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 Goger

Global Market Manager
Supply Chain Traceability

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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🐦

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Databases and Infrastructure for Traceability

Gregory Goger

September 17, 2019

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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.

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Treating people

In 2018, AbbVie medicines helped

Over
30m+
patients

In more than
175+
countries

Treating over
32+
conditions

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Agenda

Importance of Data

The Types of Data to Collect

How Much Data to Collect

Types of Reporting Models
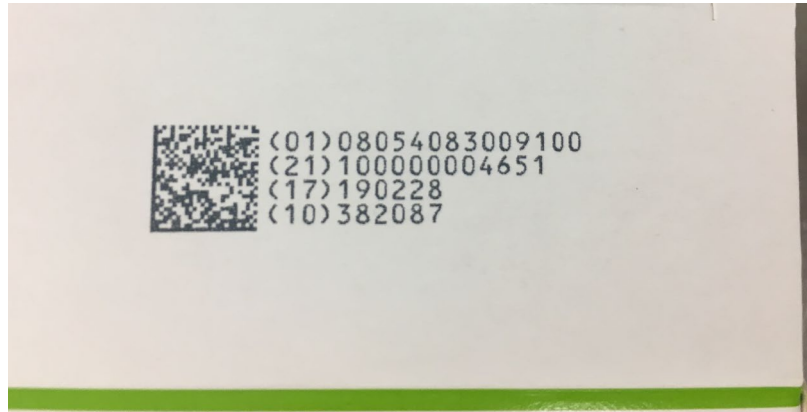
Timeline and Development Considerations

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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

(01)08054083009100
(21)100000004651
(17)190228
(10)382087

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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

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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

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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

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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

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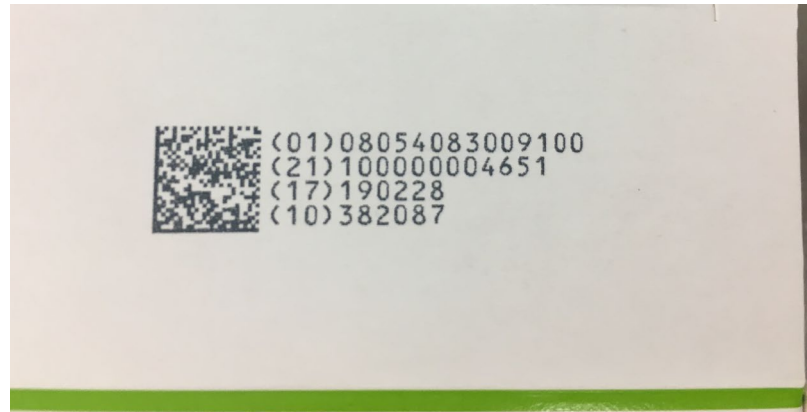
Transaction Data

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?

Manufacturer   **Distributor**   **Pharmacy or Hospital**   **Patient**

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

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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

| Scenario	Supply Chain Components
Counterfeit detection	Manufacturers and dispensers
Diversion	Distribution Network
Reimbursement Management and Fraud	Dispensers and patients

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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

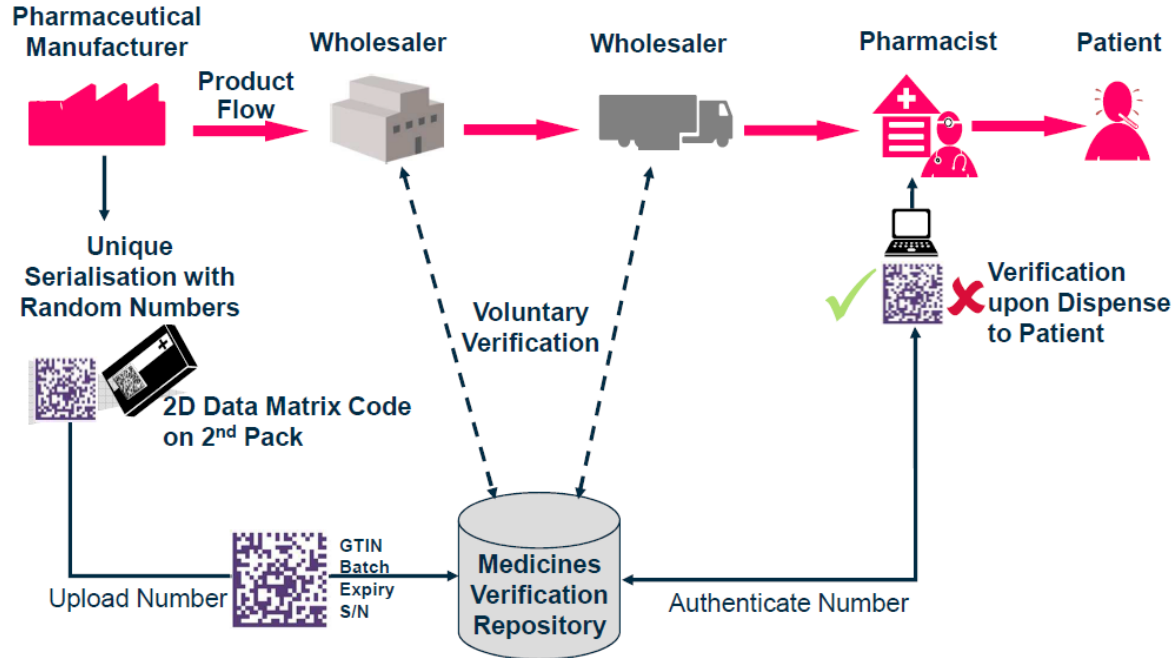
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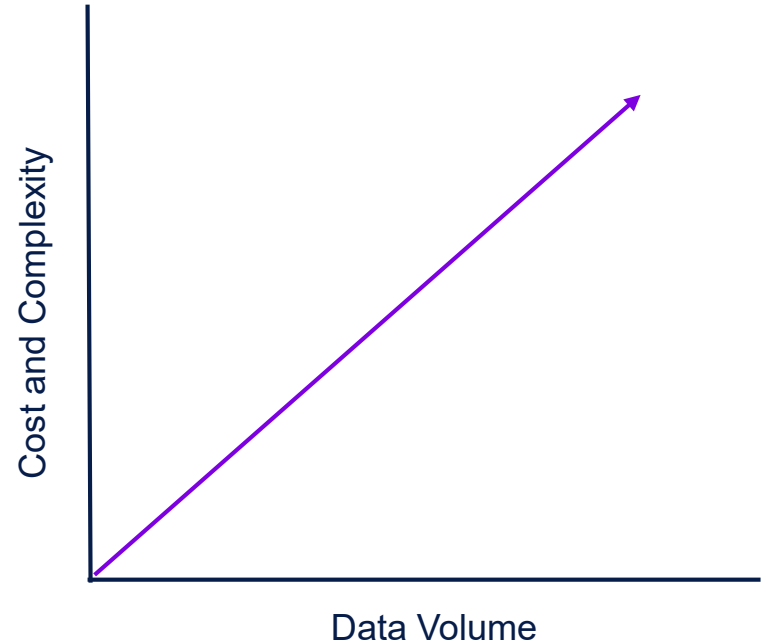
What Type of System to Build?

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.
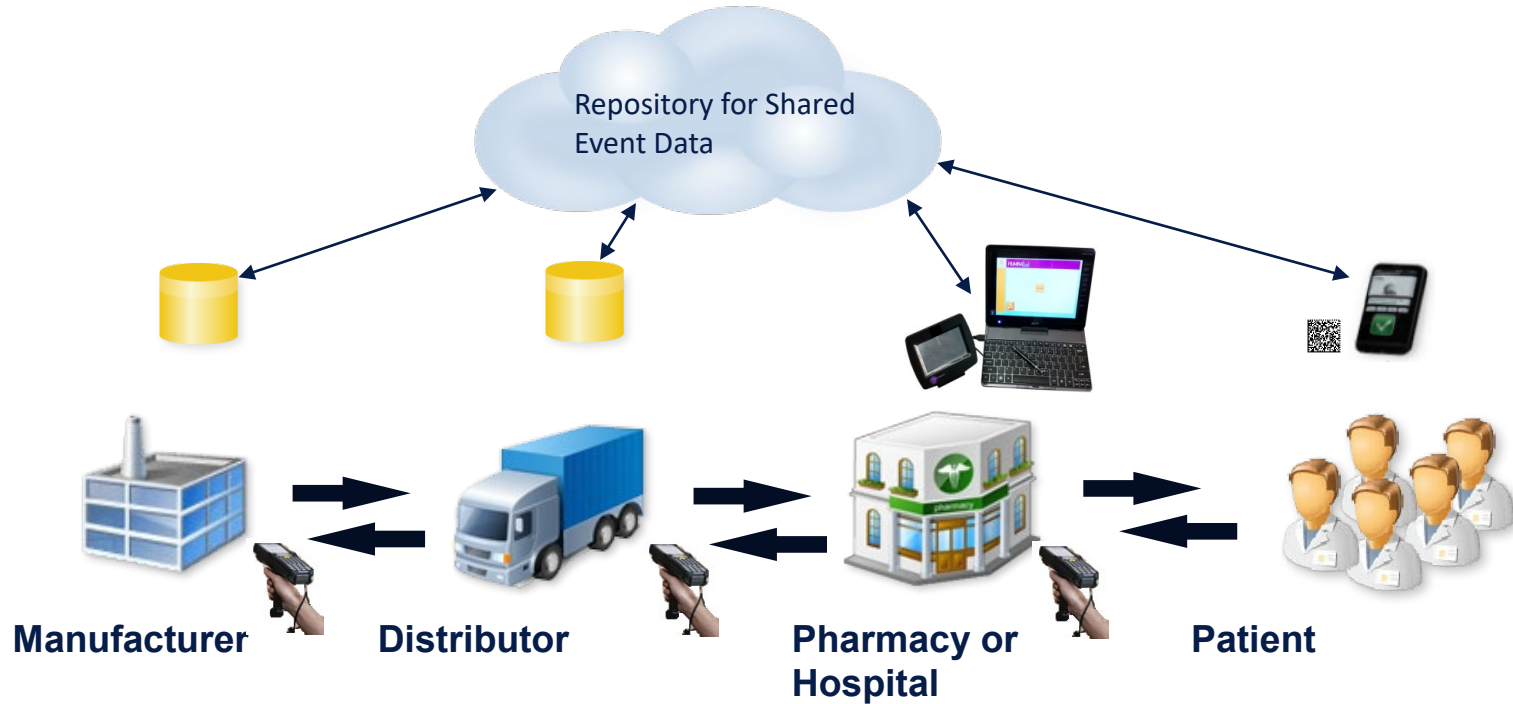
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Point of Dispense Verification Process

Full Track and Trace Process

Repository for Shared Event Data

Manufacturer

Distributor

Pharmacy or Hospital

Patient

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Comparison of Traceability Models

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

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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

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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

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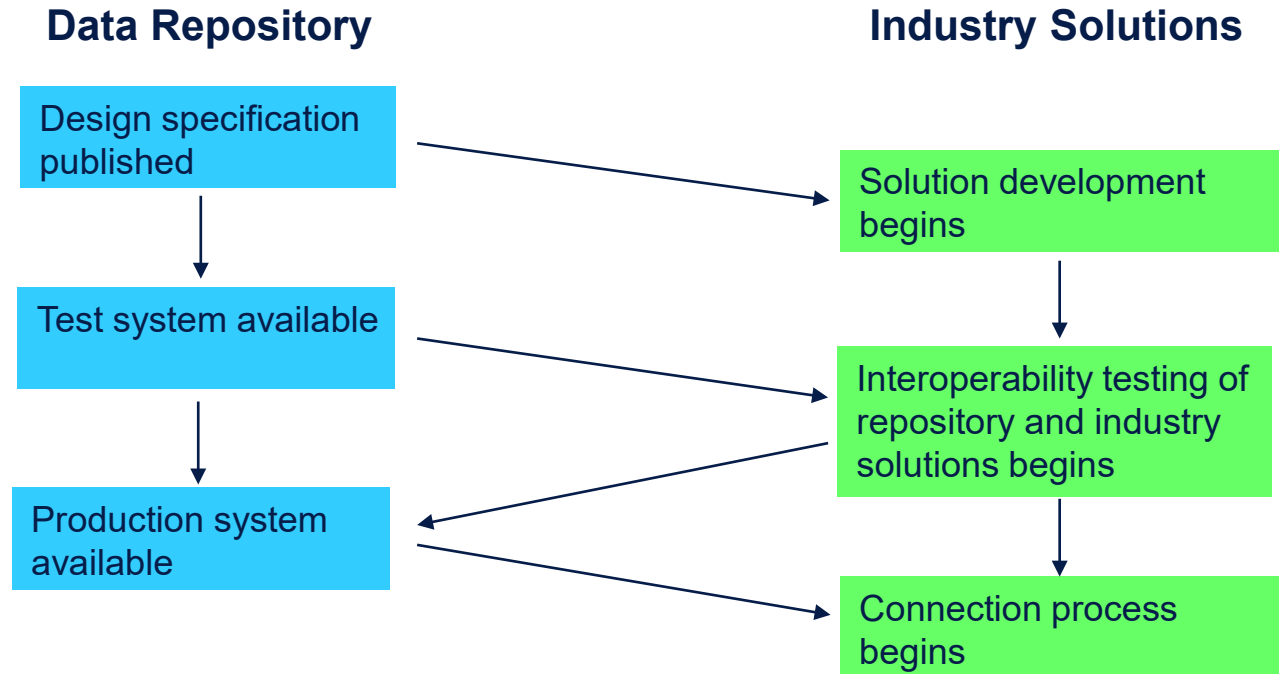
GS1 Healthcare's Traceability Roadmap shows an example timeline for implementing traceability

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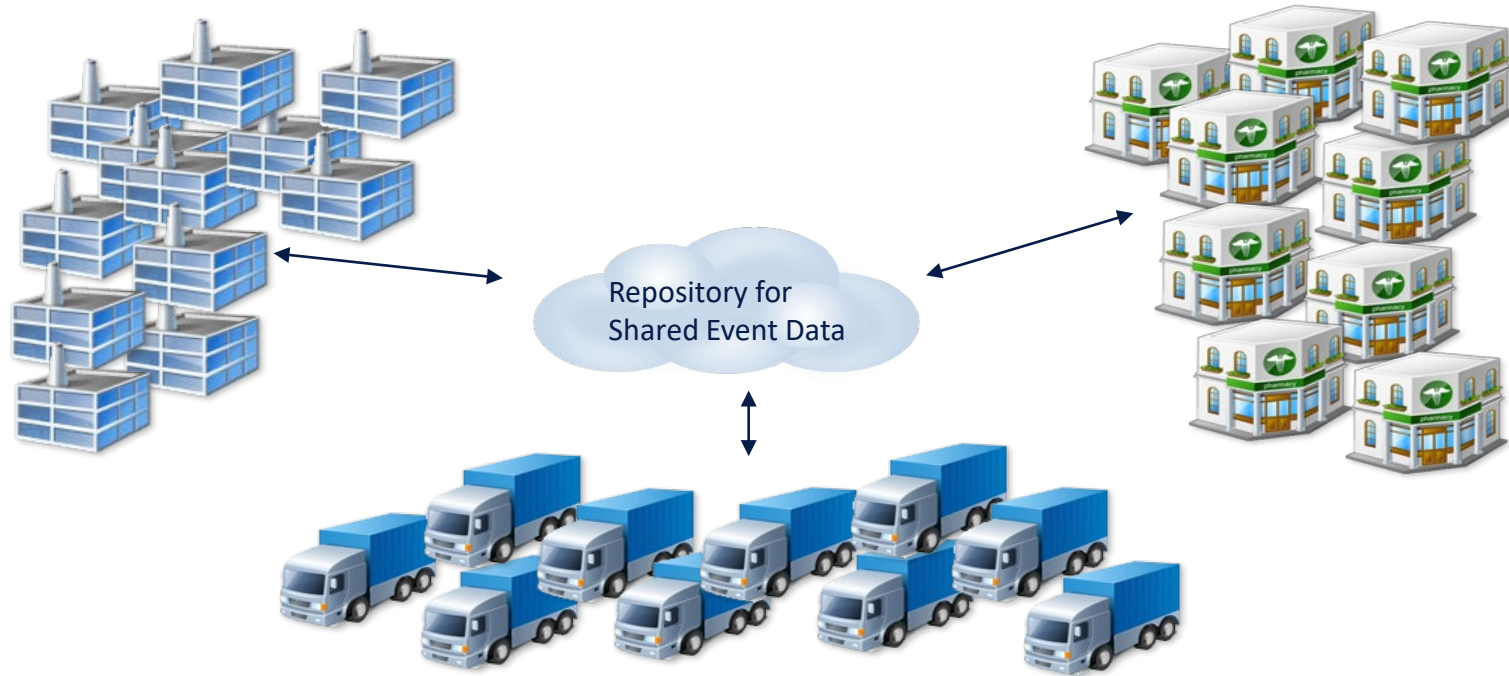
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Repository Development Considerations

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

Data Repository   **Industry Solutions**

Repository Development Considerations

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

Repository for Shared Event Data

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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

GS1

The global language of business

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People. Passion. Possibilities.®

Dirk Van den Wouwer

Sr. Mgr. EMEA Deployment Digital Identification and Traceability, Johnson & Johnson Supply Chain

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.

dvdwouwe@its.jnj.com

LinkedIn

Product Data, Databases & Infrastructure Supporting Traceability
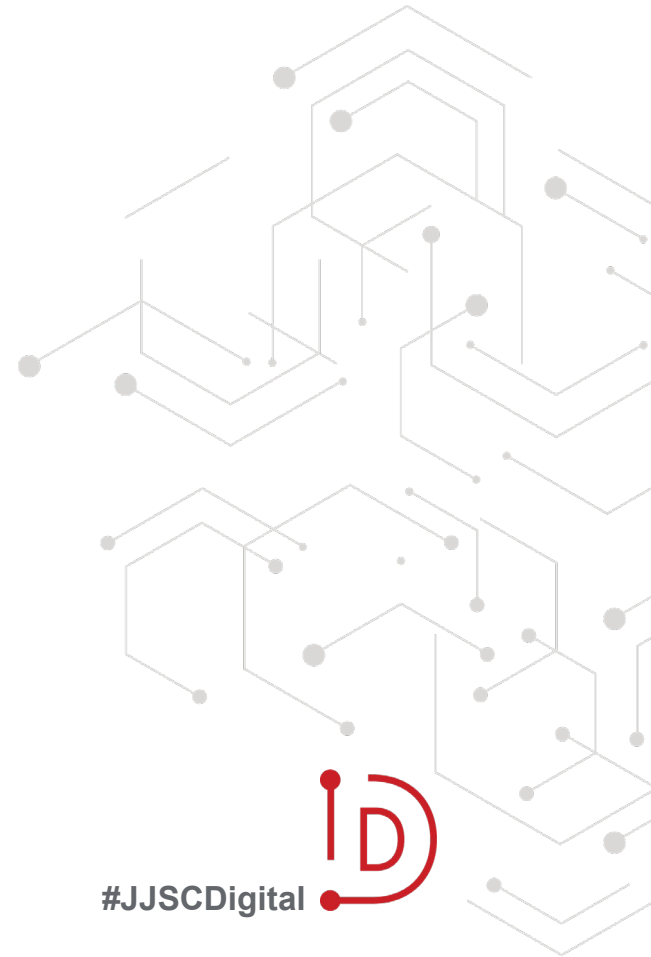
Deployment in a global company

Dirk Van den Wouwer
EMEA Deployment, Digital Identification &Traceability
GS1 Healthcare Conference, Lagos, Nigeria
September 2019

Johnson & Johnson

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

Johnson & Johnson

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 fulfil 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
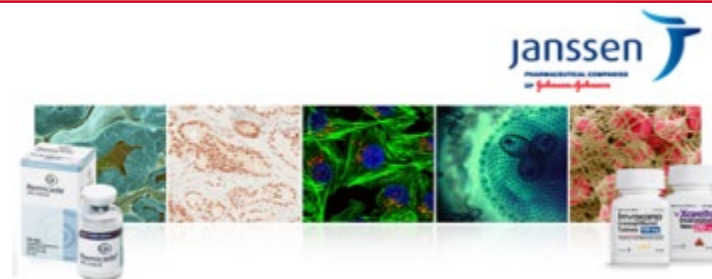
Self Care • Skin Care • Essentials

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

Countries

Examples:
- Pharmaceuticals
- Consumer
- Medical devices

Business units

Functional Domains

Examples:
- Labelling
- Manufacturing
- Distribution
- IT
- Quality
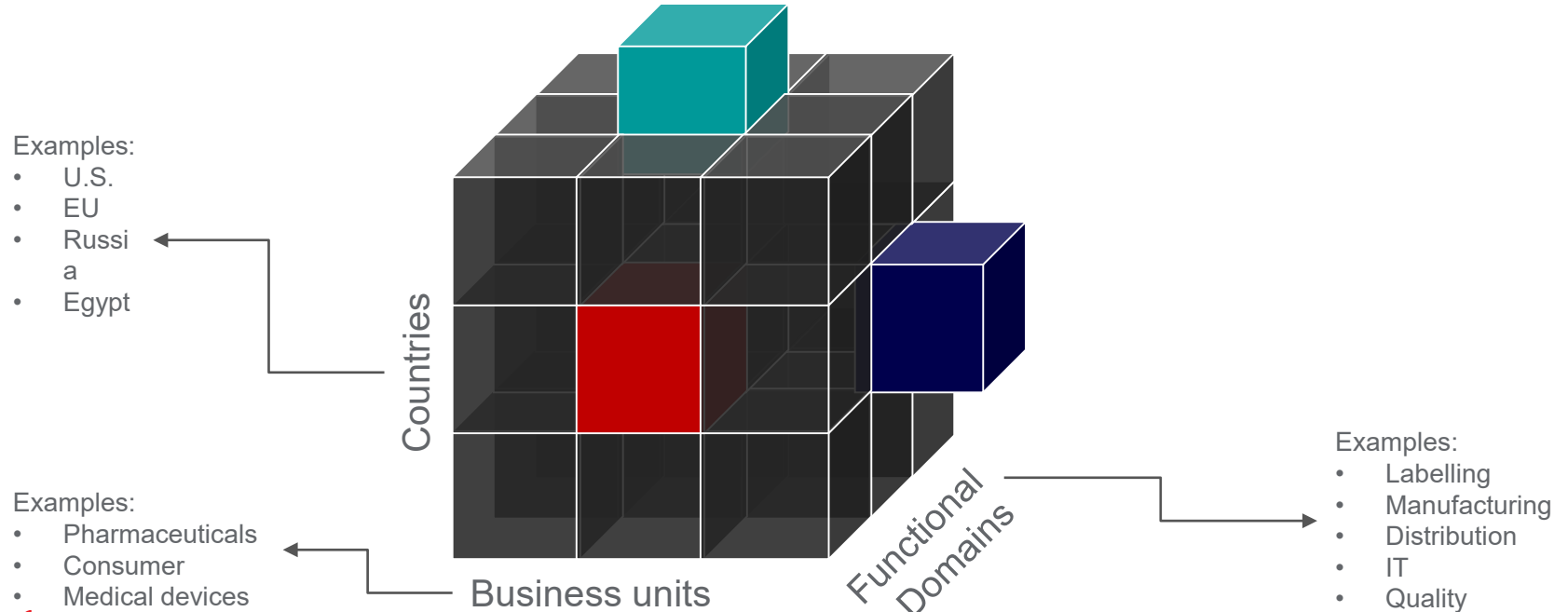
Traceability Touches Multiple Domains

Assessment required over different parts of the business

Internal Manufacturing

External Manufacturing

License Plate

Aggregation

Track & Trace

Cost Control Value Beyond

DataMatrix

Packaging Lines

Enterprise IT Architecture

Artwork Review

Regulations Timelines

Distribution

Partnerships

Traceability Entails an Integrated Systems & Processes Approach

Enabled by GS1 Global Standards (GTIN, GLN, SSCC, EPCIS,…)

Regulatory Reporting

ERP/ WM

Enterprise Serialization & Traceability System

(EPCIS based)

3PLs, CMOs Wholesalers, …

Pack Line / Device

Harvesting GTINs
Validating GTINs
Enumerating
Populating GTINs

Enterprise Data Management

Artwork – Labelling & Enterprise Standard
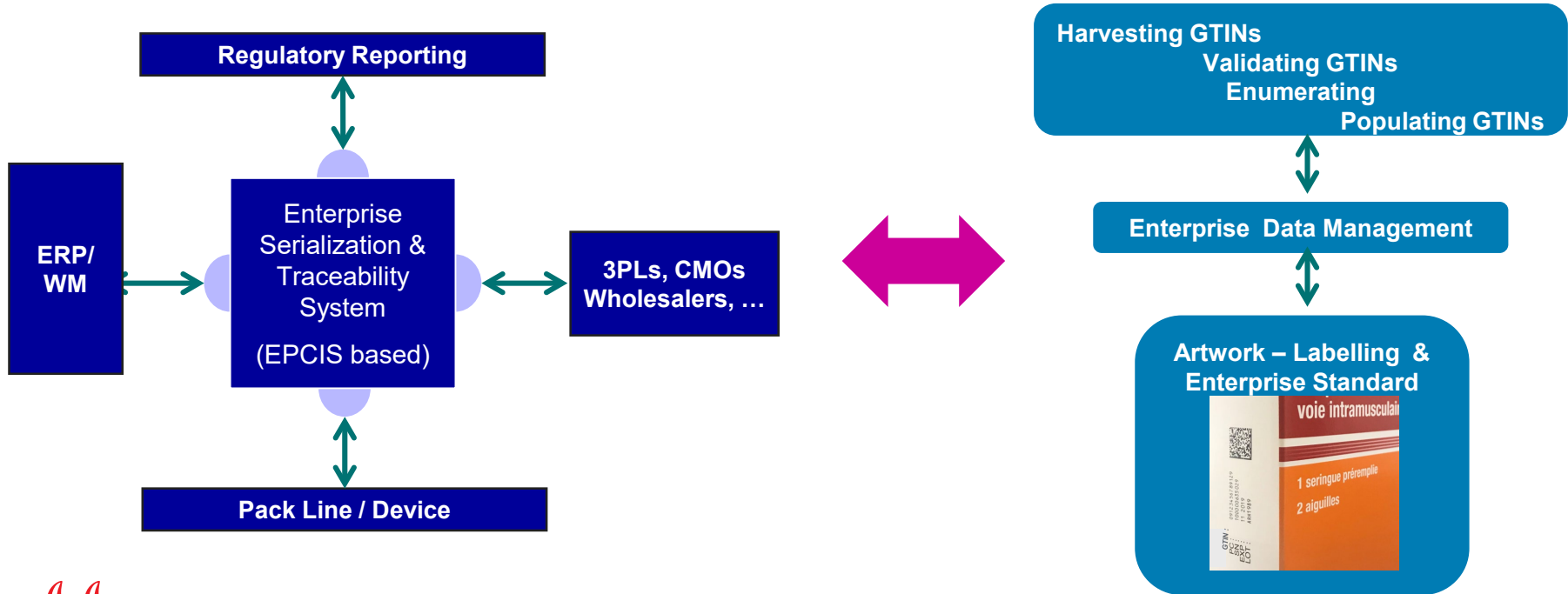
EU Falsified Medicines Directive Published in July 2011

Serialization only part of the directive

Product Safety Features	Good Distribution	Active Substances	Internet Sales
Authenticity Pack Identity Tamper Evidence	Wholesalers & Brokers GDP	GMP for Excipients **Jan 2, 2013** Registration API Activities	Community Logo
Feb 9, 2019	**2014-Q1**	**July 2, 2013**	**2015**

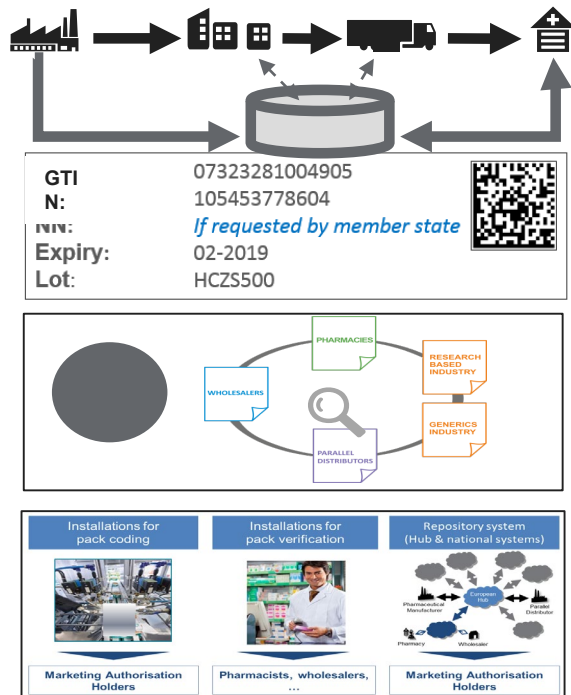# Delegated Act Mandates Rules for End-to-End Verification

Key pillars of serialization and verification published Feb 2019

Serialization by manufacturer
+
Verification at point of dispense

Unique identifier +
Tamper evidence

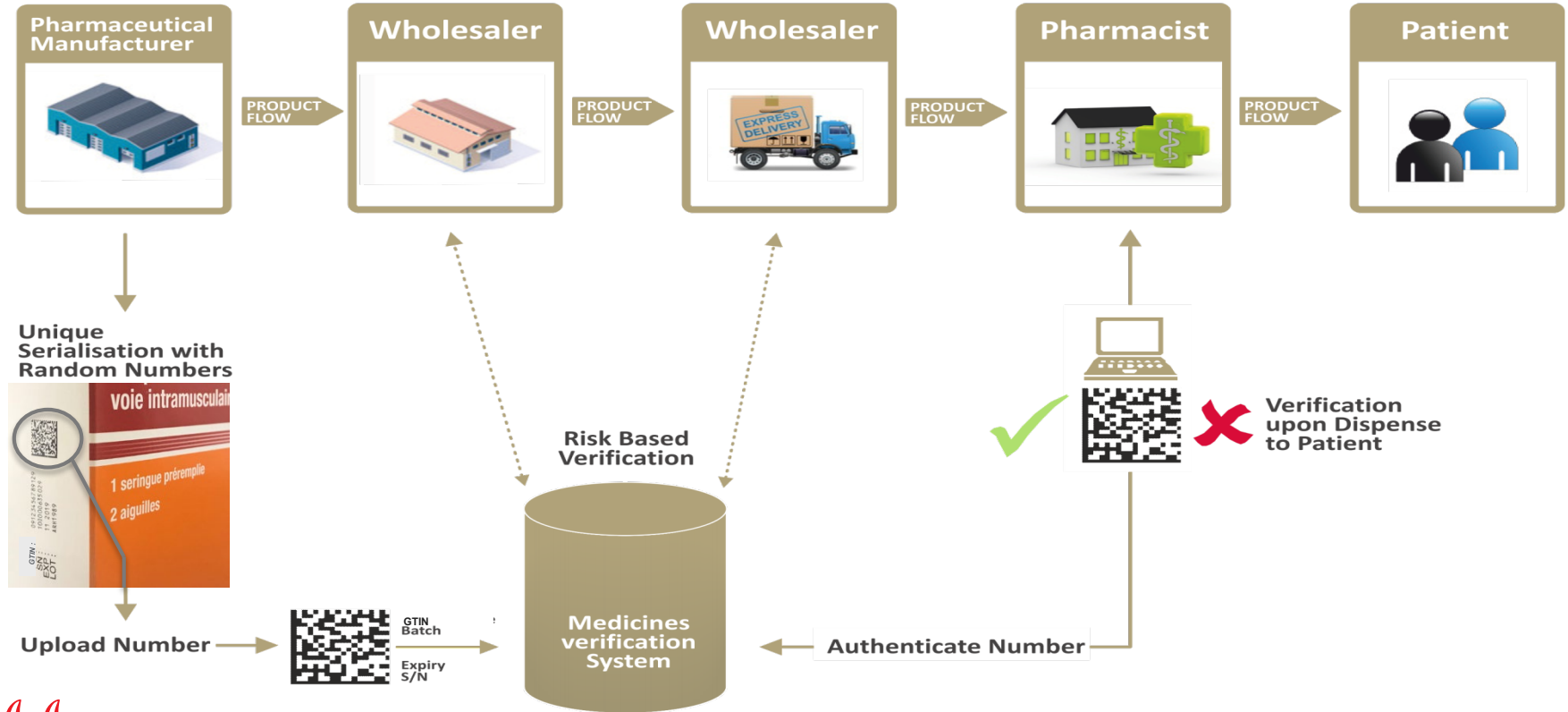System set up and governed by stakeholders under supervision of local authorities

Manufacturers pay for the system

GTIN:	07323281004905
N:	105453778604
NN:	*If requested by member state*
Expiry:	02-2019
Lot:	HCZS500

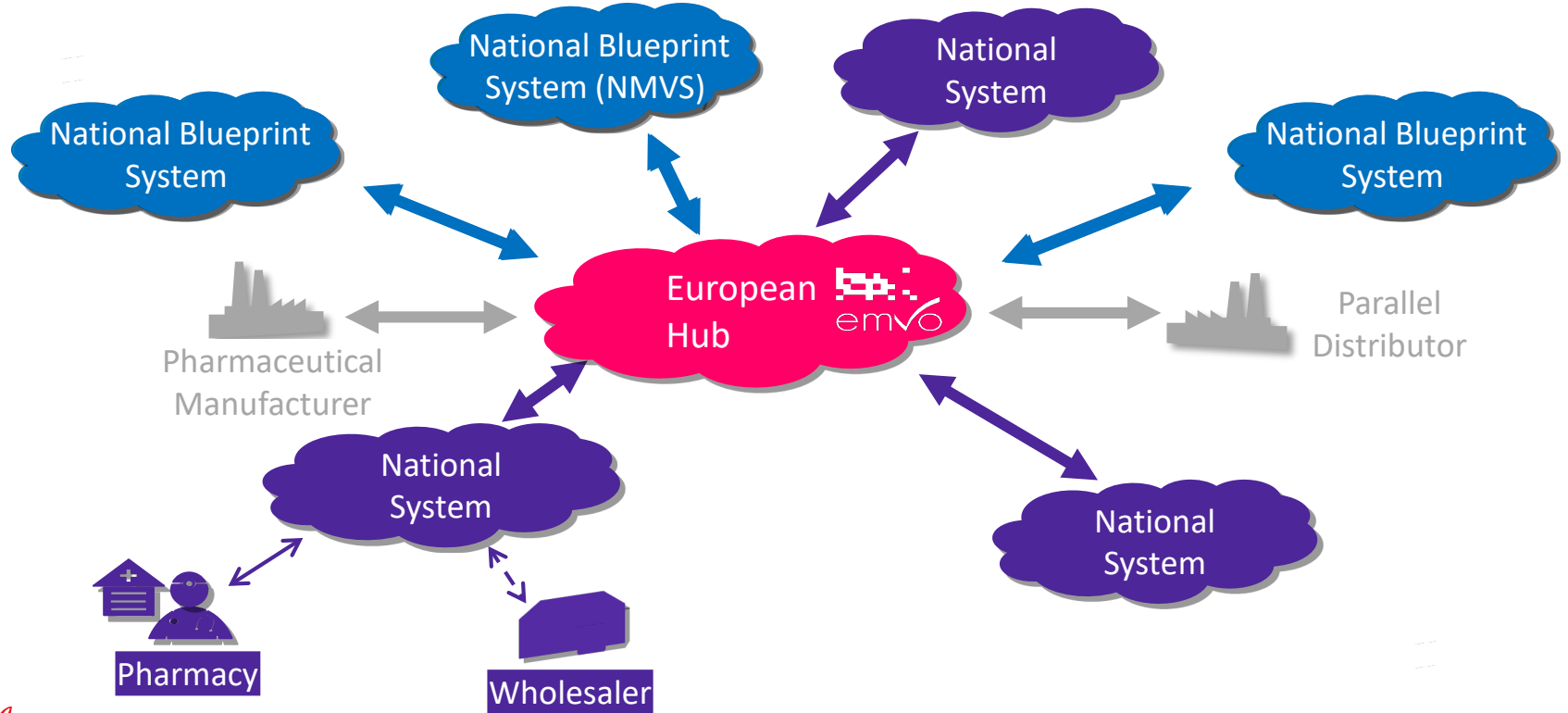# Point of Dispense Verification

All parties verify against one central system

European Repositories Systems
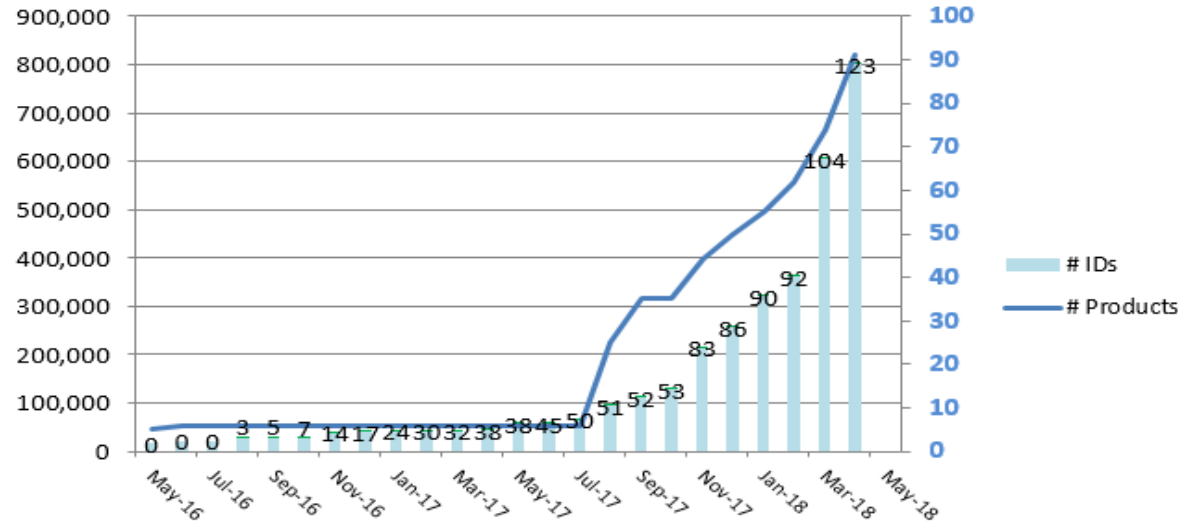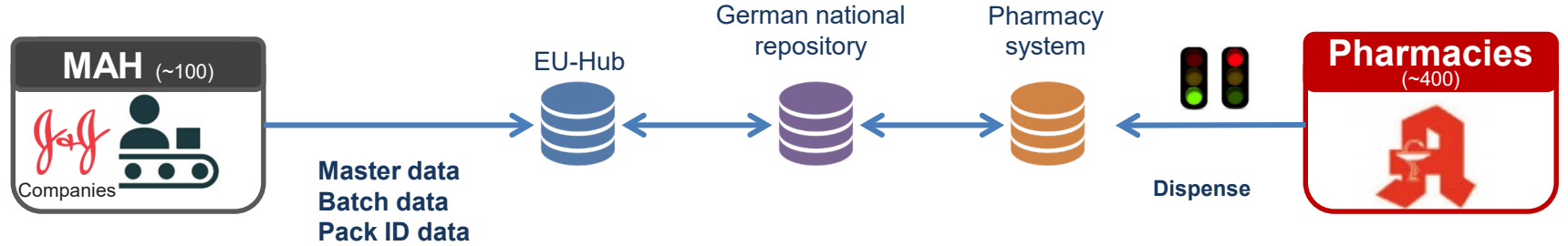
Enable systematical point of dispense verification

Piloting the German National System

Proven technology … knowledge gained by executing
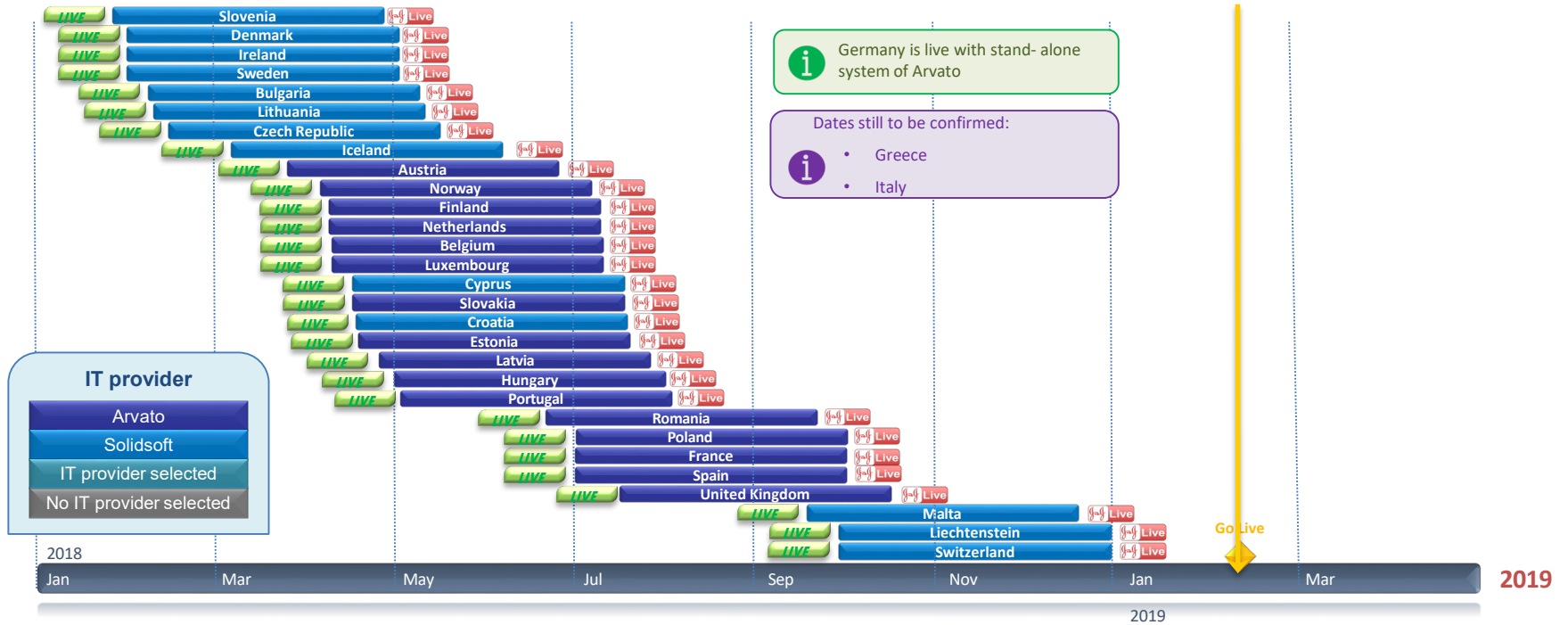

MAH (~100)

J&J Companies

Master data
Batch data
Pack ID data

EU-Hub

German national repository

Pharmacy system

Dispense

Pharmacies (~400)

End-April 2018

- 800K+ packs
- ~400 batches
- ~100 SKUs / products
- 123 dispenses

Phased Roll Out Across 30 Countries

Supported by realistic time plans, monitored centrally

Germany is live with stand-alone system of Arvato

Dates still to be confirmed:
- Greece
- Italy

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

Slovenia
Denmark
Ireland
Sweden
Bulgaria
Lithuania
Czech Republic
Iceland
Austria
Norway
Finland
Netherlands
Belgium
Luxembourg
Cyprus
Slovakia
Croatia
Estonia
Latvia
Hungary
Portugal
Romania
Poland
France
Spain
United Kingdom
Malta
Liechtenstein
Switzerland

Go Live

2018
Jan | Mar | May | Jul | Sep | Nov | Jan | Mar | **2019**

2019

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
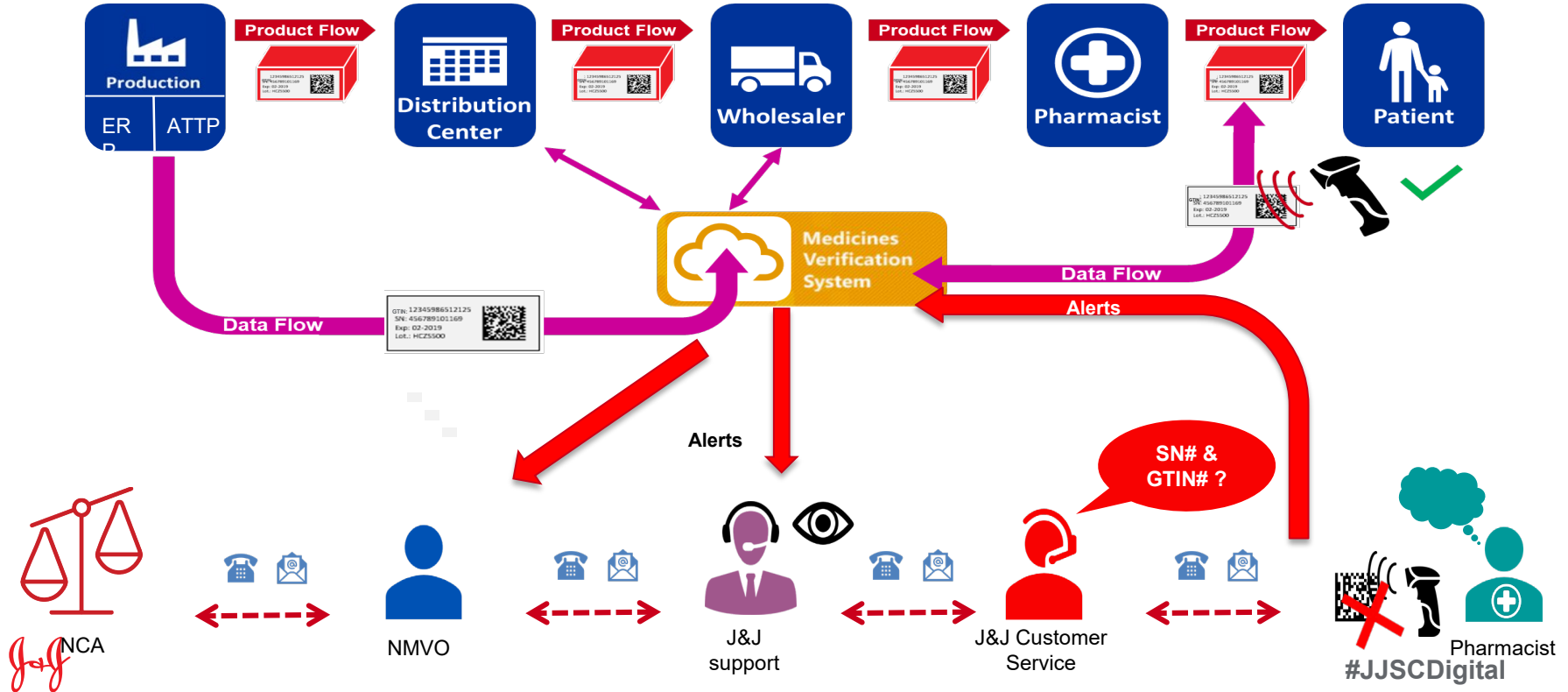- Distributor

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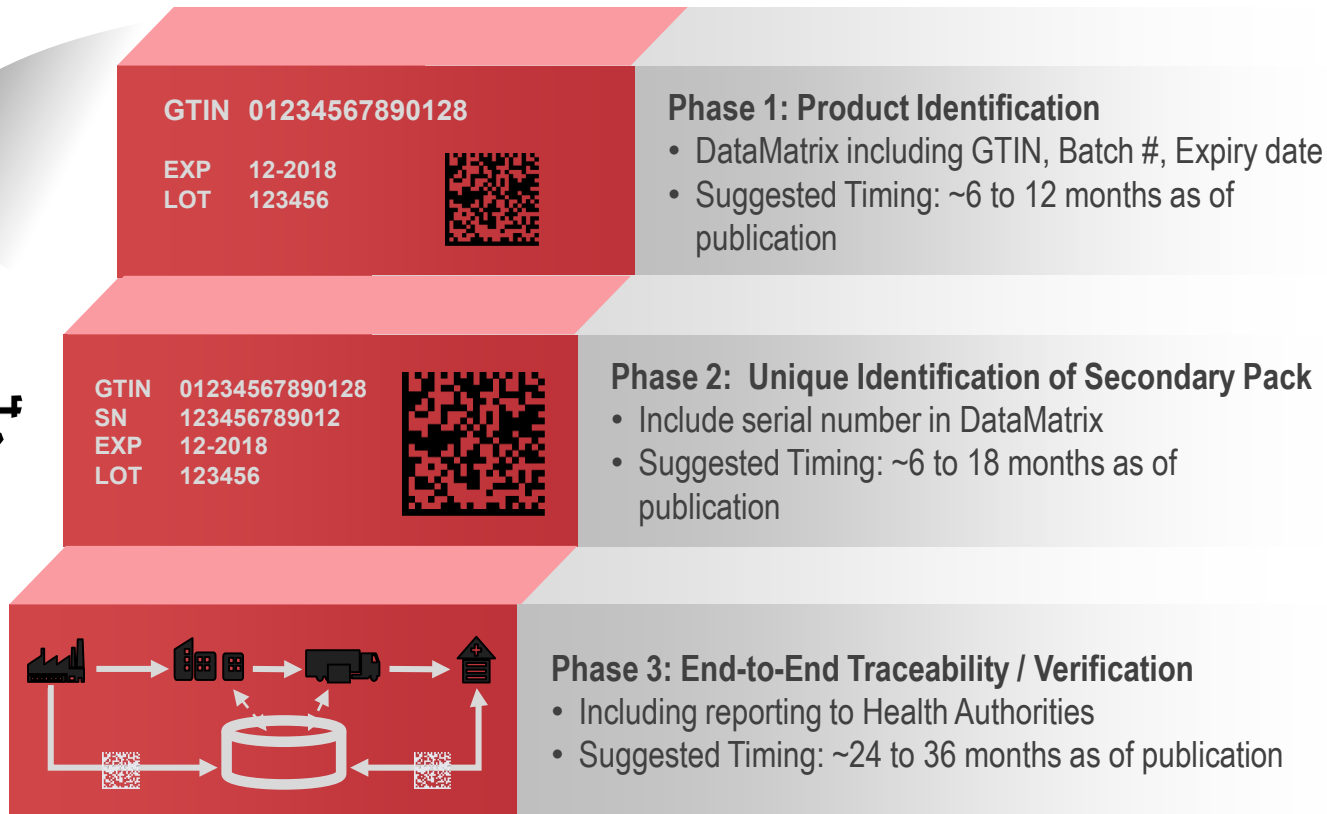- Alignment to industry standards

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

GTIN 01234567890128

EXP 12-2018
LOT 123456

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

GTIN 01234567890128
SN 123456789012
EXP 12-2018
LOT 123456

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

Sharing Product Data

Thank you.

Questions

- **Gregory Goger**, Abbvie

- **Dirk Van den Wouwer**, Johnson & Johnson

Thanks to our co-host & conference partners

Thanks to our sponsor

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#GS1HCLagos

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

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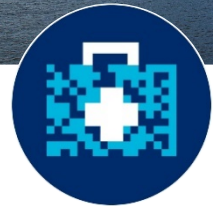
Need any help? Contact us!

Look for the turquoise scarves and ties - we are happy to help you!

COFFEE BREAK

Afternoon at a glance

Tuesday 17 September 2019		
13:00-14:30	General Networking lunch & visit of marketplace	
14:30-15:45	Two parallel streams	
	Stream I - Government and regulatory body Think Tank- Learning from other countries and regions	Stream II - Establishing Traceability: the building blocks
15:45-16:15	Coffee break	
16:15-17:30	Two parallel streams	
	Stream I - Government and regulatory body Think Tank- Learning from other countries and regions	Stream II - Databases and infrastructure for traceability

Afternoon at a glance

Wednesday 18 September 2019		
13:10-14:15	General Networking lunch & visit of marketplace	
14:15-15:45	Two parallel streams	
	Stream I – Government and regulatory body Think Tank – Discussing the possibility of regulatory alignment across Africa	Stream II – Traceability – global status – developments worldwide
15:45-16:15	Coffee break	
16:15-17:45	Two parallel streams	
	Stream I – Government and regulatory body Think Tank – Discussing the possibility of regulatory alignment across Africa	Stream II – Data as the base for supply chain

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