

Traceability Pilot United States Market

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abbvie

**21,000 Employees Strong
United for One Purpose**

Addressing global health
challenges with new
therapies that make a
remarkable impact on
people's lives



Platform Development Partners



This team was recognized
by HDMA for



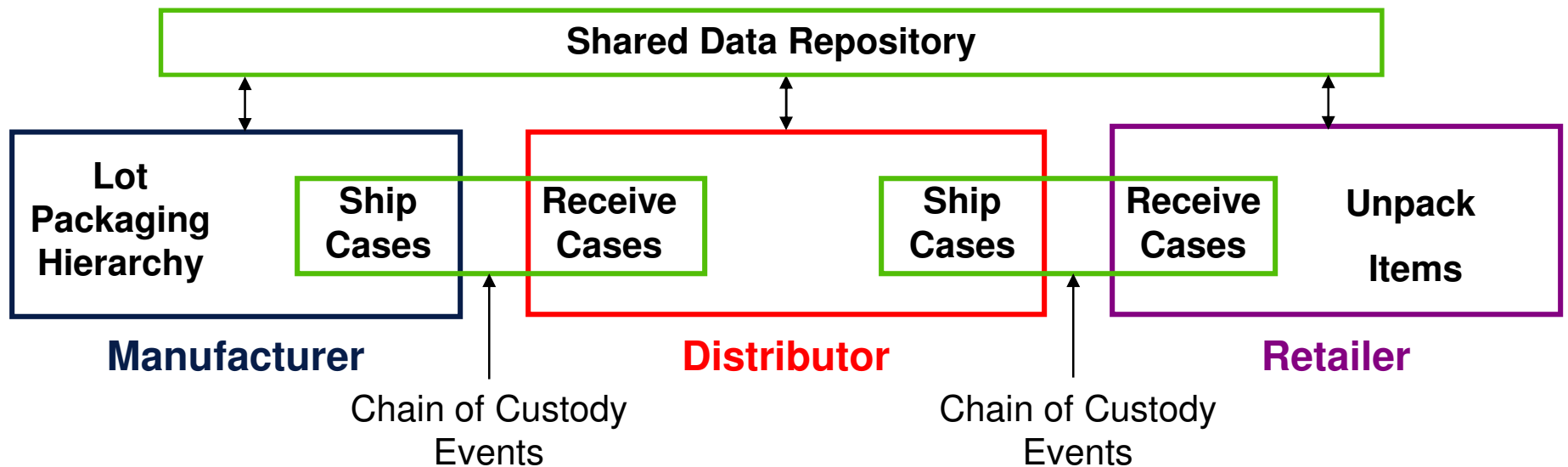
Pilot Partners



UNITED STATES
DEPARTMENT OF VETERANS AFFAIRS



Pedigree Pilot Data Set



AbbVie Data Sets:

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).

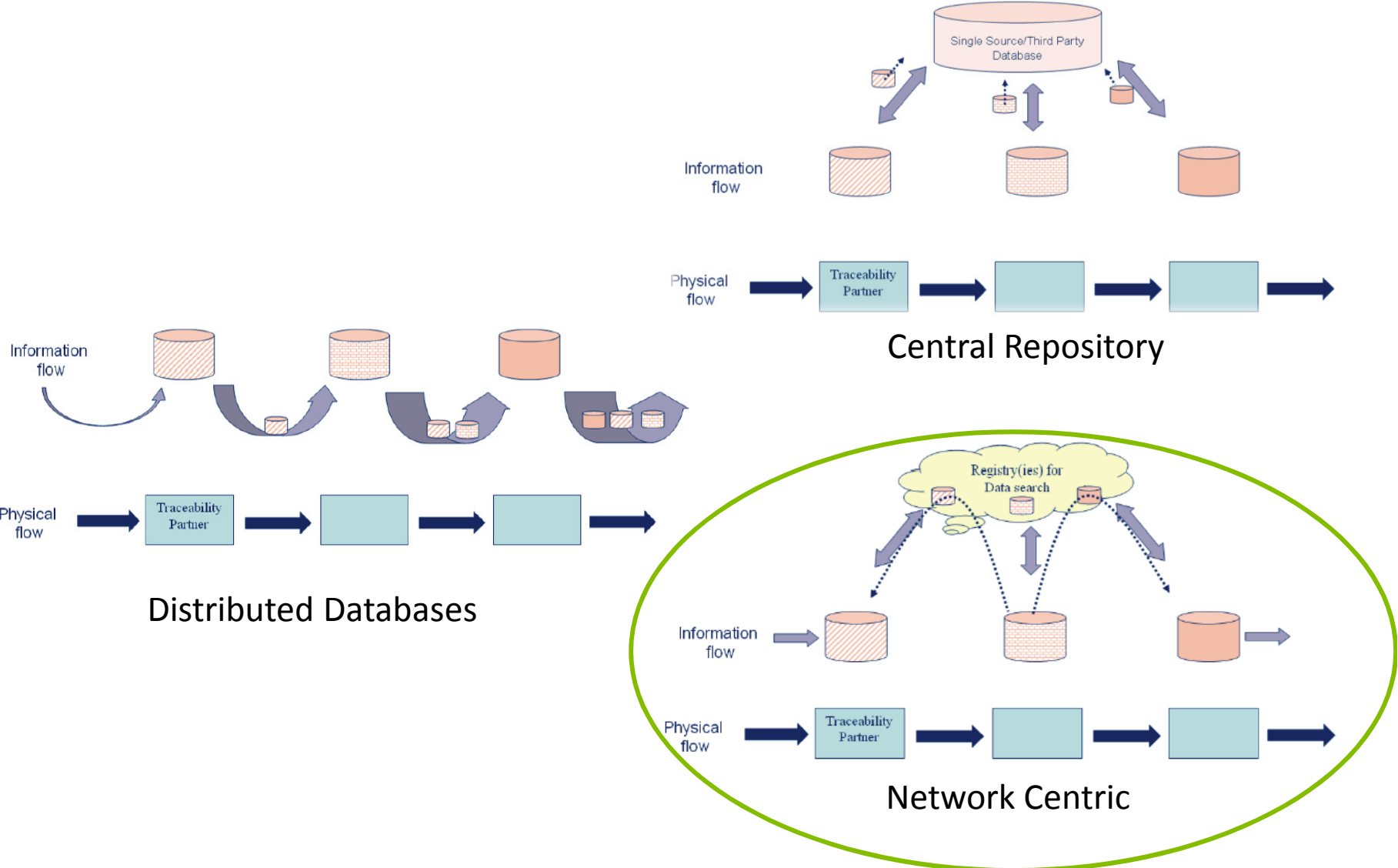
McKesson Data Sets:

1. Serial numbers of product shipped or received at the logistical unit handled (case).

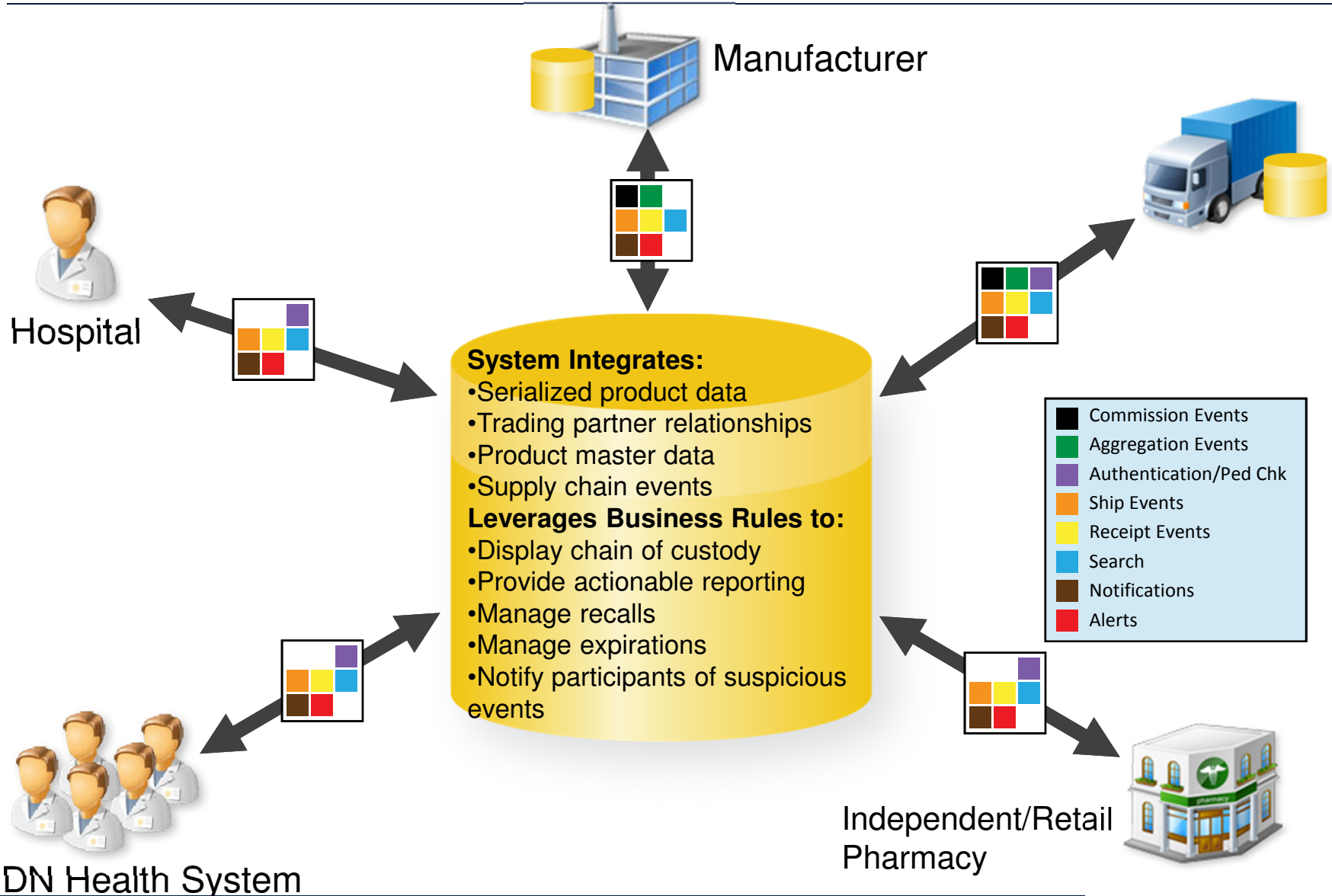
VA CMOP Data Sets:

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



Traceability System Approach



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

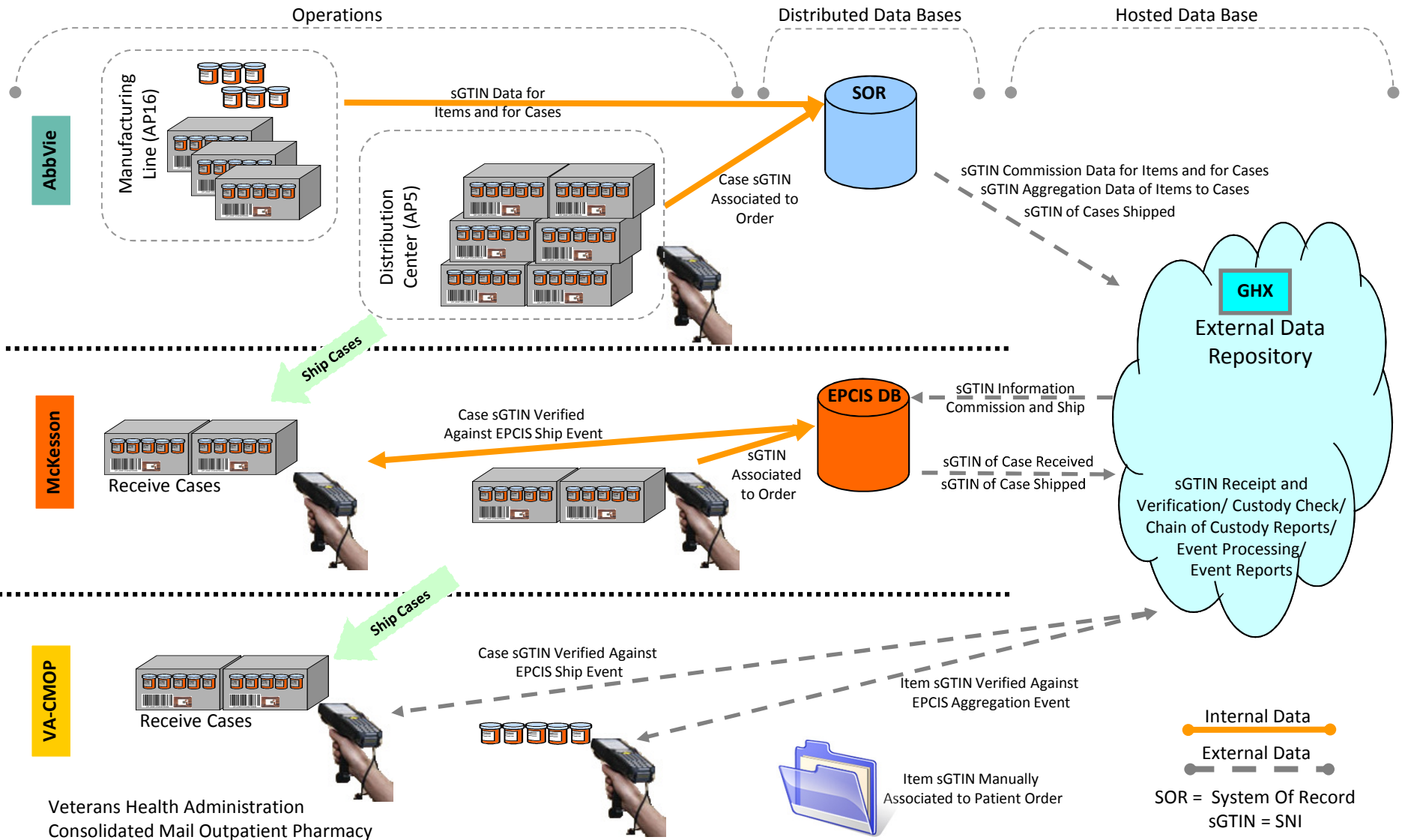
Utilize data carriers to confirm events creating a history of a secure chain of custody and ownership producing a pedigree report

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



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

Product History

Product Number	Date	Event Sequence State	Location	Business Step	Disposition
sgtin 030074.3433902.100000003370	08/22/2012	Consistent	sgln 47037130.5171.0	disaggregation	in_progress

SGTIN Uniquely Identifies Case

Drug Information

ID: **0074433902**
 Brand Name: **Humira Pen**
 Generic Name: **Adalimumab**
 Label Name: **HUMAN PRESCRIPTION DRUG**
 Package Description: **2 KIT in 1 CARTON**
 Package Size:
 Drug Strength: **0.8 mL**
 Package Quantity:
 Drug Form: **PEN**
 Classification: **TNF Blocker**

Chain of Custody

commissioning	04/20/2012 12:22:54 PM	sgln 030074.000000.0
aggregation	08/15/2012 12:34:10 AM	sgln 030074.000000.0
Custody Check	08/15/2012 12:38:20 AM	Good
shipping	08/15/2012 12:38:49 AM	sgln 030074.000000.0
receiving	08/21/2012 11:08:42 AM	sgln 0010939.18211.0
shipping	08/21/2012 05:33:43 PM	sgln 0010939.18200.0
Custody Check	08/22/2012 10:45:08 AM	Good
receiving	08/22/2012 10:45:08 AM	sgln 47037130.5171.0
disaggregation	08/22/2012 10:45:08 AM	sgln 47037130.5171.0

Last Known Location of Product (VA)

Custody: Business Step, Date, Time and Location

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.

McKesson Corporation Confidential and Proprietary

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

Baxter

PREMIER

Fisher Scientific

Medtronic

Abbott
A Promise for Life

GHX...

SIEMENS

Boston Scientific

Established in 2000

AmerisourceBergen

BAIRD

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

MCKESSON

BD

Takes costs out of healthcare

GE Healthcare

HCA

Is open and neutral, serving all parties

Johnson+Johnson

VHA

Roadmap is driven equally by providers and suppliers

COVIDIEN
positive results for life

UHC

B|BRAUN

CardinalHealth

OM
Owens & Minor, Inc.

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

Visibility Rules	AbbVie Commission	AbbVie Aggregate	AbbVie Ship	McKesson Receive	McKesson Ship	VA-CMOP Receive	VA-CMOP Dis-Aggregate
AbbVie	FULL	FULL	FULL	FULL	REDACTED	REDACTED	REDACTED
McKesson	REDACTED	REDACTED	FULL	FULL	FULL	FULL	REDACTED
VA-CMOP	REDACTED	REDACTED	REDACTED	REDACTED	FULL	FULL	FULL



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

commissioning	04/20/2012 12:22:54 PM	sgln 030074.000000.0
aggregation	08/15/2012 12:34:10 AM	sgln 030074.000000.0
Custody Check	08/15/2012 12:38:20 AM	Good
shipping	08/15/2012 12:38:49 AM	sgln 030074.000000.0
receiving	08/21/2012 11:08:42 AM	sgln 0010939.18211.0
shipping	08/21/2012 05:33:43 PM	sgln 0010939.18200.0
Custody Check	08/22/2012 10:45:08 AM	Good
receiving	08/22/2012 10:45:08 AM	sgln 47037130.5171.0
disaggregation	08/22/2012 10:45:08 AM	sgln 47037130.5171.0

08/15/2012 12:34:10 AM AGGREGATION SGLN 030074.000000.0

Business Step: aggregation
Disposition: in_progress
Parent Product Number: sgtin 030074.3433902.100000003370
Container Qty: 6
Child Product Numbers: sgtin 030074.0433902.100000060238
 sgtin 030074.0433902.100000060239
 sgtin 030074.0433902.100000060240
 sgtin 030074.0433902.100000060241
 sgtin 030074.0433902.100000060242
 sgtin 030074.0433902.100000060243

08/22/2012 10:45:08 AM DISAGGREGATION SGLN 47037130.5171.0

Business Step: disaggregation
Disposition: in_progress
Parent Product Number: sgtin 030074.3433902.100000003370
Container Qty: 6
Child Product Numbers: sgtin 030074.0433902.100000060243
 sgtin 030074.0433902.100000060241
 sgtin 030074.0433902.100000060240
 sgtin 030074.0433902.100000060238
 sgtin 030074.0433902.100000060242
 sgtin 030074.0433902.100000060239
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 validate
- Custody check performed will show negative results

Example Data from Mock Recall

Uniquely Identified Case being recalled

Product History

Product Number	Date	Event Sequence State	Location	Business Step	Disposition
sgtin 030074.3433902.100000003373	08/22/2012	Recalled	sgln 47037130.5171.0	disaggregation	non_sellable_recalled

Drug Information

ID: **0074433902**
 Brand Name: **Humira Pen**
 Generic Name: **Adalimumab**
 Label Name: **HUMAN PRESCRIPTION DRUG**
 Package Description: **2 KIT in 1 CARTON**
 Package Size:
 Drug Strength: **0.8 mL**
 Package Quantity:
 Drug Form: **PEN**
 Classification: **TNF Blocker**

Chain of Custody

commissioning	04/23/2012 12:31:26 PM	sgln 030074.000000.0
aggregation	08/15/2012 12:33:06 AM	sgln 030074.000000.0
Custody Check	08/15/2012 12:38:37 AM	Good
shipping	08/15/2012 12:38:49 AM	sgln 030074.000000.0
receiving	08/21/2012 11:08:42 AM	sgln 0010939.18211.0
shipping	08/21/2012 05:33:43 PM	sgln 0010939.18200.0
holding	08/22/2012 01:40:29 AM	
Custody Check	08/22/2012 10:38:34 AM	Bad

08/22/2012 01:40:29 AM HOLDING N/A

Business Step: holding
Disposition: non_sellable_recalled
Container Qty: 1
Child Product Numbers: sgtin 030074.3433902.100000003373

08/22/2012 10:38:34 AM CUSTODY CHECK BAD

Request by: 4703713051700
Request ID: 6ebc8880-ec6f-11e1-9ac5-02d3107575a3
Product Number: sgtin 030074.3433902.100000003373
Location: sgln 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

US FOOD AND DRUG ADMINISTRATION (FDA)

- **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.

GS1 STANDARDS INTERPRETATION

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.**

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Appendix



Standards and Guidance in Construction of Platform

Global Traceability Standard for Healthcare

Global Location Number (GLN)

Global Trade Item Number (GTIN)

FDA's Guidance SNI for Prescription Drug Packages

Serial Shipping Container Code (SSCC)

GS1 Data Carriers

GS1 Application Identifiers

EPC Information Service (EPCIS)

AS2

GLN Registry

Global Data Synchronization Network

Core Business Vocabulary (CBV)

California ePedigree Law

Healthcare Distribution Management Association (HDMA) Bar Coding Guidelines in the Pharmaceutical Supply Chain

*GS1 Healthcare US Implementation Guideline Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes

* 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.

PILOTING A MOCK RECALL

- **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.**

TRACEABILITY LIMITATIONS–DOWNSTREAM PARTNERS

- **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

Product Number	Location	Assessment	Disposition	Time
sgtin 030074.0433902.100000060034	TN	Consistent	in_progress	06/06/2012
sgtin 030074.0433902.100000060050	TN	Consistent	in_progress	07/13/2012
sgtin 030074.0433902.100000060020	TN	Consistent	in_progress	06/06/2012
sgtin 030074.0433902.100000060271	TN	Consistent	in_progress	06/14/2012
sgtin 030074.0433902.100000059976	TN	Consistent	in_progress	06/13/2012
sgtin 030074.3433902.100000003340	TN	Consistent	in_progress	07/20/2012
sgtin 030074.0433902.100000060051	TN	Consistent	in_progress	07/13/2012
sgtin 030074.0433902.100000060019	TN	Consistent	in_progress	06/06/2012
sgtin 030074.3433902.100000003377	TN	Consistent	in_progress	08/30/2012

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)