



Establishing Traceability: the building blocks

Tuesday 17. September 2019, Africa GS1 Healthcare conference, Lagos, Nigeria

Regulatory Roadmap:
Traceability of Medicinal Products

October 2018





Speakers

- Pascal Aulagnet, Market Customer Engagement EMEA, Pfizer, France
- Françoise Hirth, Serialisation Coordinator for Europe and EEMEA, F. Hoffmann-La Roche, Switzerland
- Dirk Van den Wouwer, Sr. Mgr. EMEA Deployment Digital Identification and Traceability, Johnson & Johnson Supply Chain, Belgium



Françoise Hirth

Project Leader
Single Unit Coding

F. Hoffmann-La Roche

I have been working in Supply Chain for several years. During the last 5 years, I have been Serialization Coordinator for Europe and EEMEA, heavily involved in the FMD implementation. I am now Project Leader to implement Single Unit Coding on our strategic products.

I am representing Roche at EFPIA, in the supply chain working group.

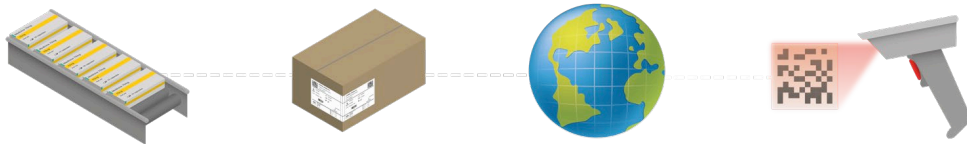


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Establishing Traceability



Definition of Traceability

- ✓ Traceability is the ability to identify and trace the history, distribution, location, and use of products. A traceability system records and follows the trail as products come from suppliers and are processed and ultimately distributed/dispensed as final products.
- ✓ Fundamental to traceability: In parallel with the flow of product, there has to be a flow of information about the product
- ✓ Throughout the entire supply chain:
 - ✓ There is Internal and External Traceability
 - ✓ Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
 - ✓ Stakeholders can have varying roles

What do we need for Traceability?



Serial Number



GTIN 07640128258120
S/N 04320054262891
EXP 01 2014
L01 U2004U01



GTIN + S/N + required variable data

Authentication / Unique identification

SSCC*



(00) 076133261002042681

SSCC *



(00) 37612345000007893

SSCC *

Traceability through Aggregation



Warehouse

Application of SSCC-pallet-labels at control point before goods issue

1. scanning label of shipping box
2. automatic assignment of SSCC-pallet-number
3. printing of SSCC-pallet-labels
4. Applying of pallet labels

Scanner



* Serial Shipping Container Code

EPCIS (Electronic Product Code Information Services)



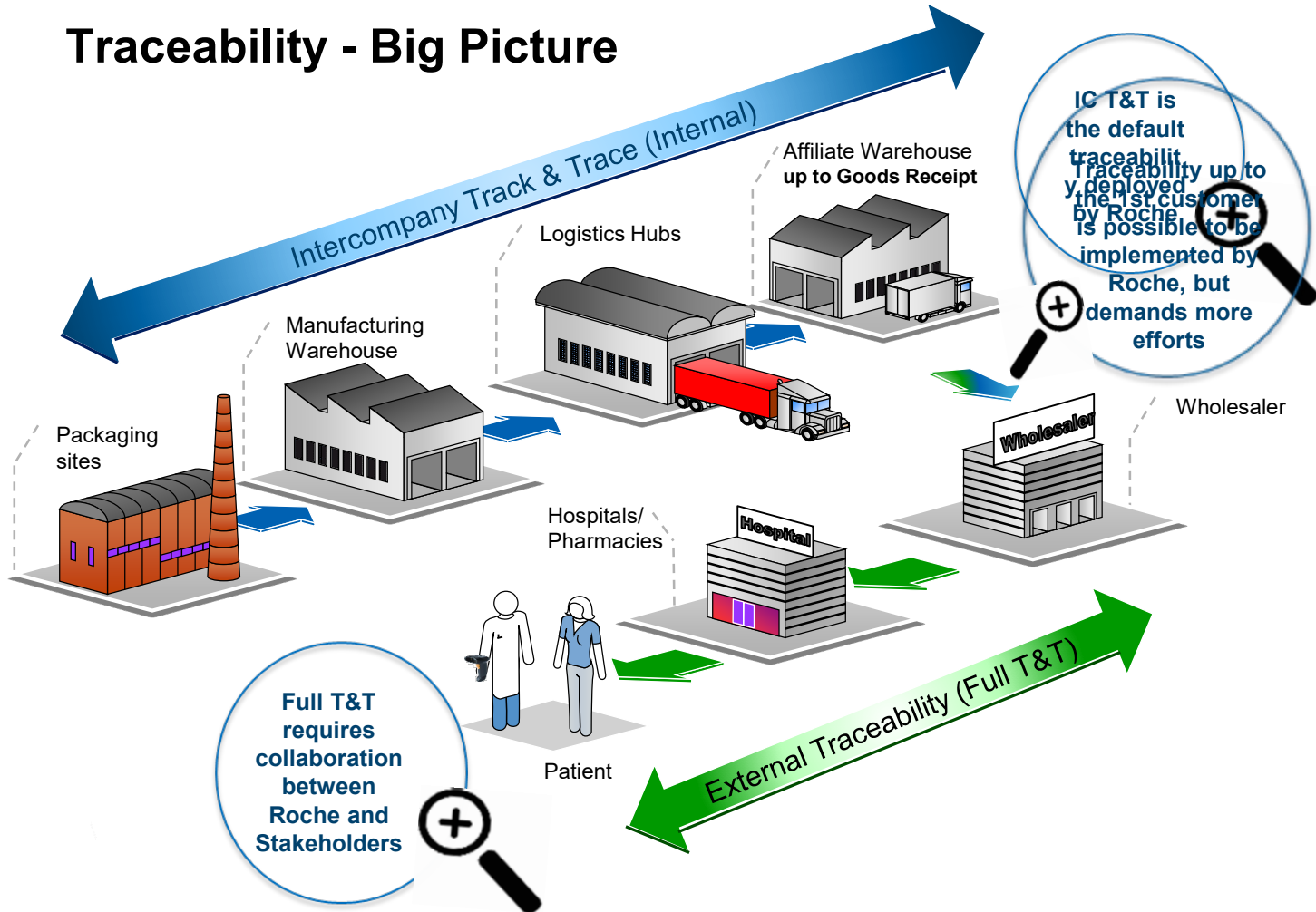
- WHAT** objects are the subject of event? *Individual objects (SGTIN)*

- WHEN** did this event take place? *Date, time*

- WHERE** did this event take place?
location *GLN(Global Location Number) of physical*

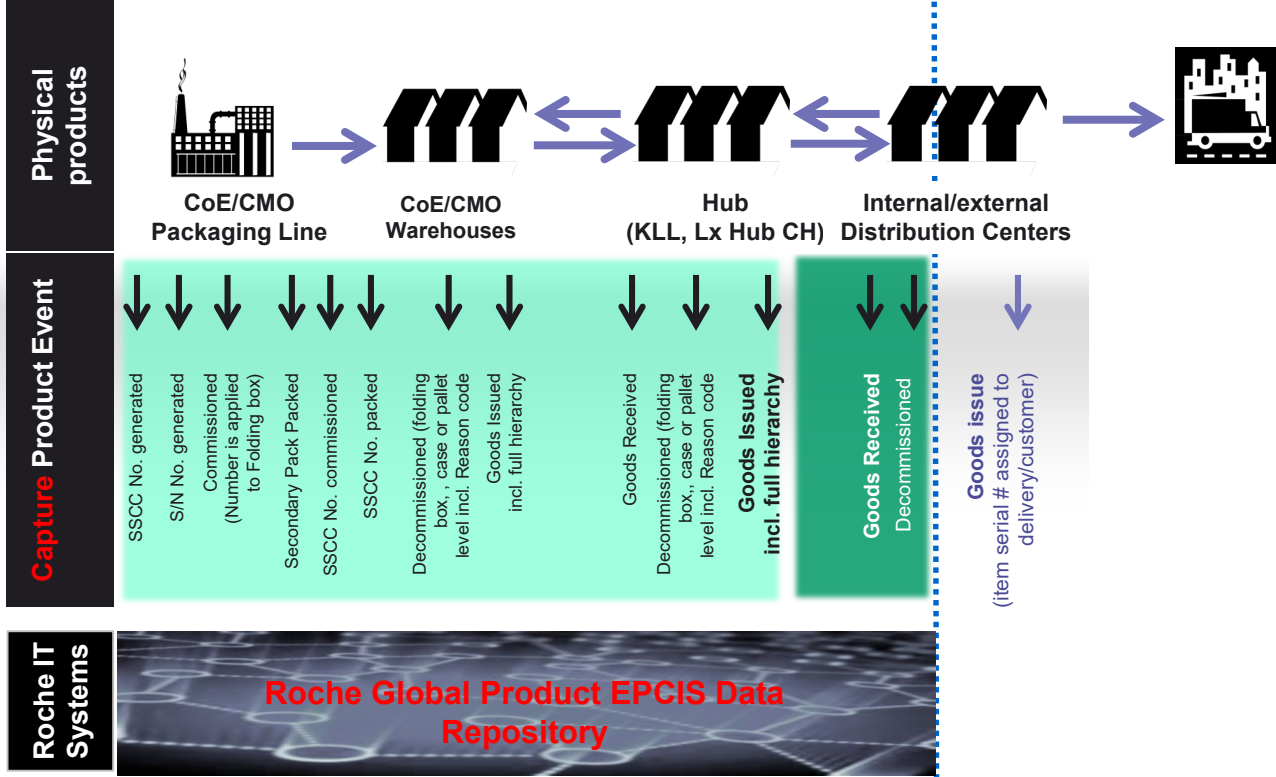
- WHY** did this event take place?
Receiving *Business step; Commissioning, Shipping,*

Traceability - Big Picture



Internal traceability

External traceability



Benefits of our internal Traceability program

- Readiness to share EPCIS data with Roche direct customers who would require traceability
- Engagement with our local partners to improve supply chain and product safety
- Be ready for future regulations

*Doing now what patients need
next*



Dirk Van den Wouwer

Sr. Mgr. EMEA Deployment, Digital
Identification & Traceability
Johnson & Johnson

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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Establishing Serialization & End-to-End Traceability Using GS1 Standards

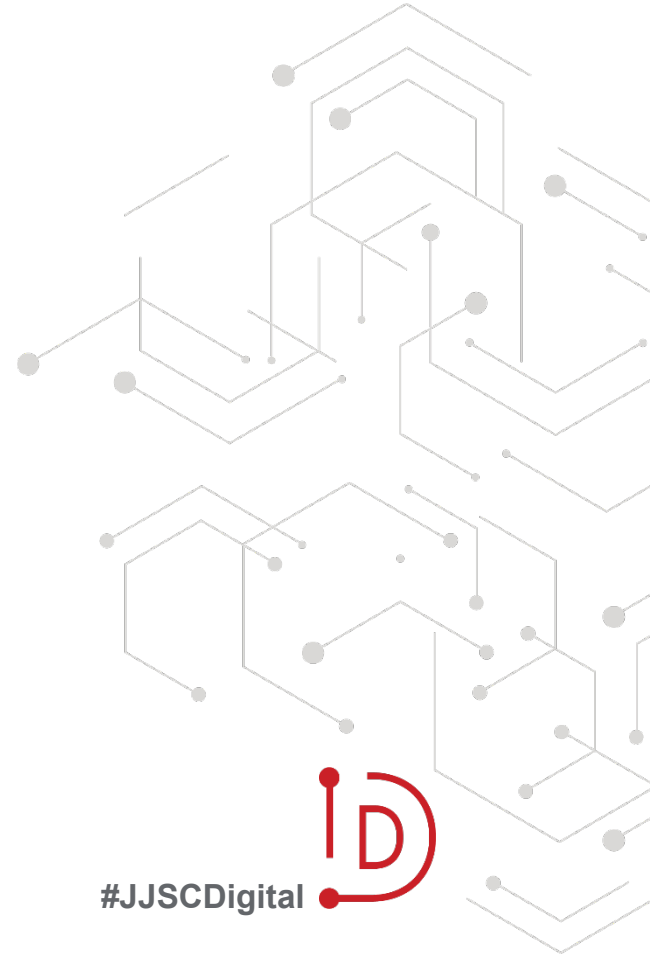
A global company perspective

Dirk Van den Wouwer
EMEA Deployment, Digital Identification & Traceability

GS1 Healthcare Conference, Lagos, Nigeria
September 2019

Johnson & Johnson

#JJSCDigital 



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



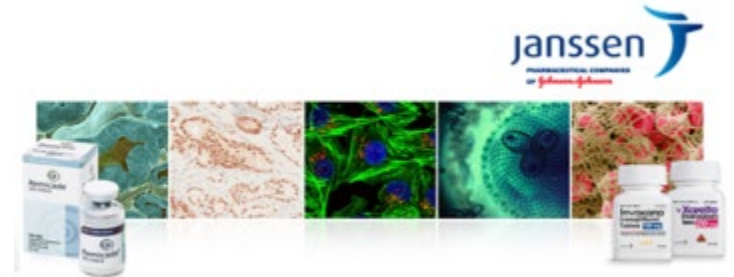
Medical Devices

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



Benefits of Serialization

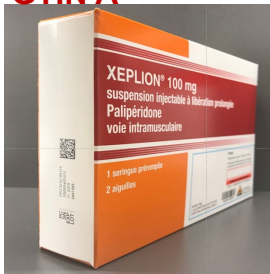
- Enables patient safety
- Allows for continued product access
- Creates end-to-end transparency
- Reduces threat of counterfeiting, theft, diversion
- Allows better control of import and reimbursement
- Minimizes errors
- Improves logistics efficiency and order accuracy



Using GS1 Stds to Uniquely Identify & Trace Products

Each product in the supply chain is assigned a globally unique identification number

GTIN A



GTIN B / SSCC



SSCC



Item into Case

Case into Pallet

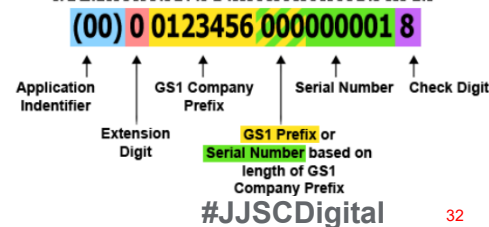
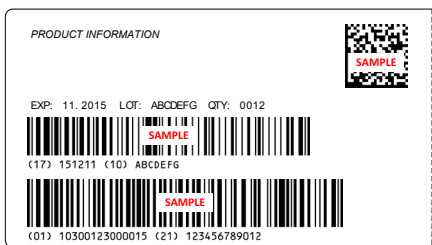
12 serialized boxes in a case

261 cases to a pallet

Complete Traded Unit

Incomplete Mixed or Non Traded Unit

| | |
|------|----------------|
| GTIN | 00359676562016 |
| S/N | 123456789012 |
| EXP | 12-2015 |
| LOT | 123456 |



The **DataMatrix** shall contain the following information:

- (01) GTIN*: 14 characters, numeric
- (21) S/N: 12 characters, numeric, randomized
- (17) EXP*: 6 characters, numeric
- (10) LOT: max. 20 characters, alphanumeric

J.J.

Regulations Deployed Globally

Protect patient safety and product integrity

DataMatrix

GTIN with Lot Number
and Expiry Date



Serialization

Item level serialization using
GS1 standards



Track & Trace

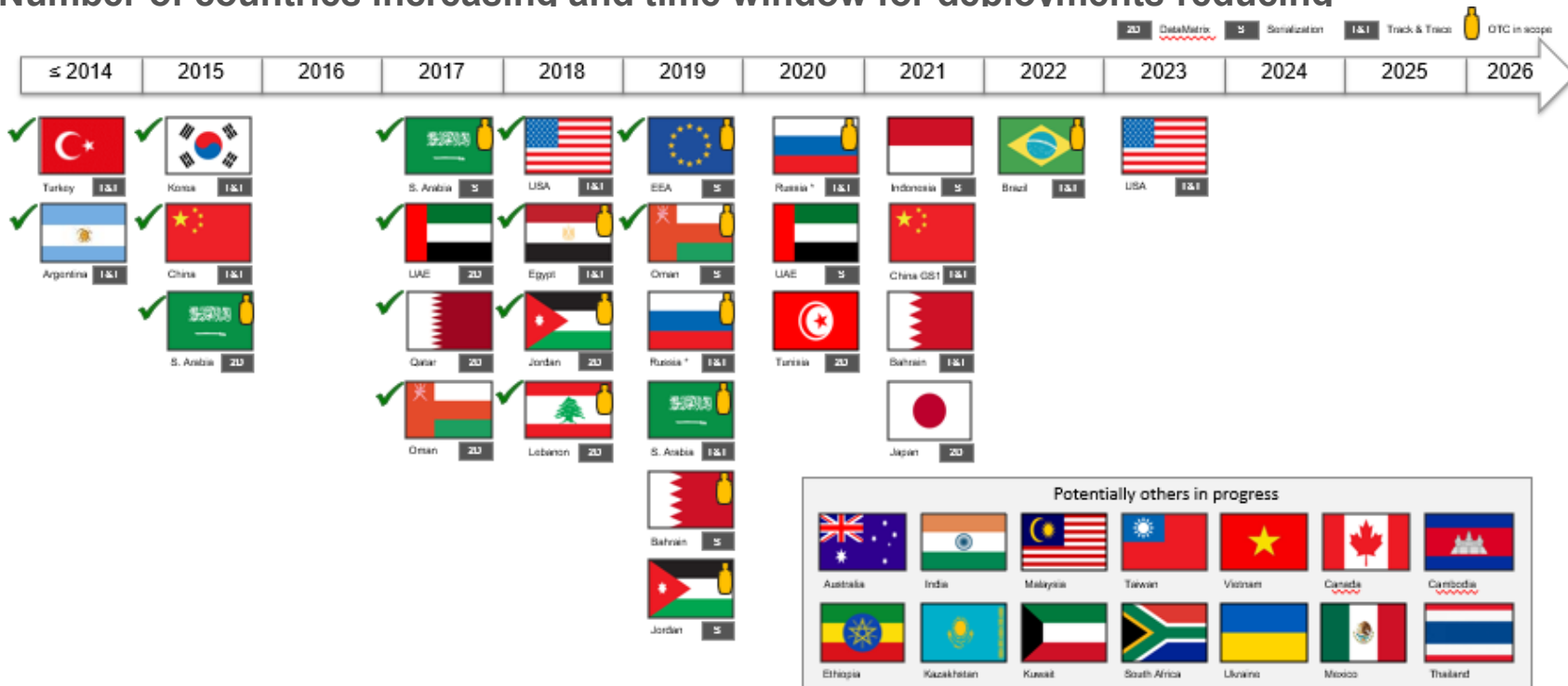
Traceability through aggregation
& reporting



* Some regulations require anti-tampering solutions as part of the regulations

50+ Countries Legislated

Number of countries increasing and time window for deployments reducing



*Russia: Pharma 12 Nosologies in October 2019, remaining SKUs in 2020



Key Deliverables in Getting Started

Getting started for the implementation

Initial Communication

Assess Legislation ● Identify Project Leads ● Assess Need for Pilot

Landscape

Draft SKU List & Volumes ● Assess Site & Packaging Line Impact ● Map Distribution Flow

License Plate

Propose License Plate and Shipper/ Pallet Label

End-to-End Process Mapping

Complete Initial High Level Use Cases and Types of Reporting

Kick Off Preparation and Presentation

Draft Project Brief ● Define Project Case ●
Assess Project Team Recourses ● Draft Project Plan

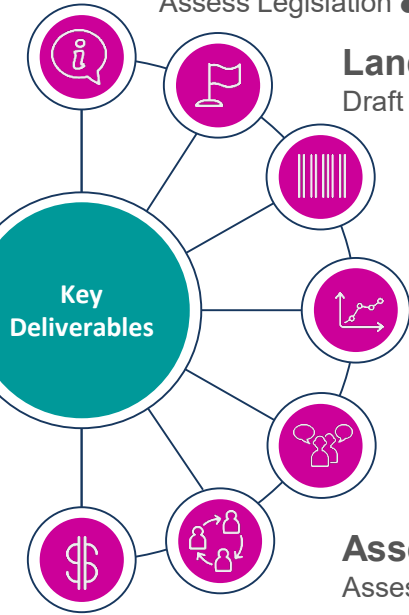
Assessments

Assess Process / Impact / Systems ● Finalize Cost Estimates ● Refine Project Plan

Obtain Capital Resources

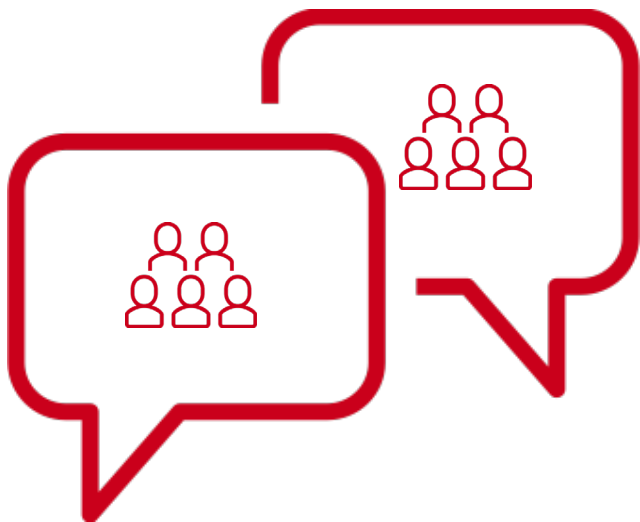
Complete Package & Obtain Funding

Health Authorities



Drive Appropriate Communications and Engagement

Streamlined audiences, messages and lots of communication!



Define the right teams

Steering Co., Core team...

Redo communications

Granularity, frequency...

Drive understanding

Feel engaged by choice

Change Assessment Survey

Well in adoption phase

Industry Workgroups

Streamline Regulations

Stakeholder Engagement

Set-up expert groups that pilot each phase

Trade Organizations
Industry Organizations
Hospitals
GSI Wholesalers
Pharmacies
Health Care Authorities
Distributors

Thank you.



#JJSCDigital

Questions



- Pascal Aulagnet, Pfizer
- Françoise Hirth, F. Hoffmann-La Roche
- Dirk Van den Wouwer, Johnson & Johnson

Thanks to our co-host & conference partners



Thanks to our sponsor



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<https://healthcare-nigeria.gs1.org/>

Need any help? Contact us!

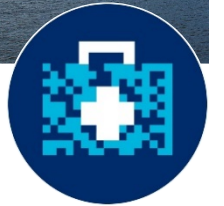


Look for the turquoise scarves and ties - we are happy to help you!





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

