Implementation Reality – Traceability

How to enable/implement traceability?

2nd April 2014, Seoul/Korea

Round 2 (15:30 – 17:00)

- <u>Moderator</u>
    - Grant Courtney, Business Lead, Fingerprint Serialisation, Global Manufacturing & Supply GSK

- <u>Panelists</u>
    - Mike Rose, J&J
    - Heather Zenk, AmeriSource Bergen
    - Margot Drees, GHX
    - Christian Riediger, Bayer

Agenda

- Introduction: Traceability and the GS1 standards as base for it - the different models for traceability across the world

- What does serialisation mean for a manufacturer (Mike Rose, J&J)

- Traceability – everybody needs to be involved – the wholesaler view (Heather Zenker, AmeriSource Bergen)

- Traceability pilot in the US – experiences and learnings (Margot Drees, GHX)

- Experiences in Europe/Pilot in Germany (Christian Riediger, Bayer)
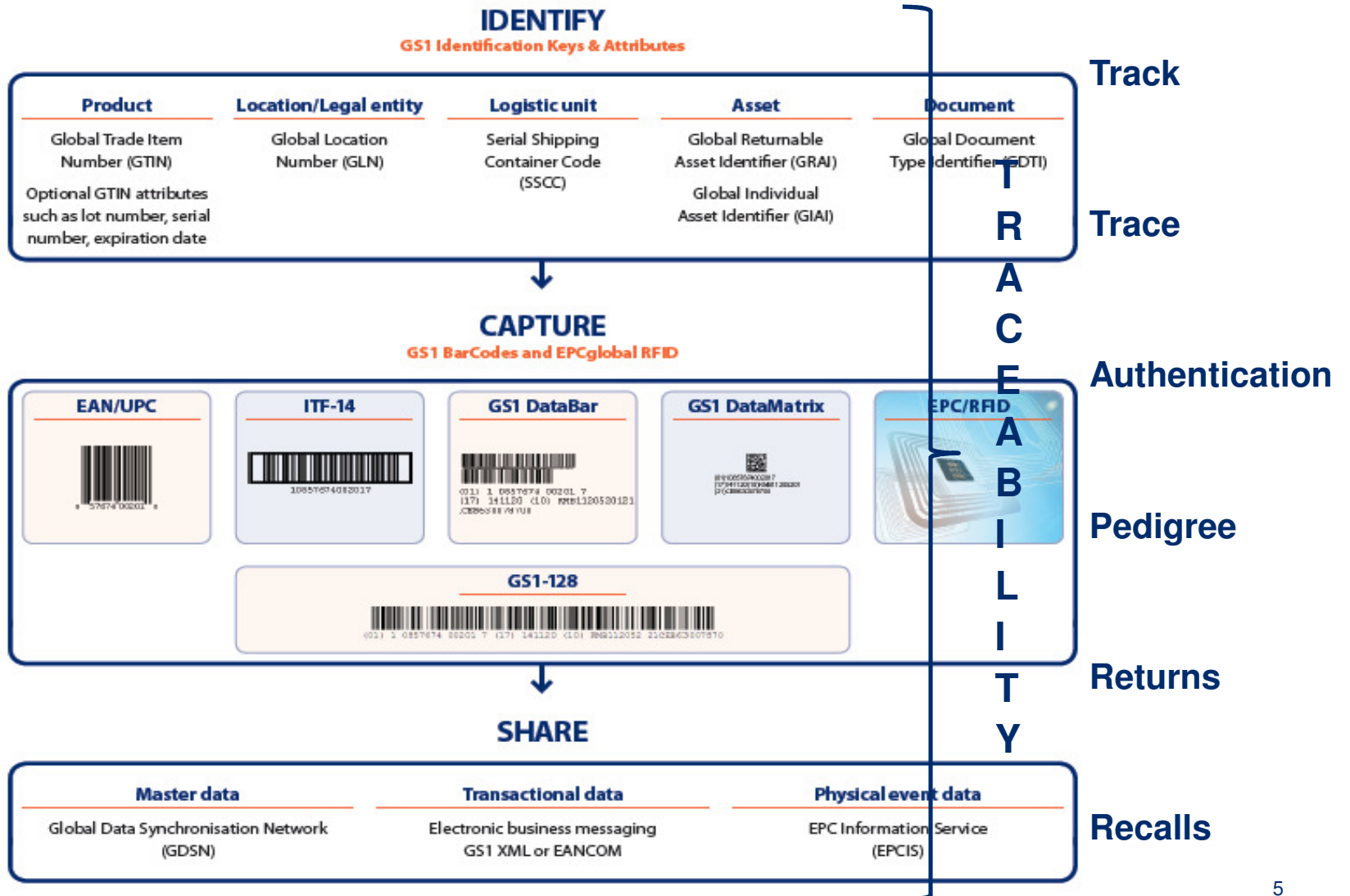
- Panel discussion

- Conclusions

Introduction

The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

Product	Location/Legal entity	Logistic unit	Asset	Document
Global Trade Item Number (GTIN)	Global Location Number (GLN)	Serial Shipping Container Code (SSCC)	Global Returnable Asset Identifier (GRAI)	Global Document Type Identifier (GDTI)
Optional GTIN attributes such as lot number, serial number, expiration date			Global Individual Asset Identifier (GIAI)	

CAPTURE
GS1 BarCodes and EPCglobal RFID

EAN/UPC	ITF-14	GS1 DataBar	GS1 DataMatrix	EPC/RFID

GS1-128

SHARE

Master data	Transactional data	Physical event data
Global Data Synchronisation Network (GDSN)	Electronic business messaging GS1 XML or EANCOM	EPC Information Service (EPCIS)

Track

Trace

Authentication

Pedigree

Returns

Recalls

T R A C E A B I L I T Y

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Serial No. AI(21)), if applicable, at point of production

- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life

- All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain

- All **patients and care givers**, when in a care giving environment, are identified with the appropriate **GS1 identification Keys** (e.g. AI 8017; AI 8018)

- Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners

- Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners

- Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

SO THAT:

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time

- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time

- Item identification is available for use at patient bedside to ensure the Patient Rights[3] are achievable

- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification

- Counterfeit products are detected when entering the legitimate supply chain

- A **product recall** would be fast, efficient and effective

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user

Traceability in Healthcare Phase I (TH-I)

DELIVERED:

Global Traceability Standard for Healthcare (GTSH)

PUBLISHED 27th February 2009

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf

GTSH Implementation Guideline

PUBLISHED 24th April 2009

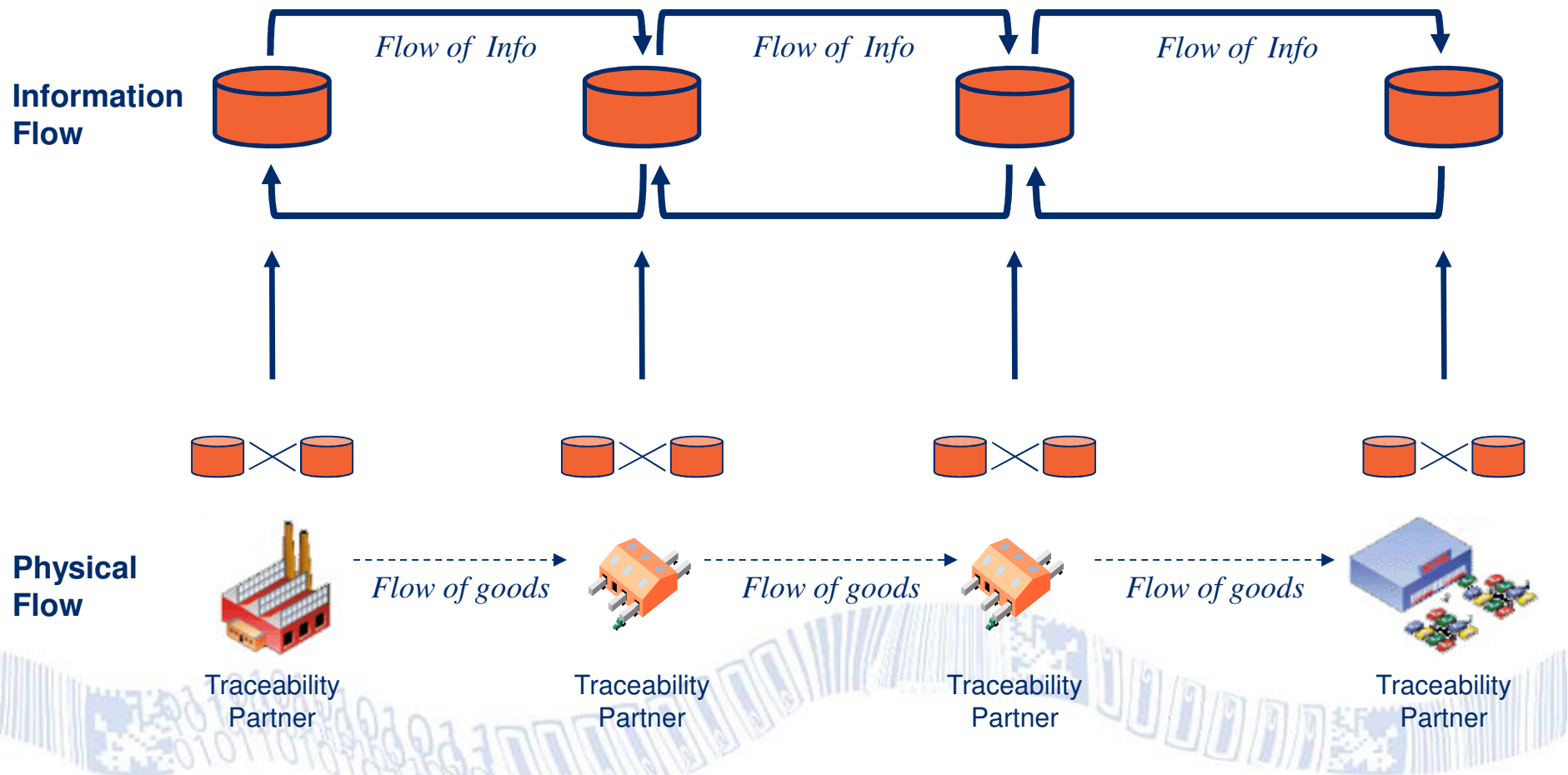http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Implementation_Healthcare.pdf

Common themes

- Global Traceability Standard for Healthcare (GTSH) is a PROCESS Standard

- Definition of Traceability: both track & trace (downstream/upstream; forwards/backwards)

- Establishes the minimum model for traceability:

    "One up, One Down"

- In parallel with the flow of product there **has to be** a flow of information about the product

GTSH "One up, One down"

Information Flow

Flow of Info *Flow of Info* *Flow of Info*

Physical Flow

Flow of goods *Flow of goods* *Flow of goods*

Traceability Partner   Traceability Partner   Traceability Partner   Traceability Partner

Healthcare Traceability
Emerging Models

Pharma – Different emerging models… Turkey

Driver: Reimbursement Fraud; pharmacists claiming more than once for dispensed product

Ownership: Government developed and controlled, Centralised Track & Trace system (iTS)

- Enforcement date 2010
  - Phase 1: Manufacturers published data to MoH central database (2010)
  - Phase 2: Distributors (2012)
  - Future phases: ePrescriptions, Patient access
- ROI in ONE YEAR!
  - Reimbursement fraud eliminated
  - Examples of counterfeits being detected entering legitimate supply chain
  - Prosecutions…
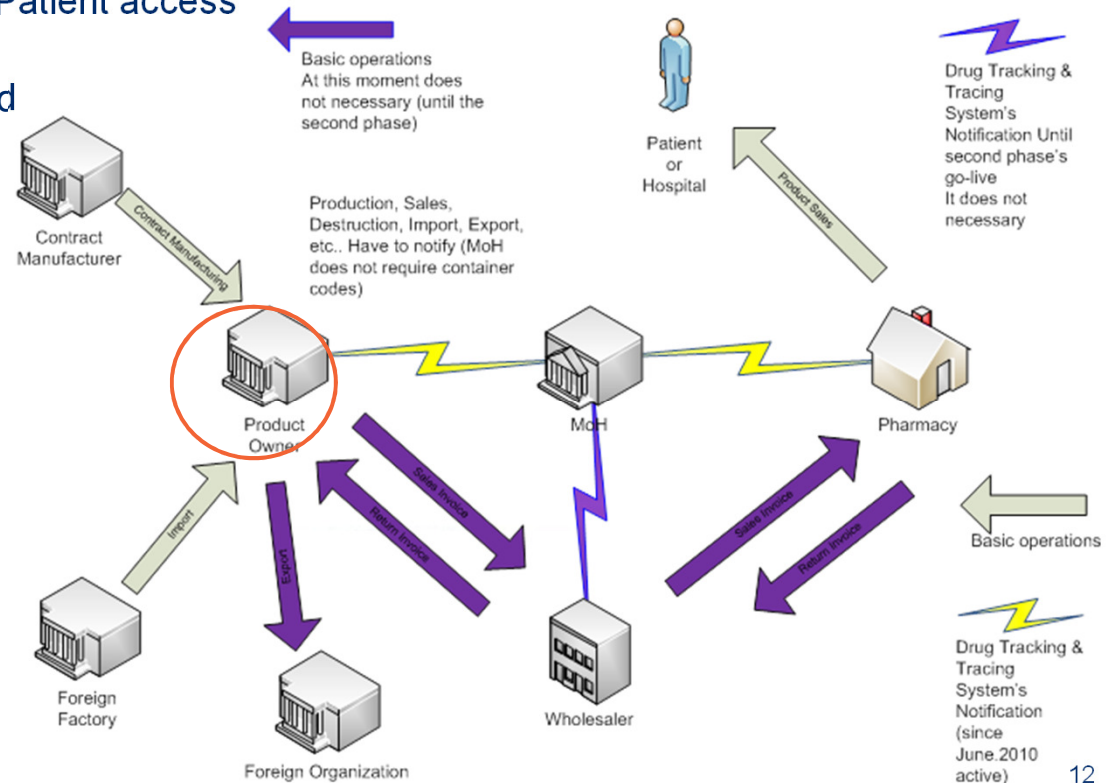
Pharma – Different emerging models... Europe

Driver: To address counterfeiting (falsified medicines), prevent them reaching the patient

Ownership: Stakeholders, access for regulatory bodies

- **European Stakeholder Model (ESM)**
    - A pan-European end-to-end system enabling medicines to be verified at point of dispensing
    - Interoperable across markets and supports standard interfaces
    - Developed and maintained by the stakeholders who will use it on a day-to-day basis
    - Run on a non-profit basis; Costs to be borne by Manufacturing Authorisation Holders
    - Effective system expected in 2017
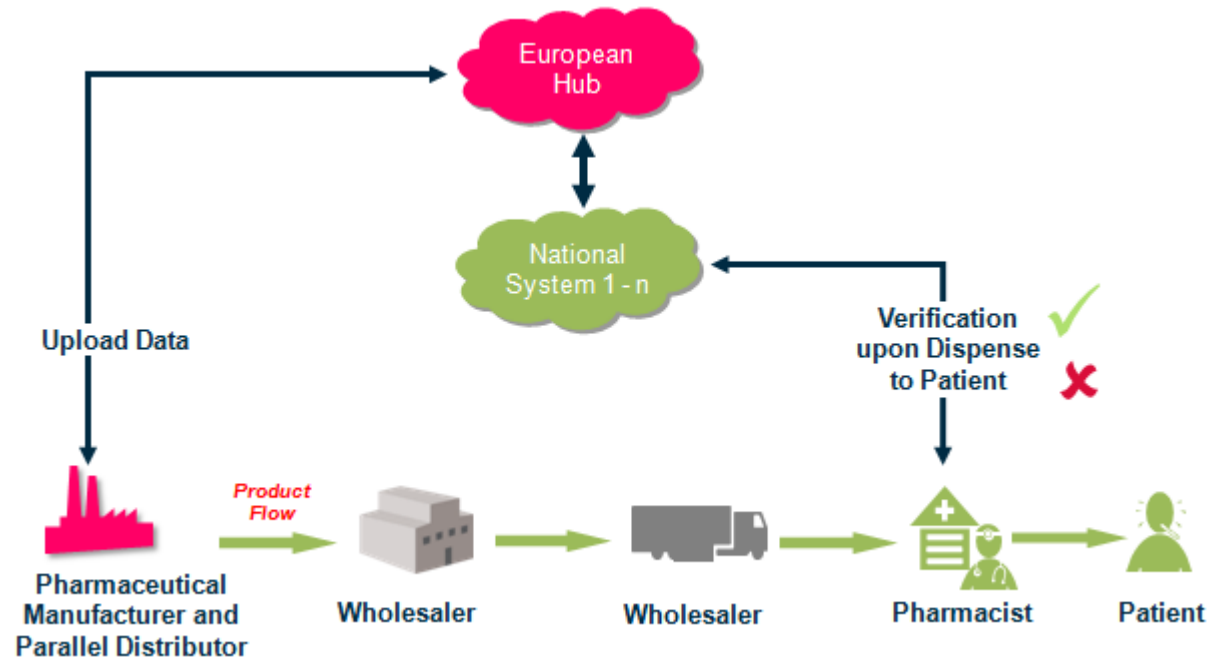
What does serialisation mean for a manufacturer

Mike Rose, J&J

What is serialization?

Unique number for every item

PREZISTA® 600mg serialized label with 2D data matrix

N3 59676-562-01 6

GTIN: 00359676562016
S/N: 123456789012
EXP: JAN 2015
LOT: 12G123456 X

Standard Product License Plate GS1 Compliant with 2D Data Matrix

Used for Component Control

GTIN: 00359676562016
S/N: 123456789012
EXP: JAN 2015
LOT: 12G123456 X

59676-562-01

60 Tablets
NDC 59676-562-01

PREZISTA®
(darunavir) tablets

600 mg

Each tablet contains darunavir ethanolate equivalent to 600 mg of darunavir.

Rx only

Store at 25°C (77°F); with excursions permitted to 15°-30°C (59°-86°F).

USUAL DOSAGE: See package insert for full Prescribing Information.
Keep out of reach of children.

ALERT
Find out about medicines that should NOT be taken with PREZISTA.

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Serialization changes the way we handle our products.

A unique identification number is assigned to each item identifying it with a product number and associated serial number. It's applied at every package level (bottle, case, and pallet).

These unique numbers are uploaded into a database and can be accessed by our company and made available to our customers as appropriate.

Manufacturer Perspective

- Importance of standards

- Complexities of operating in a GxP environment

- Engaging the extended network

- Maintaining focus through competing priorities

- Opportunity to reduce complexity

- Stakeholder engagement – e.g., European Stakeholder Model

Opportunities for impact

1	Protecting patients from counterfeit products
2	Reducing medication errors
3	Improving recall efficiency and effectiveness
4	Reducing inventory assets and associated costs
5	Improve reimbursement accuracy
6	Reducing complexity
7	Improving transaction accuracy

Traceability – everybody needs to be involved – the wholesaler view

**Heather Zenker,
AmeriSource Bergen**

Wholesaler Perspective
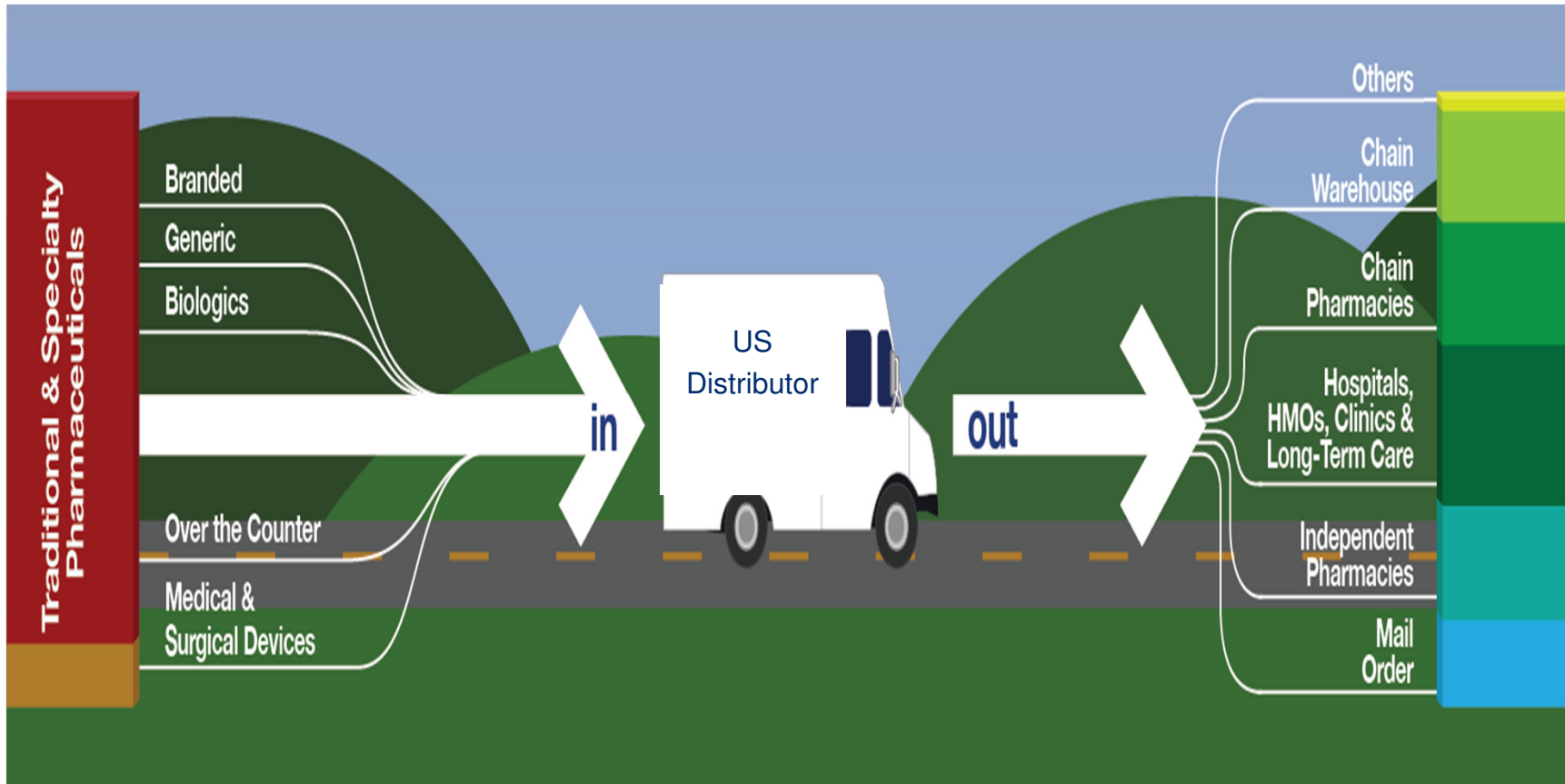
Wholesaler Perspective

- Importance of standards

- Processes that support the standards also need to be explored and updated within the industry

- Complexities of operating in the middle of the supply chain
  - 700+ pharmaceutical manufacturers
  - 200,000 + dispensing entities

- Speed of through put – patient demand for pharmaceuticals

- Attention to detail, without losing focus on the big-picture

Wholesaler Perspective

- Data exchange

- Exception management

- Flexibility - patience needed by all with trading partner relationships
  - This is new to the entire pharmaceutical industry

- Continued industry collaboration / knowledge sharing

- ROI will be driven by critical mass and continued development of process to align with standards

Traceability pilot in the US – experiences and learnings

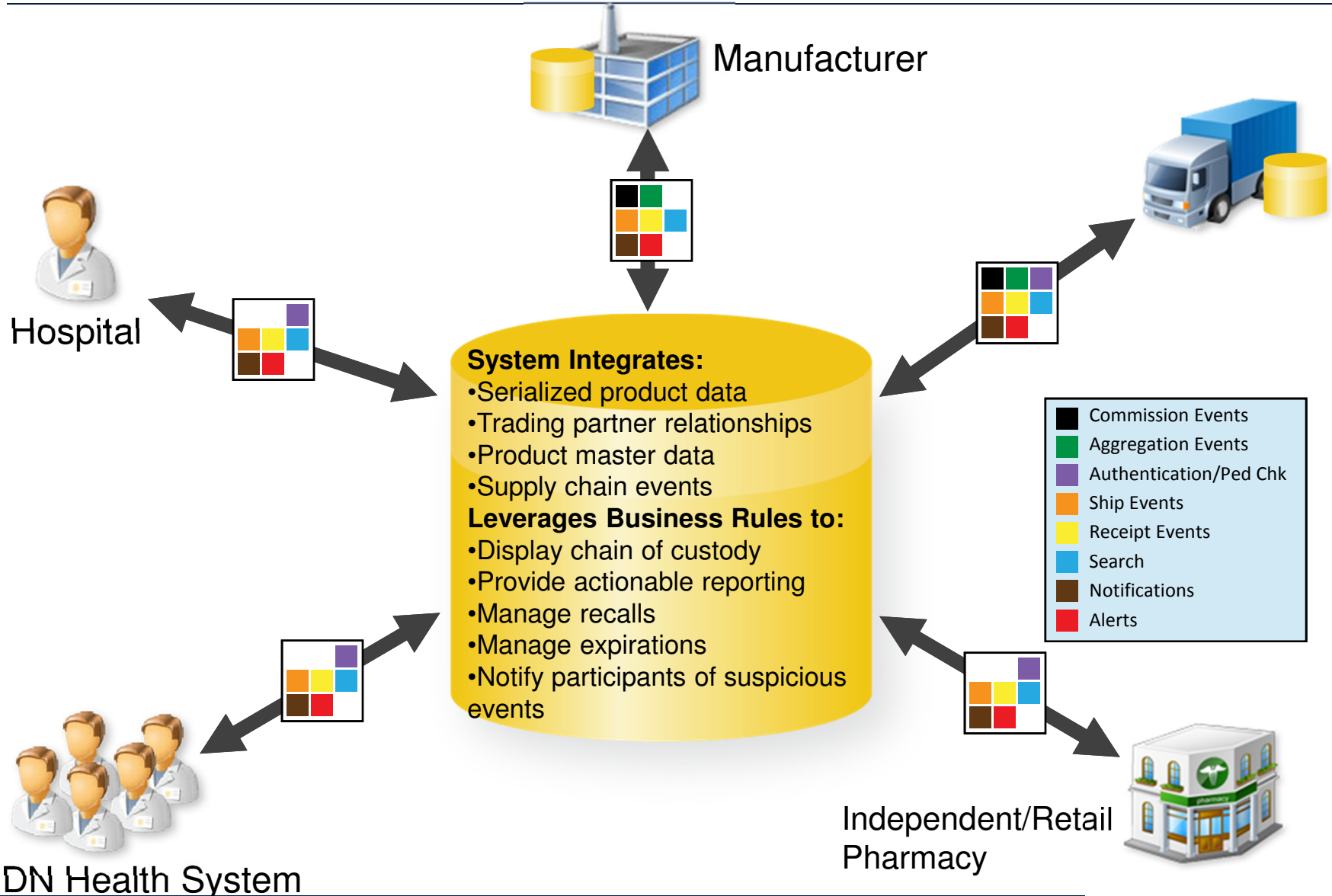**Margot Drees, GHX**

Traceability Pilot
United States Market

Platform Development Partners

GHX · Abbott / abbvie · Johnson & Johnson

AmerisourceBergen · MCKESSON · CardinalHealth

This team was recognized by HDMA for

DISTRIBUTION MANAGEMENT AWARD 2013

CHDMA
Healthcare Distribution Management Association

Pilot Partners

abbvie · MCKESSON · UNITED STATES DEPARTMENT OF VETERANS AFFAIRS

Traceability System Approach

Manufacturer

Hospital

IDN Health System

Independent/Retail Pharmacy

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

- ■ Commission Events
- ■ Aggregation Events
- ■ Authentication/Ped Chk
- ■ Ship Events
- ■ Receipt Events
- ■ Search
- ■ Notifications
- ■ Alerts

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 capture and share of supply chain events 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
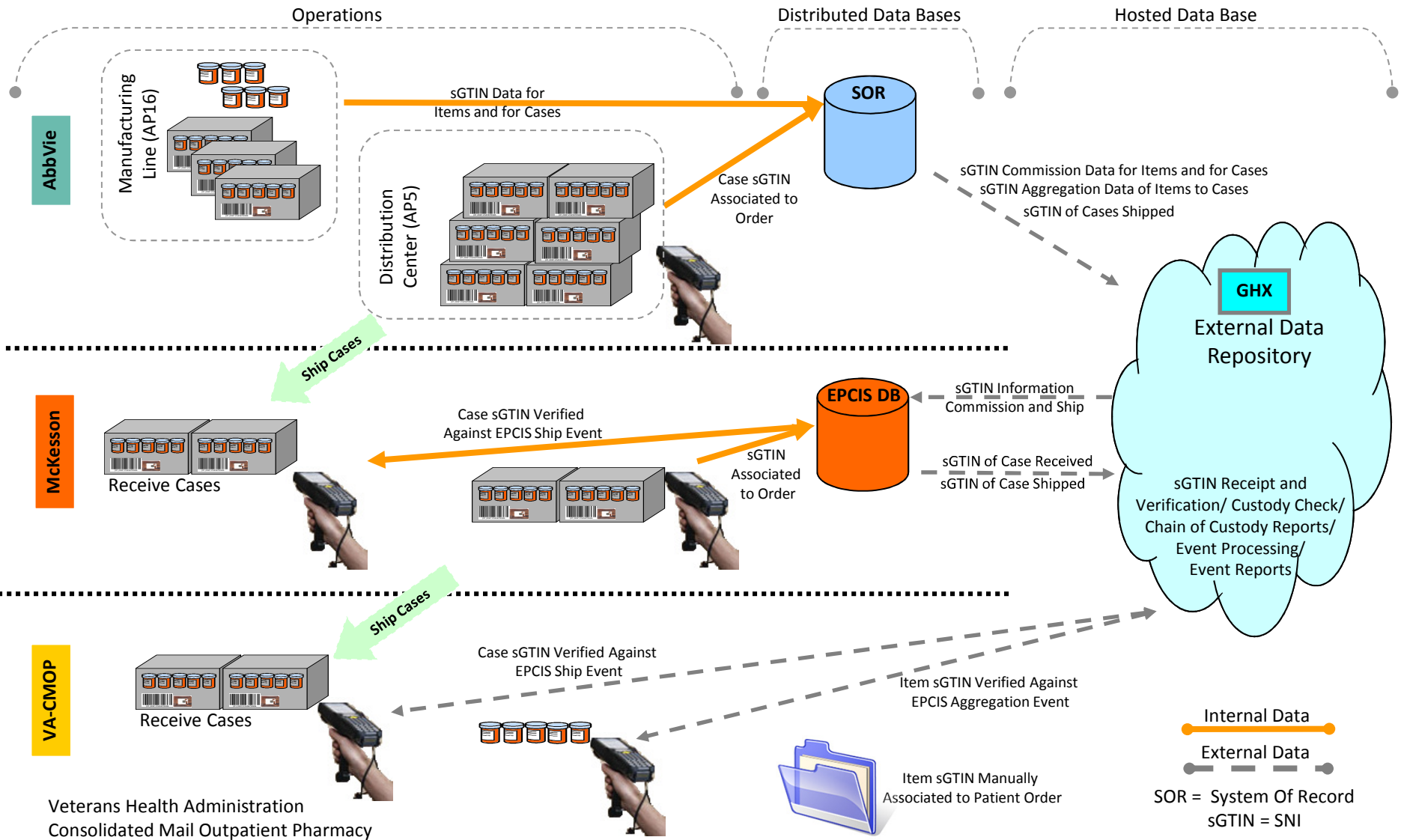
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Product Packaging

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

Traded homogenous 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 | Distributed Data Bases | Hosted Data Base

AbbVie

Manufacturing Line (AP16)

Distribution Center (AP5)

sGTIN Data for Items and for Cases → **SOR**

Case sGTIN Associated to Order

sGTIN Commission Data for Items and for Cases
sGTIN Aggregation Data of Items to Cases
sGTIN of Cases Shipped

GHX

External Data Repository

McKesson

Ship Cases

Receive Cases

Case sGTIN Verified Against EPCIS Ship Event

sGTIN Associated to Order → **EPCIS DB**

sGTIN Information Commission and Ship

sGTIN of Case Received
sGTIN of Case Shipped

sGTIN Receipt and Verification/ Custody Check/ Chain of Custody Reports/ Event Processing/ Event Reports

VA-CMOP

Ship Cases

Receive Cases

Case sGTIN Verified Against EPCIS Ship Event

Item sGTIN Verified Against EPCIS Aggregation Event

Item sGTIN Manually Associated to Patient Order

Veterans Health Administration
Consolidated Mail Outpatient Pharmacy

Internal Data

External Data

SOR = System Of Record
sGTIN = SNI

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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

sGTIN Uniquely Identifies Case

Last Known Location of Product (VA)

Custody: Business Step, Date, Time and Location

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

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 Stength: 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

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: 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

Three Database Models

View of db structures in 2012 when the pilot was designed

Checking Services absent

Central Repository

Distributed Databases

Semi Central
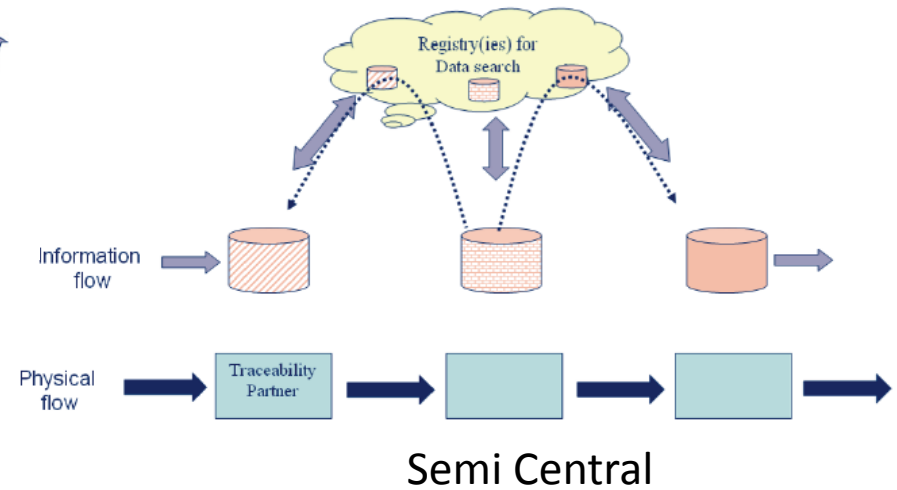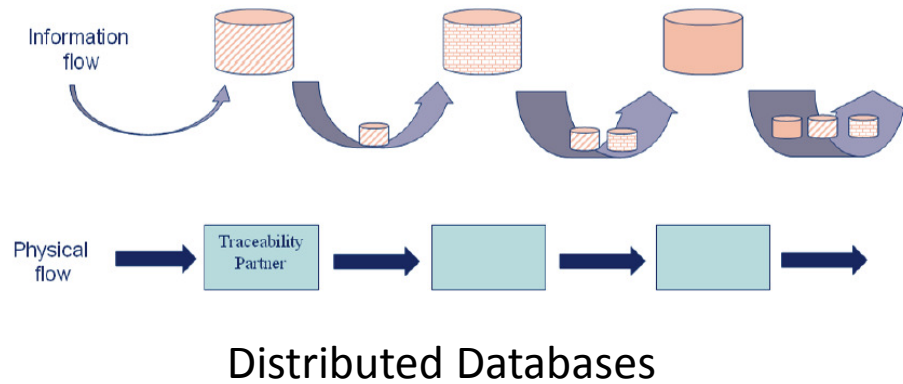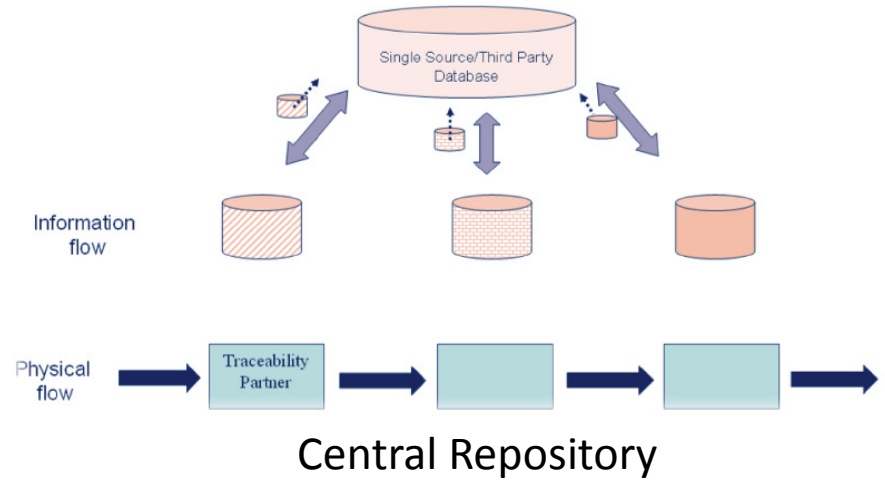
Event Based Traceability (EBT)

Under development within the GS1 Global Standards Management Process (GSMP) by a Mission Specific Working Group (MSWG) focused on EBT

Event Based Traceability Strawman

Non-Normative Document

Draft 0.7, March 2014

Utilizes of GS1 Standards & tools:

Global Traceability Standard for Healthcare (GTSH)

Electronic Product Code Information Services (EPCIS) 1.1

Core Business Vocabulary (CBV) standard

Object Name Service (ONS)
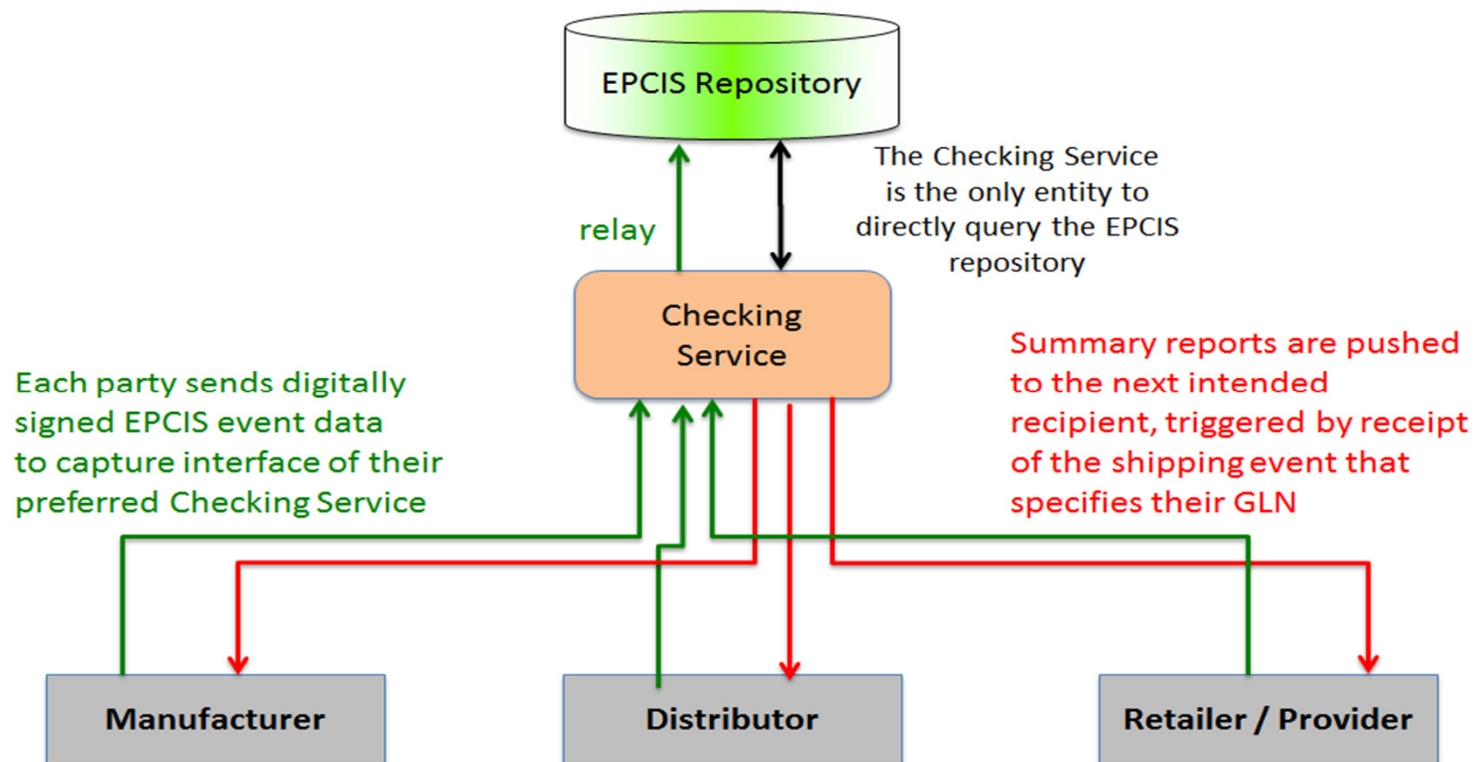
Checking Service and Security Framework

Secure Checking Service – Common to All Models
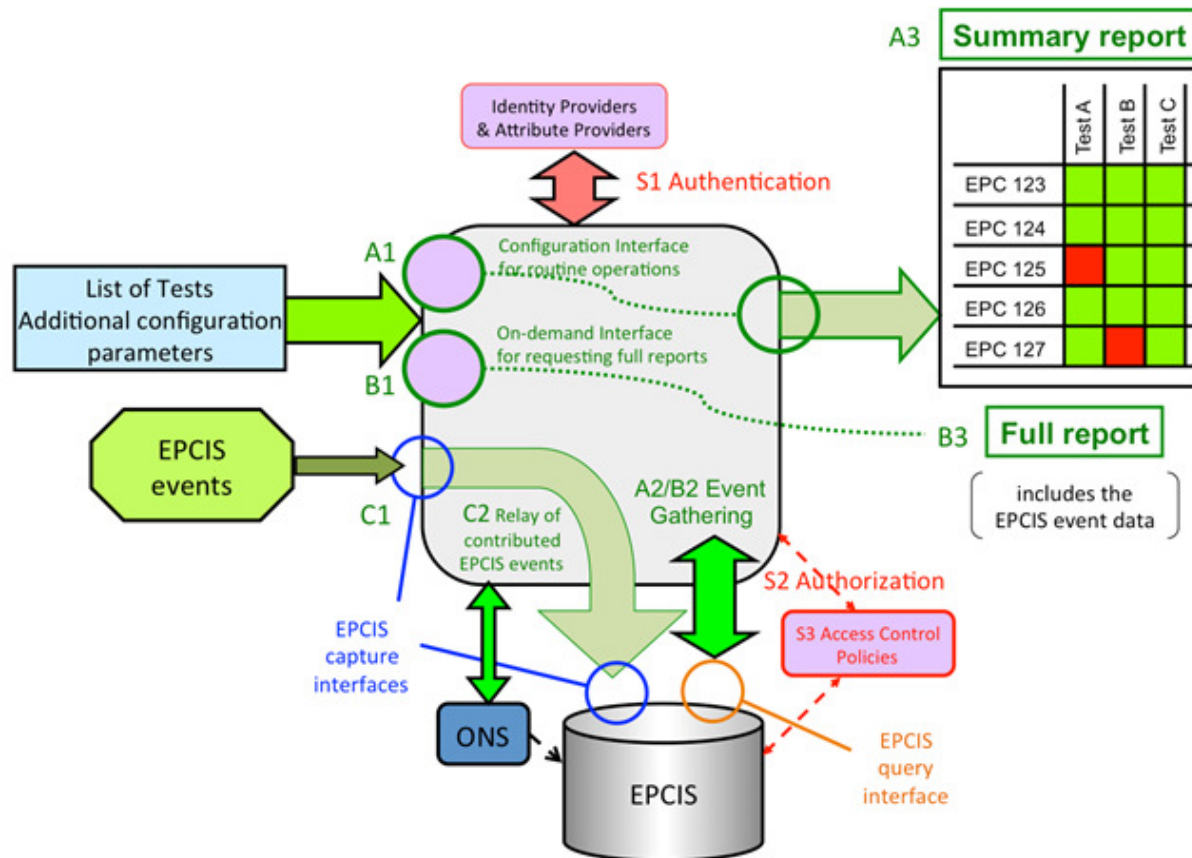
Checking services "protects" the EPCIS repositories

The checking service manages the data verification, authorization and access control rules for the data and the supply chain parties
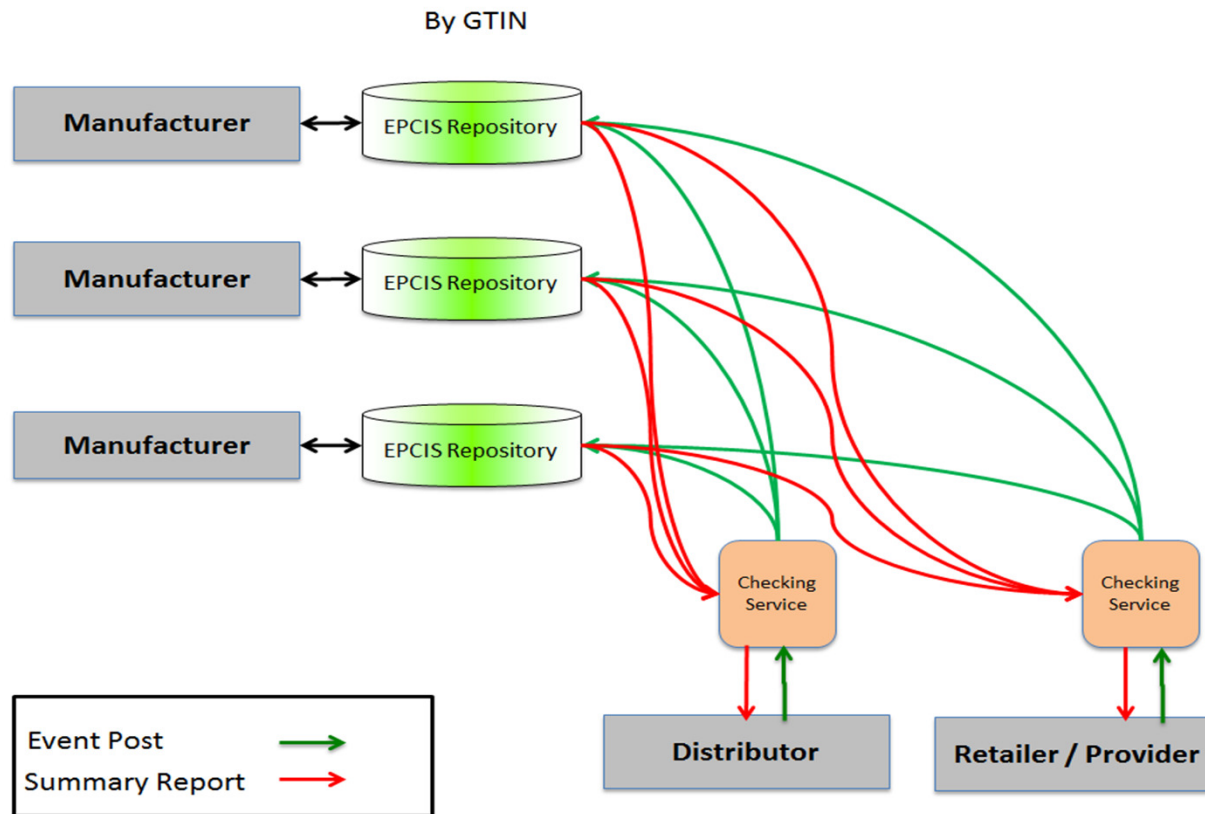
Centralized Model

Repository stores all data specific to users of a defined community

The checking service queries a single known repository containing all commission and event data required to meet the objectives
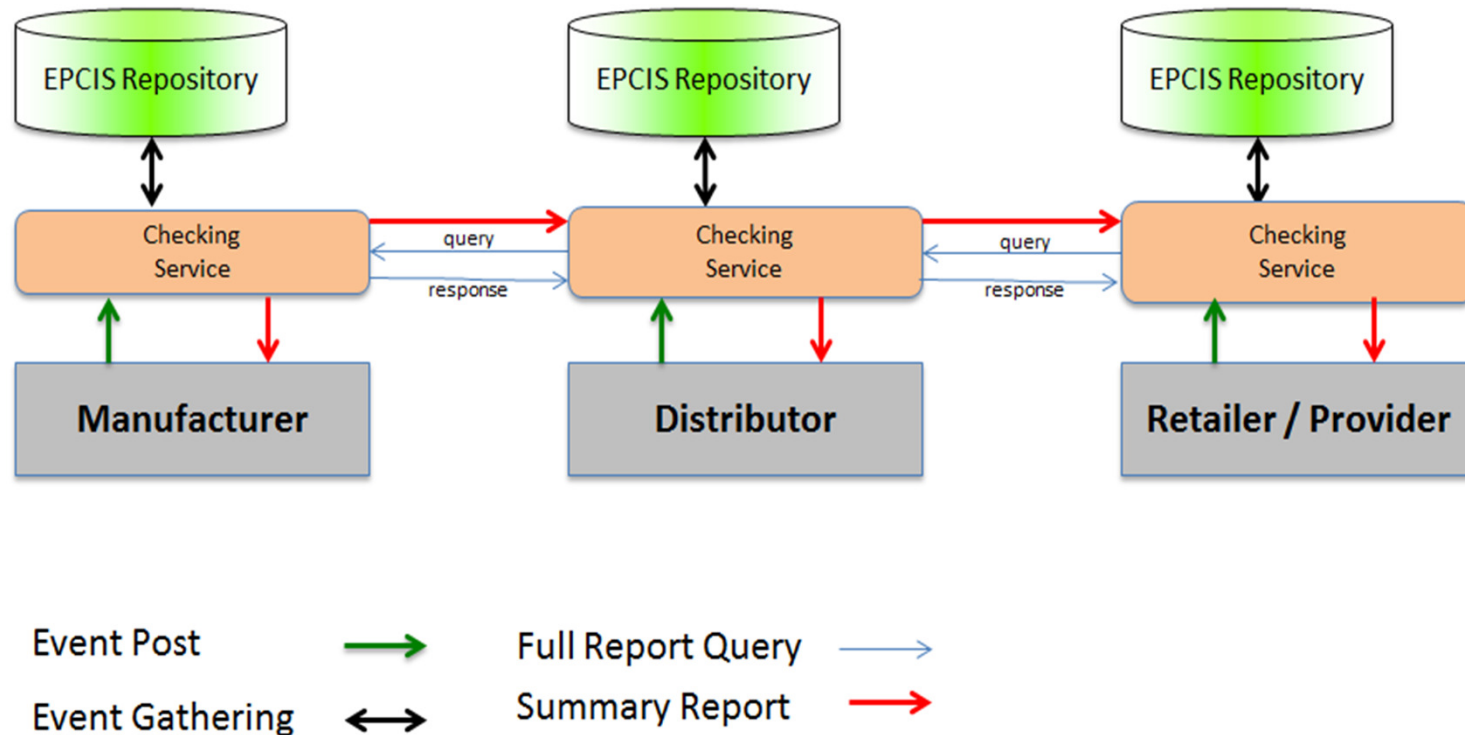
Semi - Centralized Model

Repositories specific to product (GTIN) store commission data and associated created Events

The checking service queries the ONS on **GTIN** to determine which EPCIS repository to interact with. (Commission data with associated events)

Distributed Model

Multiple Repositories store data as determined by the data creator or owner

The checking service queries the ONS on **GLN** to determine all of the EPCIS repositories to interact with. (Commission + Event + Event + Event)

Global Models Existing or Emerging

Central

Turkey, Argentina, EU's ESM, China

Semi-Central

Brazil (defined by regulation)

Distributed

None

Hybrid

US Stakeholders likely to discuss

Thoughts on questions

- What is the biggest challenge for you when implementing traceability?

- What has been your greatest learning?

- Traceability is often a regulatory requirement – do you see also benefit in it?

- What do you see as cornerstone for a successful implementation?

- If you would need to regulate traceability for the fight against counterfeiting, reimbursement fraud etc. – what would you do?