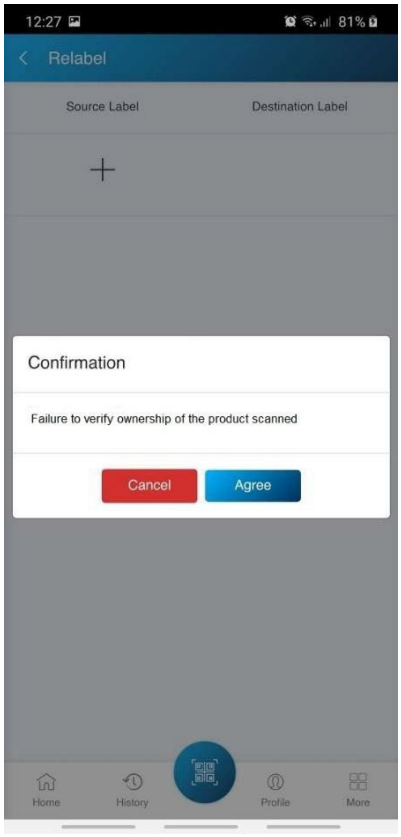
3.13 Error detection during custody transfer

IDLogiq has built-in robust error detection and prevention technology to mitigate problems caused by human/mismanagement of items while aggregating, repackaging and disaggregating, erroneous transfer of ownership, and cryptographic authentication tampering. IDLogiq maintains a real-time, complete chain of custody record for each product throughout its entire lifecycle. This allows us to verify transfer of ownership when a new EPCIS event is initiated by the manufacturer, repackager, or dispenser. A successful transfer of ownership takes place when the entity initiating the EPCIS event has ownership over the item specified by the event.

Our design pays careful attention to error and exception handling, especially human errors within the supply-chain, which could result in corrupted or erroneous history of track and trace. Stringent error detection techniques are employed to prevent/detect any discrepancies during packaging and the operator is warned with clear indicator/notification.

3.13.1 Detection of erroneous ownership

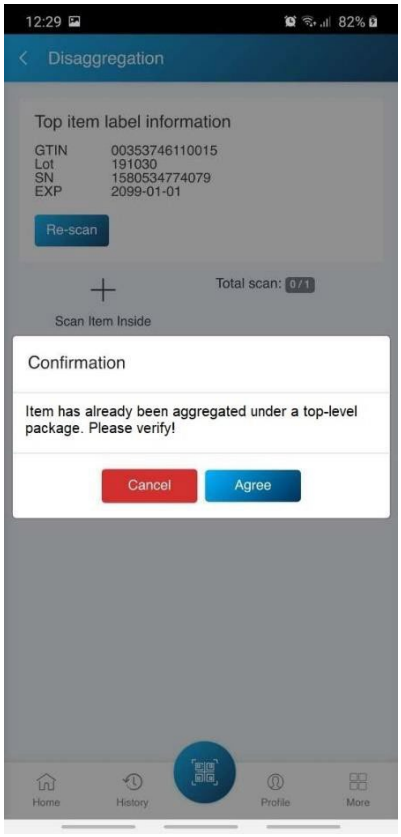
During creation of every EPCIS event, such as repackaging, shipping, aggregation and disaggregation, IDLogiq application performs an ownership check for every product to ensure that the entity performing the EPCIS event has ownership claims to change the state of that product.



Screenshot 29. Error notification provided to the user after detecting invalid ownership of product

3.13.2 Detection of erroneous aggregation

During aggregation event, IDLogiq application performs a check whether the child item to be aggregated is already aggregated into another package. Such check help prevent errors that can happen due to human mismanagement of products during aggregation.



Screenshot 30. Error notification provided to the user after detecting invalid child item aggregation

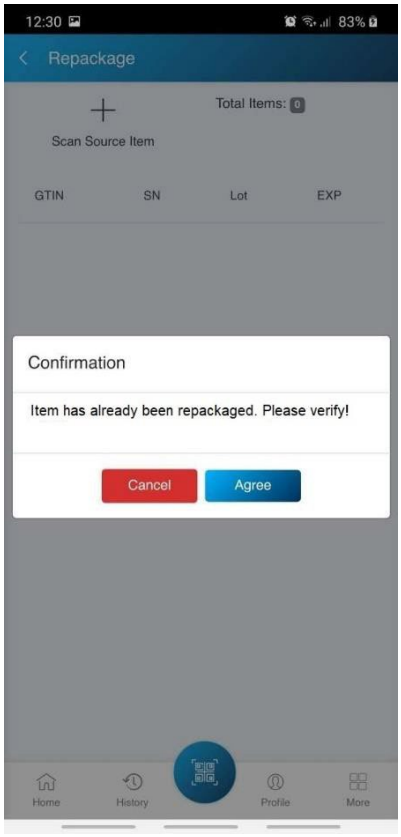
3.13.3 Detection of erroneous disaggregation

During disaggregation event, IDLogiq application performs a check whether the parent item to be disaggregated is already disaggregated into another package. Such check help prevent errors that can happen due to human mismanagement of products during disaggregation.

Screenshot 31. Error notification provided to the user after detecting invalid parent item dis-aggregation

3.13.4 Detection of erroneous repackaging

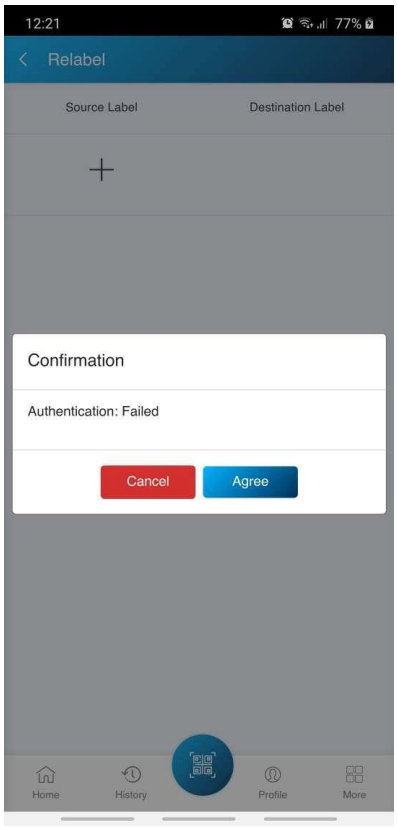
During repackaging event, IDLogiq application performs a check whether the product to be repackage has already gone through the repackaging . Such check help prevent errors that can happen due to human mismanagement of products during repackaging.



Screenshot 32. Error notification provided to the user after detecting invalid repackaging

3.13.5 Detection of cryptographic authentication tampering

IDLogiq application performs a cryptographic authentication check whether the product participating in the EPCIS event is tampered with or counterfeited.



Screenshot 33. Error notification provided to the user after detecting failure in cryptographic authentication

4 Project Focus Area

4.1 Project Focus Area 1: Interoperability

Over our pilot test period, we learned from our partners (Alexso) about heavy usage of ASN EDI 856 or other form of XML files supported by Tracelink (but support lot tracking only, still without SN support). We updated our IDLogiq system with backward compatibility to ASN EDI 856. Current version of IDLogiq supports interoperability between partners through EPCIS 1.2 format and ASN EDI 856.

4.2 Project Focus Area 2: Barcode

4.2.1 Objectives

1) Issue GS1 standard data matrix labels and manage the serialization.
2) Issue GS1 standard data matrix labels that support package level identification by adjusting GTIN number and check-sum digit
3) Issue GS1 standard data matrix labels with IDLogiq cryptographic authentication and manage their serialization.
4) Issuer GS1 standard data matrix labels with IDLogiq cryptographic authentication that support package level identification by adjusting GTIN number and check-sum digit.
5) Allow scanning of GS1 standard barcode and identifying differences between item-level and package- level barcodes to extract necessary information to develop an EPCIS event.
6) Detect errors by checking authentication and validity of ownership during creation of new supply chain EPCIS events.

7) Issue GS1 standard Near-field communication labels that support item level identification and cryptographic authentication.

4.2.2 Process

4.2.2.1 Methods used for the issuance of GS1 standard barcode and manage the serialization

1) SN generation: each serial number is generated using cryptographic function so that an attacker cannot predict or guess the next valid serial number in the serialization process.

4.2.2.2 Methods used for the issuance of GS1 standard barcode with IDLogiq serialization and manage the serialization

1) SN generation: each serial number is generated using cryptographic function so that an attacker cannot predict or guess the next valid serial number in the serialization process.
2) IDLogiq cryptographic authentication: each GS1 data matrix barcode coupled with self-contained cryptographic authentication.

4.2.2.3 Detect errors by checking authentication and validity of ownership during creation of new supply chain EPCIS events

1) Authenticity check: During creation of every EPCIS event (issuance, repackaging, shipping), IDLogiq application allow to check authenticity of the product using GS1 standard data-matrix barcode with IDLogiq cryptographic authentication.
2) Validity check: During create of every EPCIS event (issuance, repackaging, shipping), IDLogiq application allow to check the validity of ownership, e.g. whether the product embedded in the current EPCIS events belongs to the owner who initiates the EPCIS event.

4.2.2.4 NFC labels serialization with Cryptographic Identity Authentication to prevent counterfeiting of products

1) SN generation: each serial number is generated using cryptographic function so that an attacker cannot predict or guess the next valid serial number in the serialization process.
2) A Cryptographic Identity Authentication function is also applied to protect the entire payload.

Potential issues to examine in test	Evaluation methods	Results/Comments
Readability of a barcode either printed or affixed to product, including impact of environmental and human factors. Application of linear barcode and 2D barcode on product. Distinguishing which barcode to read/use	After attaching the barcode to bottles, we performed scanning of each barcode in our repackaging process. We performed scanning and testing of GS1 standard package-level barcodes.	Both product-level and package-level barcodes where successfully scanned on curved and flat surface. Our system was also able to differentiate between package and product level barcodes, contributing to successful aggregation and disaggregation simulation. We also coupled barcodes with additional NFC hardware. NFC test was successful. We were able to issue NFC under SA3 and also cross-verify those labels using IDLogiq mobile application.

4.3 Project Focus Area 4: Aggregation/Disaggregation

4.3.1 Objectives

1) Examine impact of aggregation/disaggregation
2) Exception handling: errors, accuracy

4.3.2 Process

Potential issues to examine in test	Evaluation methods	Results/Comments
Test multiple levels of adoption of inference, by different trading partners Impacts when inference is used vs. when inference is not used; impact on trading partner Identify gaps in data or errors, accuracy of data, particularly downstream when searching or examining the data; how can errors be corrected When in distribution that inference no longer needed (e.g., the case is open and individual packages are unpacked)	Number of system and product interactions within one, and amongst multiple trading partners. Time required to conduct aggregate/ disaggregate operations and transactions. Accuracy of aggregation data (measure error counts). Time to gather aggregation/ disaggregation data for investigations and notifications. Time to resolve errors in data.	We successfully performed homogenous package level simulation that involved aggregation and disaggregation in 5-pack, 6-pack, 10-pack and 12-pack containers for period of 5monts. We were successful in tracking an individual EPC with fine grained detail. From issuance, aggregation into parent package, disaggregated back to child element, repackaging and shipped to point of sale pharmacy. We have performed simulation prescription bottles to study the entire process rigorously and had a very high accuracy to track individual EPCs. We used both GS1 standard data-matrix label and GS1 standard data-matrix label with IDLogiq cryptographic authentication. We also performed repackaging at three levels: one-to-one, many-to-one and one-to-many. The only slow-down in the process was the time required to split and package all the bottles together into containers, due to requirement of scanning individual bottles before aggregating and after disaggregating to ensure accurate tracking and cross-checking possibility of human errors occurred during aggregation.

4.4 Project Focus Area: Verification/Notification (Optional Enhancement: Real Time Suspect/Illegitimate Product Detection and Notification)

4.4.1 Objectives

1) Demonstrate the REAL-TIME response system (track and trace, verification, request for information, etc.)
2) Optional Enhancement: Demonstrate pre-emptive REAL-TIME anti-counterfeit technology using Cryptographic Identity Authentication

4.4.2 Process

Potential issues to examine in test	Evaluation methods	Results/Comments
Process for investigation of suspect or illegitimate product, including any communication or Coordination: Making and responding to verification requests Making, responding to, and termination of notifications. Responding to requests for information Testing boundaries of the system Response time for real-time system Response time under high load	Response times: Current vs. new process. Time needed to obtain product tracing information to respond to a request for verification. Time needed to make, respond to, or terminate a notification. Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall. Percentage of items that are successfully verified vs. those that were targeted for verification. Number of connections/ queries needed to gather product tracing information in response to a verification or notification request.	Any counterfeit product or human errors due to mismanagement are detected immediately during transition of products or initiation of new EPCIS events. Screenshot from 29 to 33 showcases the example of how errors are notified to the user performing repackaging, aggregation, disaggregation, and shipping. Time required to detect and report error after scanning of an erroneous label is in milli-seconds ~500ms. Time required is the summation of (time required to query web server + time required to traverse graph database index to identify status of requested query and the time required for the response for the web server). Time required to gather product tracing information to suspect or illegitimate product or recall based on mismanagement of product is also in milliseconds approximately ~700ms. Time required is the summation of (time required to query web server + time required to traverse graph database index to identify status of requested query and the time required for the response for the web server). Time required to detect an erroneous cryptographic authentication is very negligible due to the nature of IDLogiq technology to verify counterfeits using the self-contained cryptographic authentication in the Datamatrix or NFC label. All items subjected to the verification test where successful verified (200 out of 200). The number of connections required for the query to gather product tracing information is directly proportional to the number of connections or transfers the product goes through. Due to indexing we can reduce to O(N) complexity. Time for sample of queries with 7 transfer of ownerships can be averaged out to 100ms.

4.5 Project Focus Area: Exception Handling/ Errors/ Inconsistencies.

4.5.1 Objectives

Demonstrate on how error can be handled.

4.5.2 Process

Potential issues to examine in test	Evaluation methods	Results/Comments
• Identify and correct 'honest errors' (e.g., over/under shipments, clerical errors,	• Percent of errors detected: Compare exceptions introduced vs. exceptions detected: Identify the first step in the process where an error is detected. • Number of new or changed processes needed to accomplish DSCSA goals: Time and resource impacts.	Any errors Screenshot from 21 to 27 detected during EPCIS events is notified to the issuer through email shown in example Screenshot 13. IDLogiq error detection (cryptographic authentication and mismanagement of goods) can be seamlessly integrated into current supply chain tracking, with an internet-enabled device and GS1 standard labels.

5 Summary

We've successfully executed aggregation, disaggregation and repackaging tests using different GS1 standard data carriers, including data matrix and Near-Field communication (NFC) labels.

Aggregation and disaggregation need to have support from automation software to detect human generated errors during packaging and transfer. We have built-in, automated support in our IDLogiq software to prevent such errors and accurately record transfer of items through entire lifecycle of products, i.e. Issuance/creation, aggregation in parent package, disaggregation from parent package, and shipping events.

Repackaging need to have adequate support from automation software to achieve accurate track and trace functions. This is built-in to IDLogiq software intelligence.

Shipping shall also need software support to automate the process. This is also built-in to IDLogiq software.

For NFC issuance and repackaging, it's necessary to have software support for NFC write functionality, write-protection, and also link repackaged products to its previous source. All these functionalities are built-in to IDLogiq software along with cryptographic authentication of the NFC payload as an additional measure for anticloning/counterfeit detection. Using IDLogiq Cryptographic Identity Authentication technology, counterfeit product can be easily detected, even without the presence of track and trace records.

Currently, FDA does not define and standard for the details of the report and terminology used inside TI and TH, which we think might create interop issues with data interchange due to incompatible terms used by different vendors. It would be helpful if FDA can provide examples of the TI and TH report in different scenarios so that it is easier for software vendors to follow. We would love to be involved in the process.