Databases and infrastructure for traceability

Data sharing

Lagos, Nigeria
18 September 2019
Speakers

- **Gregory Goger**, Supply Chain Track and Trace Project Manager, Abbvie, USA

- **Dirk Van den Wouwer**, Senior Manager, EMEA Deployment Digital Identification and Traceability, Johnson & Johnson Supply Chain, Belgium
Gregory has been a member of AbbVie’s Supply Chain Traceability Operations group since 2011. In Gregory’s role as a Global Market Manager, he works with local affiliates to ensure serialization and traceability regulations are understood and implemented correctly. Prior to joining AbbVie Gregory spent 17 years in software development and data management.

Gregory is currently a member of the GS1 Healthcare Leadership Team.

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AbbVie: An introduction

We’re a biopharmaceutical company.

We’re guided by people, powered by passion and in awe of the possibilities ahead of us.

We’re highly focused, research-oriented and patient-centric.

We are AbbVie.
Treating people

In 2018, AbbVie medicines helped

Over 30m+ patients  
In more than 175+ countries

Treating over 32+ conditions
Agenda

Importance of Data
The Types of Data to Collect
How Much Data to Collect
Types of Reporting Models
Timeline and Development Considerations
Importance of Data to the Supply Chain

You receive a drug product with the barcode below
• It has a GTIN
• It has a serial number

Is it safe to use? How do you know?

The key lies in the data associated with that GTIN and serial number
Types of Data to Collect

What are some of the types of data to consider when building a traceability system?

• Master Data
• Commissioning Data
• Transaction Data
• Final Disposition
Master Data

What is master data?

• Gartner definition: Master data is the consistent and uniform set of identifiers and extended attributes that describes the core entities of the enterprise

• Good master data allows clear communication with a minimal amount of data being exchanged
Master Data - example

With the scan of a single GTIN, what master data could be retrieved for a given product?
• Product name (brand name and generic drug name)
• Dosage form (tablet, syringe…)
• Dosage strength
• Pack size
• Package type
• Who is the manufacturer
• Where is the product manufactured
• Registration date
• Storage conditions
• Picture of the product
Commissioning Data

How will members of the supply chain determine if a serial number is valid?

A data repository containing all of the valid, live serial numbers allows for verification to occur.

As products are serialized within the country it should be the responsibility of the manufacturers to ensure the valid serial numbers are uploaded to the system.

- In the case of imported product, it could be the manufacturer or the importer that uploads the data.
Transaction Data

Transaction data is the history of an individual product’s movement.

Where has a serial number been?

Where is a serial number supposed to be? Is it there?
Final Disposition

Eventually an individual product will reach an end of life state

If the data repository clearly identifies that a serial number is no longer available for use, attempts to re-use serial numbers or product packaging can be detected

Common end of life states include:

• Sample
• Dispensed
• Destroyed
How Much Data to Collect

There are many opportunities for data collection, and many points of the supply chain at which that data could be collected.

To determine how much data to collect, first you need to identify why you are collecting the data. What problems are you trying to solve?

Each scenario requires data from different components of the supply chain. Focus on the highest priorities first.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Supply Chain Components</th>
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<tbody>
<tr>
<td>Counterfeit detection</td>
<td>Manufacturers and dispensers</td>
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<tr>
<td>Diversion</td>
<td>Distribution Network</td>
</tr>
<tr>
<td>Reimbursement Management and Fraud</td>
<td>Dispensers and patients</td>
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</tbody>
</table>
How Much Data to Collect

You must determine what you are willing to spend in terms of cost, resources and effort to collect the data.

Each data element being collected adds to the complexity of the system.

Additional transactions may increase the number of supply chain entities that are required to participate, or involve additional functions within those entities.
What Type of System to Build?

There are 2 primary traceability models:

- Point of Dispense Verification
  - Currently implemented in the European Union

- Full Track and Trace
  - Currently implemented in Turkey and Argentina. Under development in the U.S.
Point of Dispense Verification Process

Pharmaceutical Manufacturer

Unique Serialisation with Random Numbers

2D Data Matrix Code on 2nd Pack

Upload Number

Medicines Verification Repository

GTIN
Batch
Expiry
S/N

Voluntary Verification

Authenticate Number

Pharmacist

Patient

Verification upon Dispense to Patient

Point-of-Dispense Verification Process
Full Track and Trace Process

Repository for Shared Event Data

Manufacturer → Distributor → Pharmacy or Hospital → Patient
## Comparison of Traceability Models

<table>
<thead>
<tr>
<th></th>
<th>Point of Dispense Verification</th>
<th>Full Track and Trace</th>
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</thead>
<tbody>
<tr>
<td><strong>Benefits</strong></td>
<td>Provides ability to detect counterfeit product before dispense to patient</td>
<td>Full visibility to product movement throughout entire supply chain</td>
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<td></td>
<td></td>
<td>Identify potential issues earlier and trace anomalies back to a specific point in the supply chain</td>
</tr>
<tr>
<td><strong>Ease of Implementation</strong></td>
<td>Responsibility on manufacturers to post data, dispensers to verify data</td>
<td>All supply chain parties must scan product with every product movement. Aggregation becomes a necessity</td>
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<tr>
<td><strong>System requirements</strong></td>
<td>Minimum amount of data created. Fewest number of transactions</td>
<td>Volume of data, transaction count, number of parties connected to the system all significantly higher</td>
</tr>
</tbody>
</table>
Comparison of Traceability Models

Data is now a part of the supply chain. Here are some examples of data transmission requirements in both models:

• Point of Dispense Verification
  - If a dispenser scans a product and receives a “serial number does not exist” message. The product will not be immediately dispensed to the patient. Additional effort is now required to determine if the product is safe
  - Benefit: The system has protected the patient in the event that bad product has been introduced to the supply chain
  - False errors: A failure to upload the commissioning data will trigger a false error message. A patient is now being prevented from receiving good product. The dispenser is forced to spend extra time investigating the situation
  - Data requirements: A manufacturer must ensure commissioning data is uploaded prior to product reaching the point of dispense. This most commonly allows at least a period of days before false errors would occur
  - Challenge: In the event of a true counterfeit scenario, where was the counterfeit introduced into the supply chain? There is no data associated with this product
Comparison of Traceability Models

Data is now a part of the supply chain. Here are some examples of data transmission requirements in both models:

• Full Track and Trace
  • A hospital receives a shipment of product, scans it, and attempts to upload a “receive” event. The system returns an error message stating there is no “ship” event. The hospital moves the product to quarantine while the situation is investigated
  • Benefit: The hospital has kept illegitimate product out of inventory and safely away from patients. A potential issue with a supplier has been revealed
  • False Errors: The distributor may have simply failed to upload the “ship” event. This is good product now sitting in quarantine due to a data issue
  • Data Requirements: The distributor must have data uploaded within hours of shipping product. An outage with the data repository may even cause distributors to delay shipments for fear of triggering false error messages
  • Challenge: Physical product and the data must move together. Data issues can stop the physical product, and the entire supply chain must stay connected to the data repository
Reporting System Timeline

Once a reporting model has been decided on when do you start building the reporting system and data repository? **VERY EARLY IN THE PROCESS**

GS1 Healthcare’s Traceability Roadmap shows an example timeline for implementing traceability

https://www.gs1.org/industries/healthcare (Regulatory Roadmap link)
Repository Development Considerations

There is a natural dependency between data repository development and industry solution development.

Data Repository:
- Design specification published
- Test system available
- Production system available

Industry Solutions:
- Solution development begins
- Interoperability testing of repository and industry solutions begins
- Connection process begins
Repository Development Considerations

Once a data repository goes live, how will you get everyone connected?

Repository for Shared Event Data
Repository Development Considerations

Development of the data repository is critical for the entire supply chain

Solutions and standards exist. Take advantage of those standards. Implementation will be faster, cheaper and easier to maintain if the system is built using existing technology
Mr. Van den Wouwer has a Master in Bio Engineering and Master in Industrial Management Sciences. He worked for 15 years at Mars Inc. In various Supply Chain Management functions. In 2007 he joined Johnson & Johnson in the planning department, leading the chemical platform planning department. Since 5 years he is responsible for Serialization and Traceability deployment in EMEA region where he has successfully implemented the European regulation for Medicines Verification. Since 6 months he is also in charge of Unique Device Identification and Global Data Synchronization across EMEA.

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Product Data, Databases & Infrastructure Supporting Traceability

Deployment in a global company

Dirk Van den Wouwer
EMEA Deployment, Digital Identification & Traceability
GS1 Healthcare Conference, Lagos, Nigeria
September 2019
Johnson & Johnson
World’s largest and most broadly based healthcare company

- Over 130 years of caring
- Selling products in more than 175 Countries
- Approximately 130,000 employees worldwide
Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers’ orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive working environment where each person must be considered as an individual. We must respect their diversity and dignity, and recognise their merit. They must have a sense of security, fulfilment and purpose in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must support the health and well-being of our employees, and help them fulfill both their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders, and their actions must be just and ethical.

We are responsible to the communities in which we live and work, and to the world community as well. We must help people to be healthier by supporting better access and care in more places around the world. We must be good citizens – by supporting good works and charities, improving health and education, and bearing our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programmes developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realise a fair return.
Johnson & Johnson Portfolio

Consumer
Self Care • Skin Care • Essentials

Medical Devices
Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement Sterilization • Eye Health • CSS

Pharmaceuticals
Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension • PAH
Deploying for Regulations Requires Managing Through Complex Organizational Structures

Organizing in a global, end-to-end, cross-functional context

Examples:
- U.S.
- EU
- Russia
- Egypt

Examples:
- Pharmaceuticals
- Consumer
- Medical devices
- Labelling
- Manufacturing
- Distribution
- IT
- Quality
Traceability Touches Multiple Domains

Assessment required over different parts of the business
Traceability Entails an Integrated Systems & Processes Approach
Enabled by GS1 Global Standards (GTIN, GLN, SSCC, EPCIS,...)

- Regulatory Reporting
- Enterprise Serialization & Traceability System (EPCIS based)
- Pack Line / Device
- 3PLs, CMOs, Wholesalers, ...
- Harvesting GTINs
- Validating GTINs
- Enumerating GTINs
- Populating GTINs
- Enterprise Data Management
- Artwork – Labelling & Enterprise Standard

#JJSCDigital
EU Falsified Medicines Directive Published in July 2011

Serialization only part of the directive

### Product Safety Features
- Authenticity
- Pack Identity
- Tamper Evidence

**Feb 9, 2019**

### Good Distribution
- Wholesalers & Brokers
- GDP

**2014-Q1**

### Active Substances
- GMP for Excipients

**Jan 2, 2013**

### Internet Sales
- Registration API Activities

**July 2, 2013**

### Community Logo

**2015**
Delegated Act Mandates Rules for End-to-End Verification

Key pillars of serialization and verification published Feb 2019

- Serialization by manufacturer + Verification at point of dispense
- Unique identifier + Tamper evidence
- System set up and governed by stakeholders under supervision of local authorities
- Manufacturers pay for the system
Point of Dispense Verification
All parties verify against one central system
European Repositories Systems
Enable systematical point of dispense verification
Piloting the German National System
Proven technology … knowledge gained by executing

MAH (~100)
Companies

Master data
Batch data
Pack ID data

EU-Hub
German national repository
Pharmacy system

Pharmacies (~400)

End-April 2018
• 800K+ packs
• ~400 batches
• ~100 SKUs / products
• 123 dispenses

#IDscDigital
Phased Roll Out Across 30 Countries

Supported by realistic time plans, monitored centrally

Dates still to be confirmed:
- Greece
- Italy

IT provider
- Arvato
- Solidsoft
- IT provider selected
- No IT provider selected

Germany is live with stand-alone system of Arvato
Key Attention Points
Build on experience gained in other countries

Game Changer
- Full end-to-end process
- Impacting all business units, partners, systems & platforms

Multi-Country Packs
- Refrain from using NTIN
- Alignment on National Reimbursement number

Special Flows
- Marketing Authorization Holder
- Producer
- Distributor

Regulatory Reporting
- Clear specifications needed upfront
- Alignment to industry standards

Know How
- Reuse experience build by stakeholders
- Cost & timings of implementation decreases as capabilities are being deployed
End-to-End Verification Process Requiring System Integration
**Phased Approach Realistic Timings Recommended**

**Phase 1: Product Identification**
- DataMatrix including GTIN, Batch #, Expiry date
- Suggested Timing: ~6 to 12 months as of publication

**Phase 2: Unique Identification of Secondary Pack**
- Include serial number in DataMatrix
- Suggested Timing: ~6 to 18 months as of publication

**Phase 3: End-to-End Traceability / Verification**
- Including reporting to Health Authorities
- Suggested Timing: ~24 to 36 months as of publication
Thank you.
Questions

• **Gregory Goger**, Abbvie

• **Dirk Van den Wouwer**, Johnson & Johnson
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Thanks to our sponsor
Follow us on Twitter and tweet about the conference!

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#GS1HCLagos
Be sure to complete each feedback form!

For every feedback form completed, we will donate 5USD to the chosen conference charity “The North East Children Trust”

https://healthcare-nigeria.gs1.org/
Need any help? Contact us!

Look for the turquoise scarves and ties - we are happy to help you!
<table>
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<td>Stream II - Establishing Traceability: the building blocks</td>
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<td>15:45-16:15</td>
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# Afternoon at a glance

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GS1 Healthcare Digital Thread

An interactive representation of the application of GS1 standards in healthcare in a simple and powerful way.

Test it at the Marketplace!
Visit the Marketplace during lunch time

Meet the exhibitors in the Mezzanine level of Orchid Hall

Every day during breaks and lunch
Networking event at
The Civic Centre tonight at 19:00

The Civic Centre
Ozumba Mbadiwe Avenue
Opposite 1004, Victoria Island
Lagos, Nigeria

PLEASE WEAR YOUR EVENT BADGE 😊

Bus departure: meet in the main hotel lobby at 19:00 sharp!

Bus return: beginning at 21:30 shuttle buses will take you back to the EKO Hotel

Dress code: Business casual
Join us at the to ask experts your questions

The answer to all your questions!

• After lunch today, during a 2 hours session

• meet the experts in Lantana Hall
Thank you