Traceability Pilot
United States Market

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Ron Bone – McKesson
Margot Drees – GHX
Chris Chandler – GS1 US
21,000 Employees Strong
United for One Purpose

Addressing global health challenges with new therapies that make a remarkable impact on people’s lives
This team was recognized by HDMA for
**Pedigree Pilot Data Set**

1. All serial numbers assigned to a specific packaged Lot of product (item, case, and other as desired).
2. Relationships of serialized product within the packaged Lot. Serial numbers of shipped product at the logistical unit handled (case).

**AbbVie Data Sets:**
1. Serial numbers of product shipped or received at the logistical unit handled (case).

**McKesson Data Sets:**
1. Serial numbers of product received at the logistical unit handled (case).

**VA CMOP Data Sets:**
1. Serial numbers of product received at the logistical unit handled (case).
2. Serial numbers of the items removed from the logistical unit (case).
Database Models

Central Repository

Distributed Databases

Network Centric
Traceability System Approach

System Integrates:
- Serialized product data
- Trading partner relationships
- Product master data
- Supply chain events

Leverages Business Rules to:
- Display chain of custody
- Provide actionable reporting
- Manage recalls
- Manage expirations
- Notify participants of suspicious events

Manufacturer

Hospital

IDN Health System

Independent/Retail Pharmacy
Pilot Objectives

Engage provider organizations, to understand inventory and recall processes and benefits as unique identifiers are utilized

Test the use of a database network for authentication of supply chain integrity amongst manufacturer, wholesaler and pharmacy

Investigate Recall capability

Share results with the FDA and the health care community to support standards development and ensure feasible legislation
Product Packaging

Utilize data carriers to confirm events creating a history of a secure chain of custody and ownership producing a pedigree report

Trade cases of serialized product

• Cases are serialized using GS1-128 Linear Barcode (1D) containing GTIN + Serial #
• Items are serialized using GS1 Data Matrix Barcode (2D) containing GTIN + Serial #
Pilot Overview

Operations

- AbbVie Manufacturing Line
- Distribution Center

Distributed Data Bases

- SOR
  - sGTIN Data for Items and for Cases
  - Case sGTIN Associated to Order
  - sGTIN Commission Data for Items and for Cases
  - sGTIN Aggregation Data of Items to Cases
  - sGTIN of Cases Shipped

- EPCIS DB
  - sGTIN Information Commission and Ship
  - sGTIN of Case Received
  - sGTIN of Case Shipped

- GHX External Data Repository
  - sGTIN Receipt and Verification/Custody Check/Chain of Custody Reports/Event Processing/Event Reports

- GHX Internal Data
  - External Data
  - SOR = System Of Record
  - sGTIN = SNI

Hosted Data Base

Veterans Health Administration
Consolidated Mail Outpatient Pharmacy

Receive Cases

Case sGTIN Verified Against EPCIS Ship Event

Case sGTIN Associated to Order

Item sGTIN Verified Against EPCIS Aggregation Event

Item sGTIN Manually Associated to Patient Order

GHX System Of Record
sGTIN = SNI
VA Pilot: Summary

• 21 weeks of serialized trades (60 cases, 360 items)
  • 55 cases had a valid custody trail and were received serialized at the Pharmacy
  • 1 case (1 case, 6 items) used in mock “recall”
  • 4 cases did not have EPCIS events due to manual processing issues and were excluded

• EPCIS events used to track product trades of serialized cases
  • GHX web interface was used to generate and view EPCIS events for serialized products
  • Trade partners with a secure computer and internet access can track product history

• Events posted to GHX from AbbVie and McKesson allow the chain of custody for the serialized case to be traced prior to VA receipt
About McKesson

America’s oldest and largest healthcare services company

- Founded in 1833
- Ranked 14th on Fortune’s list with $122.7 billion in revenues
- Headquartered in San Francisco
- More than 37,000 employees
- Two segments: Distribution Solutions and Technology Solutions

Together with our customers and partners, we are creating a sustainable future for healthcare. Together we are charting a course to better health.
VA Pilot: McKesson Pilot Goals

• Implement an EPCIS solution to store events

• Integrate our solution with our warehouse management system

• Assist suppliers and customers to prepare for serialization activities

• Exchange data and trade serialized product with suppliers and customers
VA Pilot: McKesson Overview

• McKesson Implemented an EPCIS that was used in this pilot:
  
  • GHX sends events to McKesson via secured AS2 communication connection when it encounters a ship event to a McKesson DC
  
  • McKesson EDI System routes EPCIS events to the McKesson Enterprise EPCIS
VA Pilot: McKesson Overview

• DC Receiving:

  • Warehouse receiving application forces capture of SGTIN for serialized SKUs
  • Warehouse receiving application checks that:
    • SGTIN on the physical product matches the SGTIN stored in our EPCIS
    • Status of the SGTIN is “OK” to receive
    • Receiving purchase order matches the supplier’s business transaction which originates from McKesson’s purchase order to the supplier
    • Receiving physical location matches the supplier’s ship-to physical location
  • Receipt events are generated and stored in McKesson EPCIS
  • Receipt events are extracted from McKesson EPCIS and loaded into GHX to update centralized system with receipt event for chain of custody
VA Pilot: McKesson Overview

• DC Shipping:
  
  • Warehouse shipping application forces the capture of the SGTIN for serialized SKUs
  
  • Warehouse shipping application checks:
    • SGTIN on the physical product matches the SGTIN stored in our EPCIS
    • Status of the SGTIN is ‘OK’ to Ship
  
  • Aggregation events are generated and stored in McKesson EPCIS – case or each sGTINs are aggregated to container (tote) SSCC
  
  • Ship events are generated and stored in McKesson EPCIS
  
  • Ship events are extracted from McKesson EPCIS and loaded into GHX to update centralized system with ship event to VA CMOP for chain of custody
GHX Unique Ownership & Investment

GHX...

Established in 2000

Synchronizes the supply chain of providers, suppliers, distributors and GPOs

Takes costs out of healthcare

Is open and neutral, serving all parties

Roadmap is driven equally by providers and suppliers
VA Pilot: Semi-Central Repository

• GHX can interface with external systems to exchange EPCIS events
  • Interoperability will be dependent upon how participants have implemented their track and trace solutions, whether EPCIS has been used or not
  • Adherence to a set interface is critical, many meetings and multiple weeks were needed to test data exchanged between the partners
  • Using an external EPCIS repository can provide a common location / method to share data
  • Using an external EPCIS repository will reduce the integration and testing of multiple manufacturers with multiple distributor with multiple pharmacies
  • GHX can forward EPCIS events to intended receiver based on ship event

• The GHX track and trace custody check is accomplished by grouping transaction events (EPCIS preferred) stored in the GHX track and trace database, ordering the events, and then applying business rules to events

• Business rules applied to the events can be used to determine if a product is valid for trade or if exception processing is needed
  • Consistency check and Custody check rules can be defined and adjusted at GHX to meet customer needs
  • Check can be performed at any time throughout the supply chain
VA Pilot: One up-One Down Visibility

- Partner visibility of event details is configurable. For this pilot we are currently configured to use “one up one down” visibility

<table>
<thead>
<tr>
<th>Visibility Rules</th>
<th>AbbVie Commission</th>
<th>AbbVie Aggregate</th>
<th>AbbVie Ship</th>
<th>McKesson Receive</th>
<th>McKesson Ship</th>
<th>VA-CMOP Receive</th>
<th>VA-CMOP Dis-Aggregate</th>
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<tr>
<td>AbbVie</td>
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<td>FULL</td>
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<td>FULL</td>
<td>REDACTED</td>
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<td>McKesson</td>
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<td>VA-CMOP</td>
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<td>REDACTED</td>
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</table>

Visibility to downstream GLNs redacted

Visibility upstream only provided for sGTIN related to shipment
VA Pilot: Item Verification

- Partners have visibility to AbbVie’s aggregation data
  - Ability to verify items aggregated to case
  - Further insurance product and data is consistent and from valid source

Chain of Custody

<table>
<thead>
<tr>
<th>date</th>
<th>time</th>
<th>sGTIN</th>
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<td>shipping</td>
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<td>sgl010939.182000.0</td>
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<tr>
<td>receiving</td>
<td>08/22/2012</td>
<td>sgl47037130.5171.0</td>
</tr>
<tr>
<td>disaggregation</td>
<td>10:45:08 AM</td>
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08/15/2012 12:34:10 AM AGGREGATION  SGLN 030074.000000.0

- Business Step: aggregation
- Disposition: in_progress
- Parent Product Number: sgl030074.3433902.100000003370
- Container Qty: 6
- Child Product Numbers:
  - sgl030074.0433902.1000000060238
  - sgl030074.0433902.1000000060239
  - sgl030074.0433902.1000000060240
  - sgl030074.0433902.1000000060241
  - sgl030074.0433902.1000000060242
  - sgl030074.0433902.1000000060243

08/22/2012 10:46:08 AM DISAGGREGATION  SGLN 47037130.5171.0

- Business Step: disaggregation
- Disposition: in_progress
- Parent Product Number: sgl030074.3433902.100000003370
- Container Qty: 6
- Child Product Numbers:
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  - sgl030074.0433902.1000000060241
  - sgl030074.0433902.1000000060242
  - sgl030074.0433902.1000000060239

Transactions: po C25011HPEN21

sGTIN of items from a case opened at VA can be verified against aggregation data from AbbVie
VA Pilot: Recalled Product

- Status of an individual case can be updated if suspect
  - Further trading of case will not be valid
- Custody check performed will show negative results

Example Data from Mock Recall

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<tr>
<th>Product History</th>
</tr>
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<tbody>
<tr>
<td><strong>Product Number</strong></td>
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<tr>
<td>sgin 030074.3433902.100000003373</td>
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</table>

<table>
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<tr>
<td><strong>ID:</strong> 0074433902</td>
</tr>
<tr>
<td><strong>Brand Name:</strong> Humira Pen</td>
</tr>
<tr>
<td><strong>Generic Name:</strong> Adalimumab</td>
</tr>
<tr>
<td><strong>Label Name:</strong> HUMAN PRESCRIPTION DRUG</td>
</tr>
<tr>
<td><strong>Package Description:</strong> 2 KIT in 1 CARTON</td>
</tr>
<tr>
<td><strong>Package Size:</strong></td>
</tr>
<tr>
<td><strong>Drug Strength:</strong> 0.8 ML</td>
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<tr>
<td><strong>Quantity:</strong></td>
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<tr>
<td><strong>Drug Form:</strong> PEN</td>
</tr>
<tr>
<td><strong>Classification:</strong> TNF Blocker</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Chain of Custody</th>
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</thead>
<tbody>
<tr>
<td><strong>08/22/2012 01:40:29 AM HOLDING N/A</strong></td>
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<tr>
<td><strong>Business Step:</strong> holding</td>
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<tr>
<td><strong>Disposition:</strong> non_sellable_recalled</td>
</tr>
<tr>
<td><strong>Container Qty:</strong> 1</td>
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<tr>
<td><strong>Child Product Numbers:</strong> sgin 030074.3433902.100000003373</td>
</tr>
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</table>

| 08/22/2012 10:38:34 AM CUSTOMERY CHECK BAD |
| **Request by:** 47037130.51700 |
| **Request ID:** 6ebc8880-ec6f-11e1-9ac5-02d3107575a3 |
| **Product Number:** sgin 030074.3433902.100000003373 |
| **Location:** sgin 47037130.5171.0 |
| **Business Step:** n/a |
| **Custody Check:** Recalled - RecalledEvent |
VA Pilot: Findings and Limitations

• Product was ordered in full cases and unopened at the distributor which is not a high volume practice for many products & pharmacies

• Partners will not be able to scan 2D DataMatrix bar code with current linear scanners

• Currently lot and expiry is not encoded at item level
  • Lot and expiry data is available at GHX, need to define a method for retrieval

• Data consistency throughout supply chain is critical
  • During initial testing we found each partner needed to agree on using the 11 digit NDC (vs. 10 digit NDC or GTIN)
  • Would be helpful to distributors, pharmacies and others to have a common source to obtain NDC
  • A master data repository such as GDSN would be helpful to exchange product information
In their efforts to protect public health and improve patient safety, the FDA’s March 2010 Standardized Numerical Identification (SNI) guidance for Prescription Drug Packages was the first of several steps to implement the FD&C Act 505D.

The SNI is a serialized National Drug Code (sNDC) generated by the manufacturer or repackager for each individual unit sold, numeric or alphanumeric and limited to 20 characters.

Manufacturers use standards based global identifiers, such as the GS-1 Global Trade Item Number (GTIN) as the SNI.
BACKGROUND ON FDA TnT ACTIVITY

• Validation and authentication of the SNI will offer security against counterfeit and substandard drugs in the supply chain; FDA intends to develop standards prior to enactment of the California Pedigree Legislation in 2015.

• In 2011, FDA held a public workshop, Determination of System Attributes for the Tracking and Tracing of Prescription Drugs. The roundtable forum supported stakeholder participation and subsequent discussion amongst partners on piloting the proposed track and trace (TnT) concepts.
TRACEABILITY PILOT CONCEPT

• Provider organizations, to gain further benefits from the investment of resources to TnT, must use these unique identifiers beyond current bar code scanning to improve processes such as inventory and recalls.

• A pilot with a serialized product will test the use of a database network for authentication of supply chain integrity amongst manufacturer, wholesaler and pharmacy.

Results shared with the FDA and health care community will support standards development and ensure feasible legislation.
Partners will need to require their suppliers to populate non-GDSN mandatory attributes such as the 10 and 11-digit NDC in the GS1 GDSN for use by their database networks to crosswalk to GTINs. Areas for GS1 involvement include:

- Beginning conversations with payors on the use of GTINs versus 10 and 11-digit NDC.

- Suggesting the additional use of GTIN for NDC-based databases such as First DataBank for additional FDA required dispensing information and drug interaction warnings.
CONTACT INFORMATION

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Connect with the GS1 US community on:
Appendix
## Standards and Guidance in Construction of Platform

<table>
<thead>
<tr>
<th>Standards and Guidelines</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Global Traceability Standard for Healthcare</td>
<td>GLN Registry</td>
</tr>
<tr>
<td>Global Location Number (GLN)</td>
<td>Global Data Synchronization Network</td>
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<tr>
<td>Global Trade Item Number (GTIN)</td>
<td>Core Business Vocabulary (CBV)</td>
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<tr>
<td>FDA’s Guidance SNI for Prescription Drug Packages</td>
<td>California ePedigree Law</td>
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<tr>
<td>Serial Shipping Container Code (SSCC)</td>
<td>Healthcare Distribution Management Association (HDMA)</td>
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<td>GS1 Data Carriers</td>
<td>Bar Coding Guidelines in the Pharmaceutical Supply Chain</td>
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<td>GS1 Application Identifiers</td>
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<tr>
<td>EPC Information Service (EPCIS)</td>
<td>*GS1 Healthcare US Implementation Guideline Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes</td>
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<tr>
<td>AS2</td>
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</table>

*Guideline content was in draft form during pilot*
EXTRA SLIDES---DEFINITIONS

FDA held a public workshop, Determination of System Attributes for the Tracking and Tracing of Prescription Drugs, to determine input on the following areas for TnT of Pharmaceuticals and provided the following definitions for discussion purposes:

**Aggregation**- Some workshop participants noted that for authentication, using aggregation, involving linking of SNIs of individual packages to a unique identifier at the case and/or pallet level, was one of the greatest costs for a manufacturer, due to the costs of optimizing the process and accounting for disruptions in the aggregation process (e.g., caused by damaged data carriers or damaged packages).

**Authentication**- As defined by the FDA, involves verifying that an SNI is a valid number for the package with which it is associated. It also involves verifying that the package was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants, and confirming that there are no discrepancies in the distribution history.

**Exceptions Handling**- Some workshop participants expressed that for authentication, there is a need for explicit directions on standard operating procedures for handling authentication failures (e.g., system or database failure, valid number but mismatched product information).

**Inference**- Some workshop participants stated that for authentication, they rely on inference to efficiently process large amounts of inventory and distribute it, and believe this minimizes the risk of security breaches by keeping the cases or pallets sealed.

**Interoperability**- As defined by FDA, establishes compatible data and process standards to enable system participants to have the capability of sharing data by integrating into the same system.
PRODUCT AUTHENTICATION AT PHARMACY- THE FINAL SAFETY CHECK

• Manufacturer labels product lot at saleable unit with 2D DataMatrix sGTIN bar code as the SNI, aggregates to 1D GS1-128 case sGTIN, scan/upload to the database network webinterface to create Electronic Product Code Information Services (EPCIS) commissioning events.

• Trading partner’s unique GLN is identified in the database network.

• Custody checks occur as trading partners choose a business step on the web interface, scan case sGTIN bar codes to upload onto the database network; business rules validate the EPCIS events and return case disposition as “good” and the sequence as “consistent.”

• Disaggregation occurs when trade partner breaks a case, scan/upload its sGTIN to database network and infer children’s chain of custody as associated with the case.
To verify traceability, the manufacturer can initiate a recall event in the database network and trading partners performing a custody check or transaction are alerted to the recall status – verifying the business rules create a secure supply chain.

Moving forward, how can we alert trading partners holding recalled product?
TnT LIMITATIONS – ALL PARTNERS

- Anti-counterfeiting measures were not included in the pilot.

- Without a hosted database network, all partners were required to exchange EPCIS events using the same centralized database network, many times a second step to existing processes.

- Without a connection to the GS1 Global Data Synchronization Network (GDSN), the prototype database hard-coded the 10-digit National Drug Code (NDC) and cross-walked to both the GTIN and the 11-digit NDC required for pharmacy transactions and third party reimbursement.
• Product was ordered in full cases and unopened at the wholesaler, which is not standard practice for many products and pharmacies.

• Downstream partners are unable to scan the product sGTIN 2D DataMatrix bar code with current 1D scanners and, therefore, used pilot handhelds to transmit to the database network.

• Pharmacy was given a GLN placeholder as the VA GLN hierarchy has not yet been established.

• Storage of product ID in downstream partner databases is currently restricted to 11 digit NDCs; sGTIN info for individual patients was maintained in manually kept spreadsheets.
VA Pilot : Lot Report

• Manufacture lot report can be used to help trace each sGTIN for a specific lot
  • Every case and item for a Lot/Batch shipped will be traceable to the state last observed
  • Assists location of cases and items

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Location</th>
<th>Assessment</th>
<th>Disposition</th>
<th>Time</th>
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<tbody>
<tr>
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VA Pilot: Business Rules

• Business rules need to align with business processes of partners
  • Adjustments were made to reduce possible security vulnerabilities
  • Manual processing among partners still needed to for some exception handling (suspect cases identified by system for valid product

• Examples of basic business rules
  • sGTIN identifier must be valid (commission event posted for sGTIN)
  • sGTIN identifier doesn't appear in two physical locations (GLNs) simultaneously
  • Paired events: Receive events must have prior Ship events
  • Ordering of events is important
  • Match expected GLN: Receive event GLN must match Ship event GLN

• Additional business rules that can be implemented include checking time frames of events based on distance between ship from and ship to locations (GLNs)