



The Global Language of Business

# Introduction to GS1 standards

37<sup>th</sup> Global GS1 Healthcare Conference, Paris

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Craig Alan Repec, Pete Alvarez

GS1 Global Office

15 November 2022

# GS1 Competition Law Caution



- GS1 operates under the GS1 Competition Law Caution. Strict compliance with competition laws is and always has been the policy of GS1.
- The best way to avoid problems is to remember that the purpose of the group is to enhance the ability of all industry members to compete more efficiently.
- This means:
  - **There shall be no discussion of prices, allocation of customers, or products, boycotts, refusals to deal, or market share.**
  - If any participant believes the group is drifting toward impermissible discussion, the topic shall be tabled until the opinion of counsel can be obtained.
- The full caution is available via the link below, if you would like to read it in its entirety: <http://www.gs1.org/gs1-competition-law-caution>

# Today's presenters



## In English



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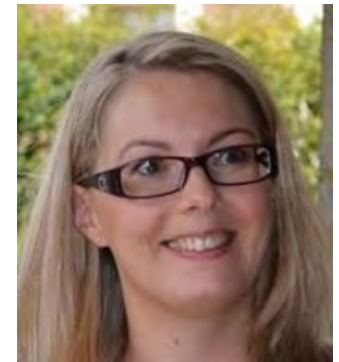


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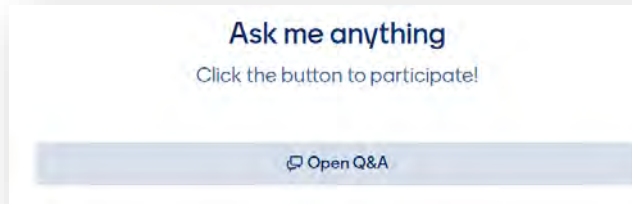
# Leave questions here for follow up after the event



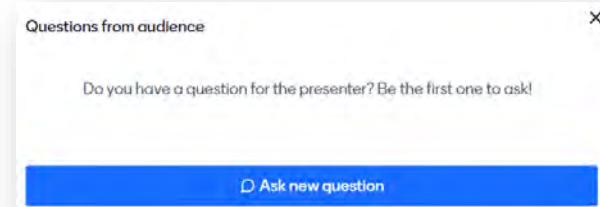
1. Go to [menti.com](https://menti.com) and enter **7678 3636** and tap on Submit



2. Tap on Open Q&A



Then



3. Enter your question

An illustration of a hand holding a fountain pen over a spiral notebook. The notebook is open to a page titled 'Agenda' with a list of five items. The background is a light blue desk with a coffee cup, a keyboard, and a potted plant.

# Agenda

- Product, Location and Logistics identification and barcodes
- Clinical Trials
- GS1 Digital Link in healthcare
- Data sharing and GDSN
- EPCIS





# Identification & Barcoding

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Products  
Logistics and  
Locations

# Safer, more efficient care starts with a simple scan



GS1 Healthcare ONE product ONE barcode, to avoid confusion and risk



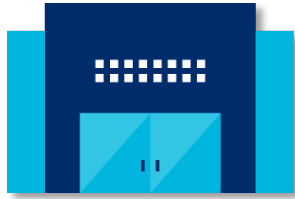
**One** of these options:  
EAN/UPC,  
GS1-128 or  
GS1 DataMatrix



Not this!



# The Basics: Trade Item identification rules



**The manufacturer / brand owner allocates the GTIN**




**One trade item, one GTIN**



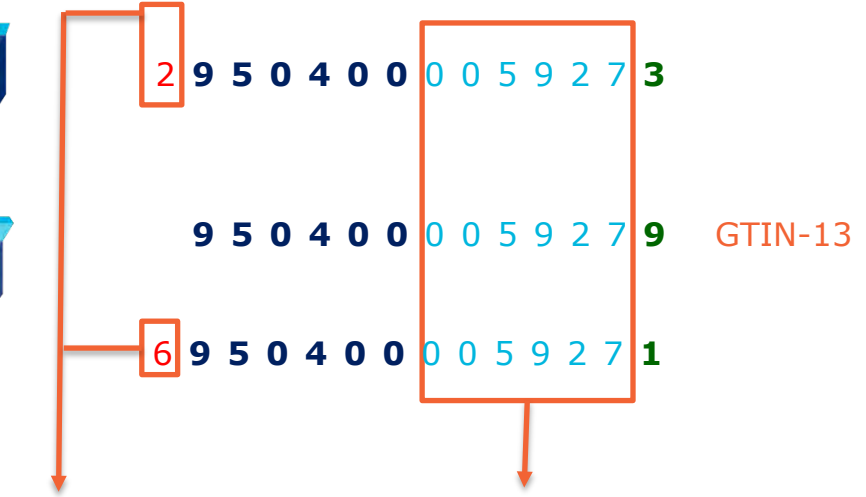
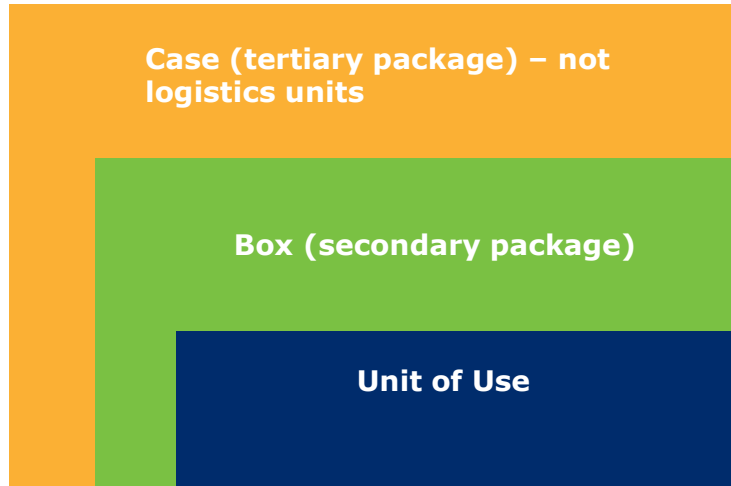
**A GTIN for every different variant of a trade item**



  
(01) 0 9524000 05926 0  
(17) 250425  
(10) ABC123  
(21) abcd1234

**Re-use of a GTIN is not permitted**

# GTIN-13 and GTIN-14: A common example



- Same GCP & Item references in a GTIN-13 and 14
- GTIN-14 uses different Indicator digits to create uniqueness. Not for point-of-sale scanning.

# Identification and the trade item hierarchy



## Pharmaceuticals



## Medical Devices

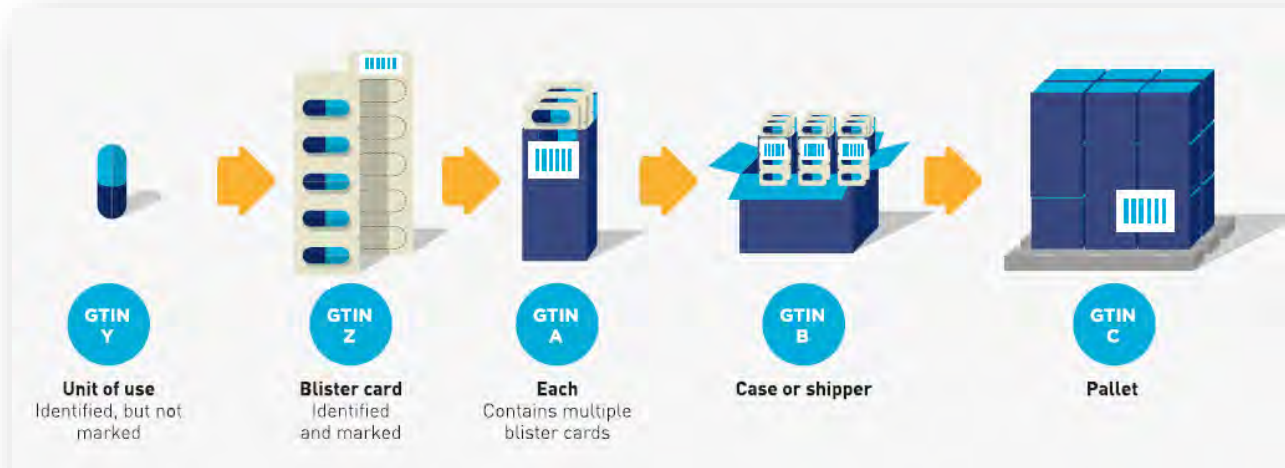


- The common practice is to assign a GTIN to the lowest level traded item (each) and higher.
- However, manufacturers are encouraged (may be required in some markets) to assign GTIN(s) to the “level(s) below the each” to facilitate unit of use scanning at the point of care.

# Pharma unique trade item identification



In this example the **blister card is identified and marked with a single GTIN**. The unit of use is identified with a GTIN but is not marked. The marking is at the discretion of the brand owner



# Pharma unique trade item identification



In this example **each blister cell is identified and marked**.  
The blister card is not identified or marked.  
The marking is at the discretion of the brand owner.



# Medical Device unique trade item identification



- Each level of the hierarchy is identified with a unique GTIN
- The unit of use can also be identified with a unique GTIN (depending on regulatory or trading partner requirements). It may or may not be marked.



# GS1 data carriers



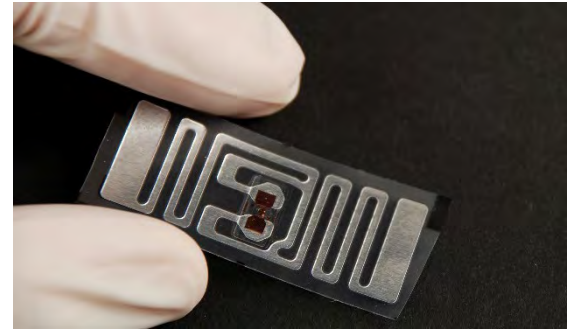
## GS1 DataMatrix



## GS1-128



## RAIN RFID



**All data carriers can contain the same kind of information. The decision for the data carrier to use depends on the sector, scanning environment and the capabilities of the actor in the supply chain.**

# GS1 Barcodes for healthcare products



EAN/UPC



GS1  
DataMatrix



(01)19506000117843  
(17)141120  
(10)NYFUL01  
(21)192837

- Each product should have one barcode only
- The data elements you need to encode, and/or the applicable regulation, can determine which barcode to use

GS1-128



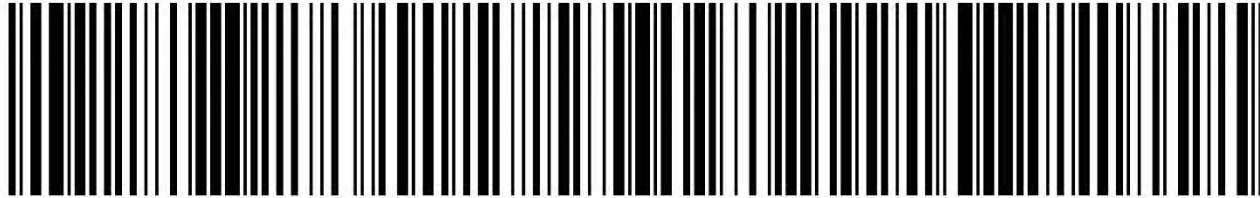
(01)19506000117843(17)141120(10)NYFUL01(21)192837



# A need to capture the GTIN & more



## GS1-128 Barcode



(01)19506000117843(17)141120(10)NYFUL01(21)192837



**GTIN-14**

(01)19506000117843

(17)141120

(10)NYFUL01

(21)192837

**Expiry Date**

**Batch Number**

**Serial Number**

A GS1 Application Identifier (AI) is an element string that carries dynamic or “production identification” data that in conjunction with the GTIN provide more granular information about the items identified at the point of scanning.

## GS1 DataMatrix Barcode





# A new standard for investigational products (clinical trials)



# Investigational Products (clinical trials) identification



## Example of a product with a GS1 DataMatrix barcode

(01) 0 9501101 53000 3 - Global Trade Item Number  
(10) AB-123 - Batch Number  
(21) 000124pc123 - Serial Number  
(7240) PR0044 - Protocol Number



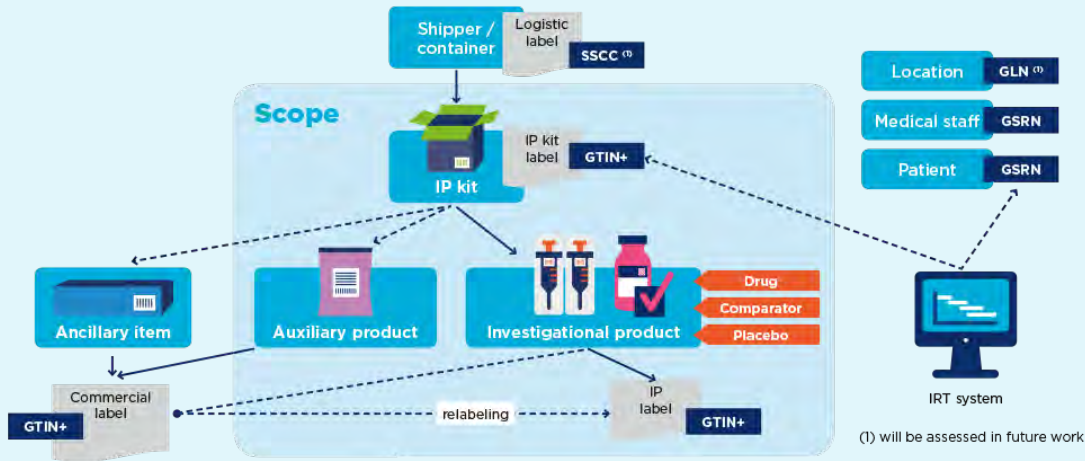
[Link to the GS1 Clinical Trials standard](#)

# Scope of work



This application standard focuses primarily on the **identification and barcoding of investigational products** from the time of kit assembly to use and, if necessary, destruction.

Investigational products include **active products, comparators** and **placebos**. Where identification of items outside of this scope, locations, patients or caregivers is required, reference is made to relevant existing GS1 standards.




[Link to the GS1 Clinical Trials standard](#)

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**How do I identify my  
logistics packages &  
containers?**

**The Serial Shipping  
Container Code (SSCC)**



# Logistics label example



<b>FJP CARRIERS</b>	
<b>FROM</b>	GS1 Avenue Louise 326 1050 BE BRUXELLES BE - Belgique GLN: 9501101100015
	+32 123456789
<b>TO</b>	Hr. F. van den Bos Kerkstraat 319 1500 KM Wormerveer NL - Nederland
SSCC 3 9501101 001300012 9 ROUTE 123+1021JK+0320+12 SHIP TO POST - 5281500KM	
 (00) 3 9501101 001300012 9	



# Serial Shipping Container Code (SSCC)



SSCC Application Identifier (00)

- The SSCC serves a license plate for the logistics unit.
- It exists from the time the logistics unit is created until it is received and unpacked.



# Who allocates the SSCC?

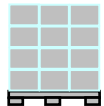
The **physical builder or brand owner of the logistic unit** is responsible for the allocation of the SSCC :

- Manufacturer
- Wholesaler / Distributor
- Third party logistic provider





# SSCC and shipment notification (i.e. EDI message)



SSCC	GTIN of content	Number of items	Batch number	Expiry date	Sent to
089123450000000022	18961234560007	40 boxes	AB12	05/07/17	Pharmacy ABC
089123450000000015	18961234560014	25 boxes	AC12	10/11/17	Retailer ONE
	18961234560021	15 boxes	BE11	15/11/17	
089123450000000022	18961234560038	10 boxes	CD55	25/03/17	Hospital HC9
	18961234560038	30 boxes	CD56	25/03/18	

# How do I manage locations?

The **Global Location Number (GLN)**

A stylized, colorful map of a city street grid. A blue river flows through the city. Several red location pins are placed on the map, and one blue location pin is also visible. The map is rendered in a clean, illustrative style with flat colors and simple lines.

# Global Location Number (GLN)



The **Global Location Number** is designed to improve the efficiency of communication with trading partners and add value to the trading partners involved, as well as to consumers.



## Legal entity

Any business, government body, department, charity, individual or institution that has standing in the eyes of the law and can enter into agreements or contracts.



## Physical location

A site (an area, a structure or group of structures) or an area within the site where something was, is, or will be located.



## Digital location

- A digital location represents an electronic (non-physical) address for communication between computer systems.



## Function

An organisational subdivision or department based on the specific tasks being performed, as defined by the organisation.



# Who creates and communicates the GLN?



## Who creates and allocates the GLN?

- GLNs are created and allocated using the GS1 Company Prefix (GCP) license assigned to the company wishing to identify locations, etc., they are allocated sequentially.

## Who communicates the GLNs?

- It is the responsibility of the company assigning GLNs to keep business partners informed of all numbers issued and their associated information.
- The mechanism for sharing the GLN varies by country and sector

950400 005926 2

950400 005927 9

950400 005928 6

# GS1 Digital Link



# Unlocking digital content with a single scan



## PHYSICAL



## DIGITAL



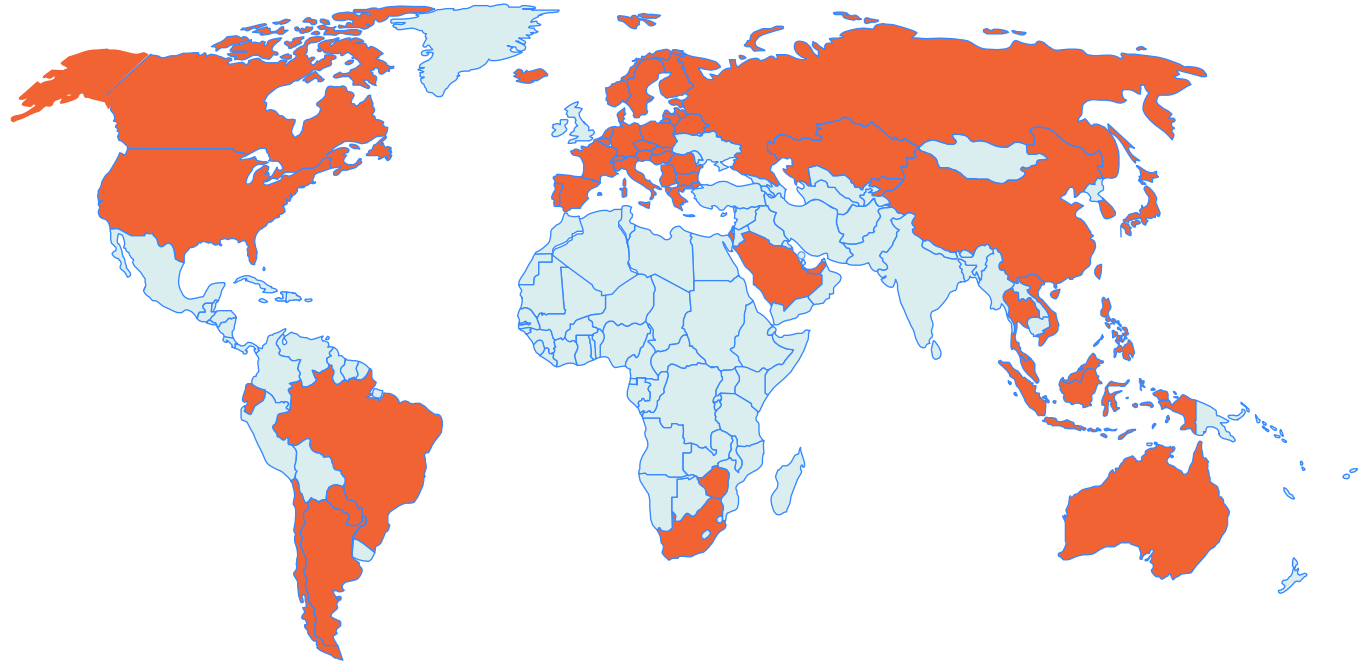
Connecting the physical product to its digital self,  
without a URL/URI in the barcode

# Electronic leaflet activity across the world



There are discussions in many countries about a transition from paper to electronic leaflets.

GS1 standards enable the access.



■ = country developing requirement or discussing ePIL and eIFU

# Safer, more efficient care starts with a simple scan



GS1 Healthcare ONE product ONE barcode, to avoid confusion and risk



**One** of these options:  
EAN/UPC,  
GS1-128 or  
GS1 DataMatrix



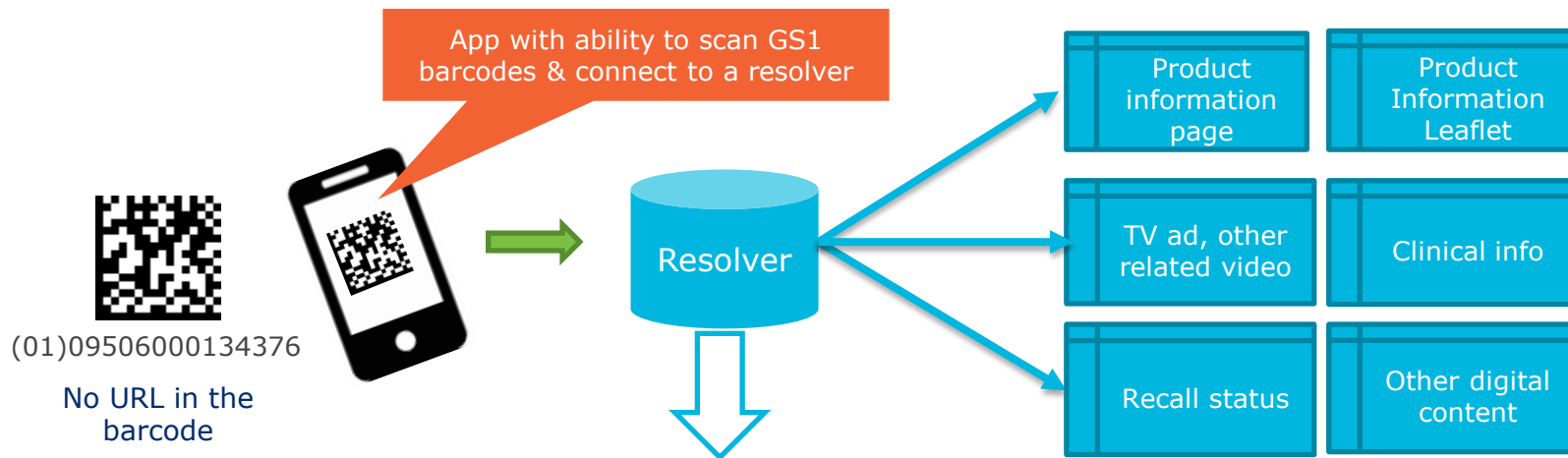
Not this!



# Solution illustration



## GS1 Digital Link standard with the existing GS1 barcode on the pack



Link Type	Lang	Target URL
Leaflet	French	https://...example...
Leaflet	English	https://...example...
Video	French	https://...example...
Clinical Information	French	https://...example...

# Case study: Pharmaceutical and Medical Devices Agency of Japan



Link to e-labeling on the PMDA database by scanning GS1 barcodes of secondary packages (sales packages) (Enforcement: 2021 August)



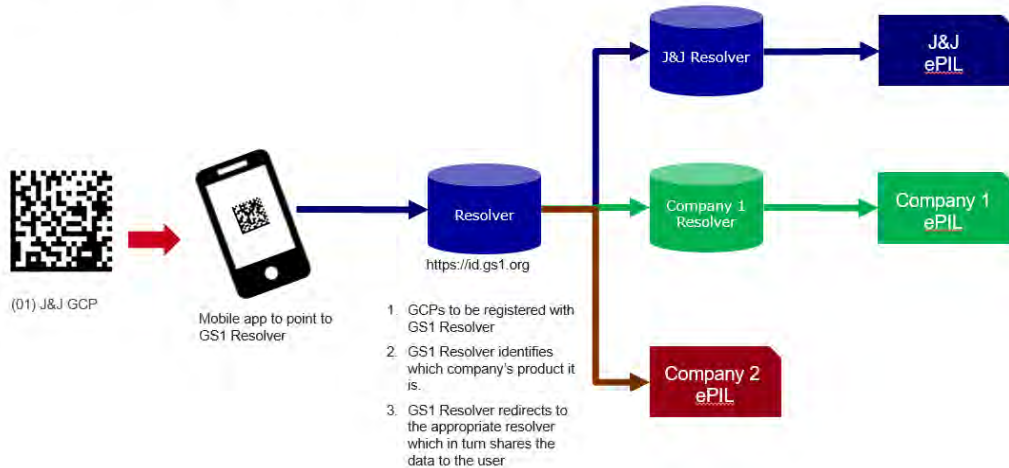
- A national solution using the GS1 Digital Link standard.
- All leaflets located in one location.
- Utilises the existing GS1 barcode.
- No need to add a second barcode just for leaflets.
- A single barcode minimised confusion at the point of care.

Source: Masayuki Muraoka, Deputy Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau. GS1 Healthcare Online Summit, November 2021

# Case study: J&J approach with an open invitation the entire industry



## Integrating with GS1 Resolver



*This implementation by J&J is currently in place in Singapore. In some jurisdictions, implementers of GS1 Digital Link Standard may need to licence Intellectual Property (IP). Please check the IP section of the GS1 Digital Link Standard for more information (<https://www.gs1.org/standards/gs1-digital-link>) as well as the relevant Implementation Guidelines.*



- An eLeaflet solution for the Singapore pilot using the GS1 Digital Link standard, resolvers & the Scan Matrix (generic) app.
- Uses the existing GS1 barcode, no need for a 2<sup>nd</sup> barcode, minimises confusion at the point of care.
- Can work on any manufacturer's GS1 barcode.
- Open for any organisation to use it.

Download the app



# Sharing Quality Master Data

A photograph of two business women in an office setting. One woman is seated at a desk, looking intently at a laptop screen. The other woman stands behind her, leaning over and pointing at the screen, appearing to be explaining or discussing something. The background shows a large window with a view of a city skyline.

# Product master data

0 9 5 2 4 0 0 0 0 5 9 6 0

Brand name

Product description

Manufacturer Name

Functional Name

Manufacturer GLN

Shelf Life from Production

Hierarchy level

Dosage Form

Child Item

Country Of Origin

Total Quantity of Next Lower  
Level Trade Item



# The master data challenge



Every company has a database filled with master data about the products they make, sell, or buy.

But when **one company changes any bit of information** in their database or adds a new item, another database becomes outdated!

# Managing master data



Policies & procedures



Roles and Responsibility



Enterprise-wide data management



Data quality rules

*Data quality starts at the source, but is a shared responsibility with all actors in the supply chain including point of care*

*The quality of the data is reflection on the quality of the product*

# The Global Data Synchronisation Network



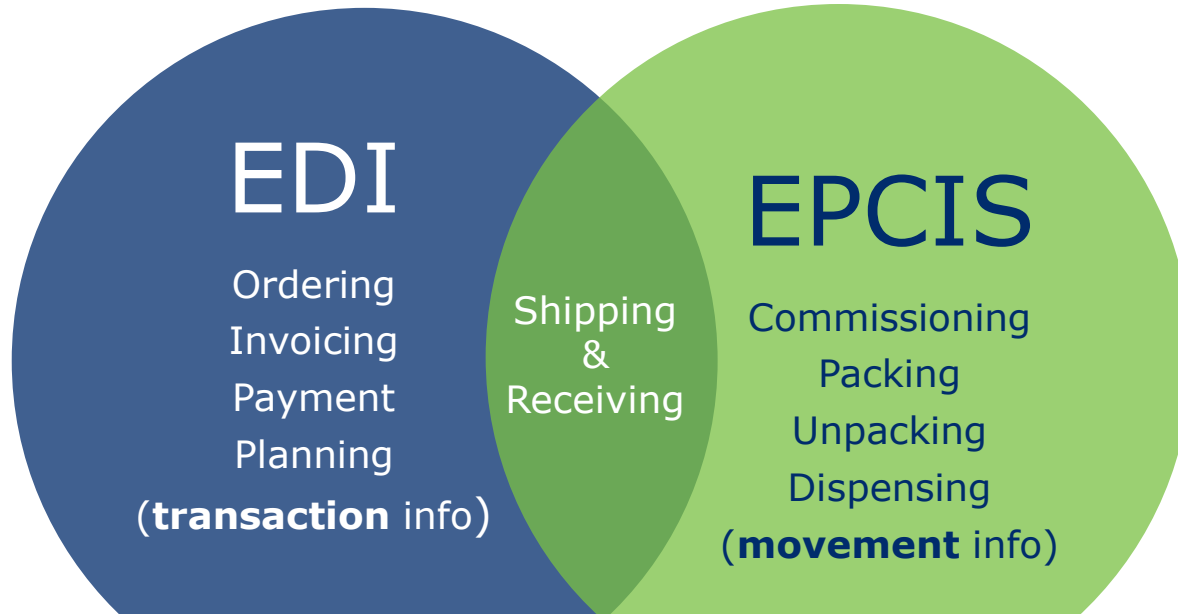


A globe of the Earth is shown, with a magnifying glass focusing on the Middle East region. The magnifying glass is positioned over the Arabian Peninsula and the surrounding waters. The text "Visibility Event Data" is overlaid in white, bold, sans-serif font across the center of the magnifying glass. Below it, the acronym "EPCIS" is also overlaid in the same style. The globe shows various geographical features, including the Red Sea, Persian Gulf, and parts of Africa and Asia. The magnifying glass has a black frame and a black handle.

**Visibility  
Event Data**

**EPCIS**

# Supply Chain Data Sharing & GS1 Standards








## Master Data

Product & location descriptive attributes

# EPCIS: a GS1 “Share” standard



- Enables data-carrier neutral sharing of supply chain visibility data
- Also published as ISO/IEC 19987
- Defines a framework data model, capture and query interfaces
- Business process steps are captured as “**events**”, which indicate:
  - **What** objects are the subject of event? 
  - **When** did this event take place? 
  - **Where** did the event occur, and where are the objects thereafter? 
  - **Why** did the event take place? 
  - **How** (*warm, humid, fast, radioactive, etc.*) are the objects? 
- **EPCIS 2.0**: New features to increase versatility, lower adoption hurdles

# Core Business Vocabulary (CBV)

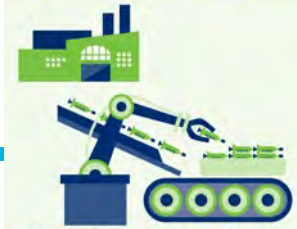


- Companion GS1 standard to EPCIS, also published as ISO/IEC 19988
- Ensures a common understanding of data semantics
- Specifies unique identifiers for “What” & “Where” of EPCIS events
  - CBV 1.2: specifies that GS1 keys shall be encoded as EPC URNs
  - CBV 2.0: constrained subset of **GS1 Digital Link URIs** as alternative
- Defines cross-sector code lists to populate EPCIS event data
  - CBV 1.2 defines URNs and definitions in a PDF document
  - **CBV 2.0** adds **Web URI** equivalents & browsable online definitions

# EPCIS enables supply chain visibility

- Tracking  
*What are the current whereabouts of products that were shipped?*
- Tracing  
*Which path did a shipment follow on its way to the recipient?*
- Chain of custody  
*Which parties had contact with these products along the way?*
- Inventory management & maintenance  
*How much inventory is available? Which of it expires soonest?  
When are technical components due for maintenance?*
- Recall  
*Where are all downstream instances of a specific production batch?*

## Product Traceability



e.g., “Where did a product come from and how was it made?”

## Inventory



e.g., “Is there enough of the product in stock?”

## Product Recall



e.g., “To which customer was a specific product shipped?”

# EPCIS enables tracking of **Aggregation** changes



- Parent-Child logistical hierarchy
  - Parent: one containing object
  - Children: one of more contained objects
- Captures **packing** and **unpacking** steps



- Keep track of logistic / packing hierarchies
- Enables the practice of **inference**

**Packing**

**Location Identification**  
GLN  
Global Location Number  
0614141000043

**Item & Case-Level Identification**  
DataMatrix  
(01) 04012345123456  
(21) AB1234  
(17) 201206  
(10) 20171009

**SSCC**  
Serial Shipping Container Code

**Event 2**

What	GTIN+Batch/Lot, SSCC
Where	GLN
When	2017-02-02, 09:30:14
Why	Packing

# US FDA Draft Guidance of July 2022

DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry



<https://www.fda.gov/media/90548/download>

## **VIII. WHAT STANDARDS SHOULD TRADING PARTNERS ADOPT FOR THE ENHANCED DRUG DISTRIBUTION SECURITY REQUIREMENTS?**

FDA recommends that trading partners use the Electronic Product Code Information Services (EPCIS) standard<sup>21</sup> to provide and maintain the data associated with transaction information and transaction statements. EPCIS is a global GS1 standard that allows trading partners to capture and share information about products as they are transacted through the supply chain. Use of EPCIS can support and enable electronic and interoperable interfaces used by trading partners to help ensure compliance with the DSCSA requirements and is compatible with a range of different technological approaches. FDA believes that EPCIS is an appropriate globally recognized standard, and FDA understands there is considerable agreement among stakeholders that EPCIS is a suitable standard to adopt for the enhanced drug distribution security requirements.

# UNICEF launch of Traceability and Verification System (TRVST) August 2022



<https://www.unicef.org/supply/stories/first-serialized-vaccine-scan-africa-marks-milestone-tackling-falsified-medical-products>

- Allows low- and middle-income countries (LMIC) to verify the authenticity of health products and track/trace them
- The GS1 standards for identification and traceability are used a foundation of TRVST (e.g., GTIN, GS1 DataMatrix, GDSN, **EPCIS**)
- Future mid/long-term developments will also leverage the use of **EPCIS for full track and trace** and of the **GS1 Digital Link** standard to enable access to online product information

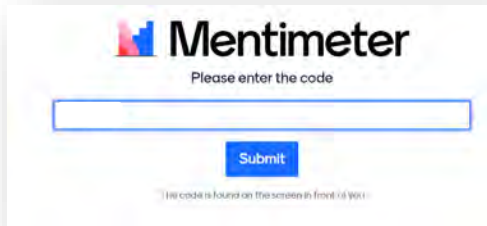


- **Sensor data** for monitoring the condition of products and assets
  - **Cold chains** and industrial IoT processes
  - Concentrations of chemicals and microorganisms, for **food safety**
- **Certification details** pertaining to products, organisations, locations
  - Details associated with reduction of carbon emissions or efficient use of natural resources, support for **circular economy & sustainability**
- **Linked, browsable online definitions** for all event data fields
- **JSON / JSON-LD** syntax
- **REST API** for capture and query of event data
- **GS1 Digital Link URI** syntax to express GS1 identifiers in event data

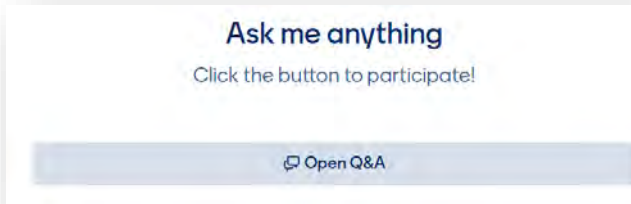
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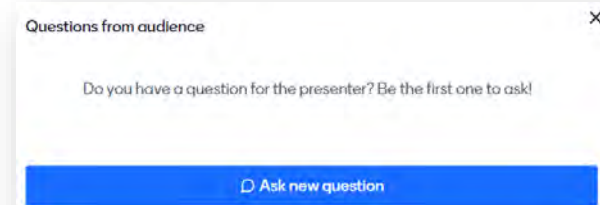
1. Go to [menti.com](https://menti.com) and enter **7678 3636** and tap on Submit



2. Tap on Open Q&A



Then



3. Enter your question

We look forward to seeing you over  
the next three days to discuss  
*Global standards for global health*



# Links to additional information



- [GS1 Healthcare GTIN Allocation Rules](#)
- The [Global Data Synchronisation Network](#)
- [GS1 Digital Link](#) standard
- [GS1 Digital Link in Healthcare: A single barcode for identification, authentication and access to information for medical products](#)
- [The key role of GS1 DataMatrix barcodes for product identification in healthcare \(2021\)](#)
- [EPCIS](#)
- You will find the recordings of the Japan and J&J case studies as presented during the November 2021 GS1 Healthcare Online Summit [here](#).

# Contact information



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