

Vaccine Traceability

Julian Sin

GS1 Hong Kong

Feb 19, 2021



GS1 - A Global Standards Organization

Headquartered in Brussels, Belgium since 1973

Neutral &
not-for-profit

Global
& local

User-driven
& governed

Inclusive &
collaborative

110+
national
chapters

100M+
products carry
GS1 barcodes

6B+
barcode beeps
everyday

2M+
globally registered
companies

Global Recognition and Partnership



GLOBAL DATA STANDARDS

Delivering Values across the Supply Chain



Identify



Capture



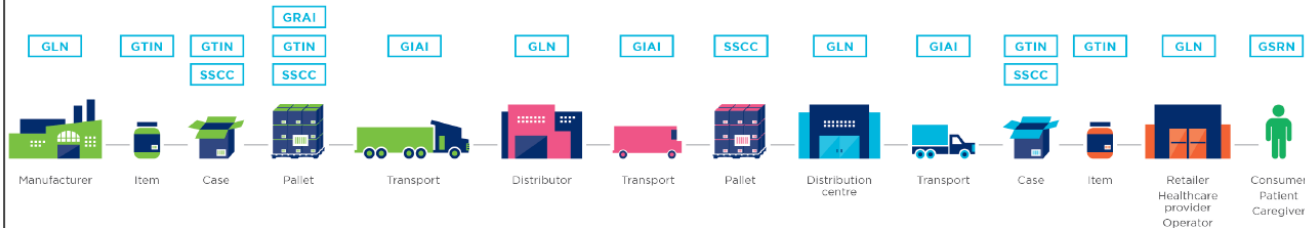
Share



Use

Identify: GS1 standards for identification

GLN Global Location Number GTIN Global Trade Item Number SSCC Serial Shipping Container Code GRAI Global Returnable Asset Identifier GIAI Global Individual Asset Identifier GSRN Global Service Relation Number



Capture: GS1 standards for barcodes and EPC/RFID

GS1 barcodes

EAN/UPC



GS1-128



ITF-14



GS1 DataBar



GS1 DataMatrix



GS1 QR Code



GS1 Composite Barcode



EPC HF Gen 2

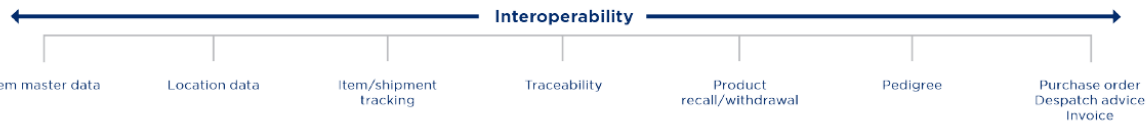


EPC UHF Gen 2



Share: GS1 standards for data exchange

Master data Global Data Synchronisation Network (GDSN) Transaction data GS1 EDI Visibility event data EPC Information Services (EPCIS)



Services



ard



Coherence

Harmonization

GS1 Hong Kong

Founded by
The Hong Kong
General Chamber of
Commerce in 1989

32 Years

in Hong
Kong

~8,000

Corporate
Members

3.5B+

Barcode Scans
per year

~20M

EDI Messages
per year

GS1 Standards

Visibility of goods throughout the supply chain



Identify

Globally-recognised unique identification of products, assets, locations and more



Capture

Real-time accurate and automatic capture of data



Share

Efficient sharing of information from trusted and authentic sources



Use

Combine different GS1 standards to streamline business processes

Governments

- **What** is the product?
- **When** was it shipped from/to?
- **Where** was it shipped from/to?
- **Why** it was shipped from/to?
- **Who** shipped the product to whom

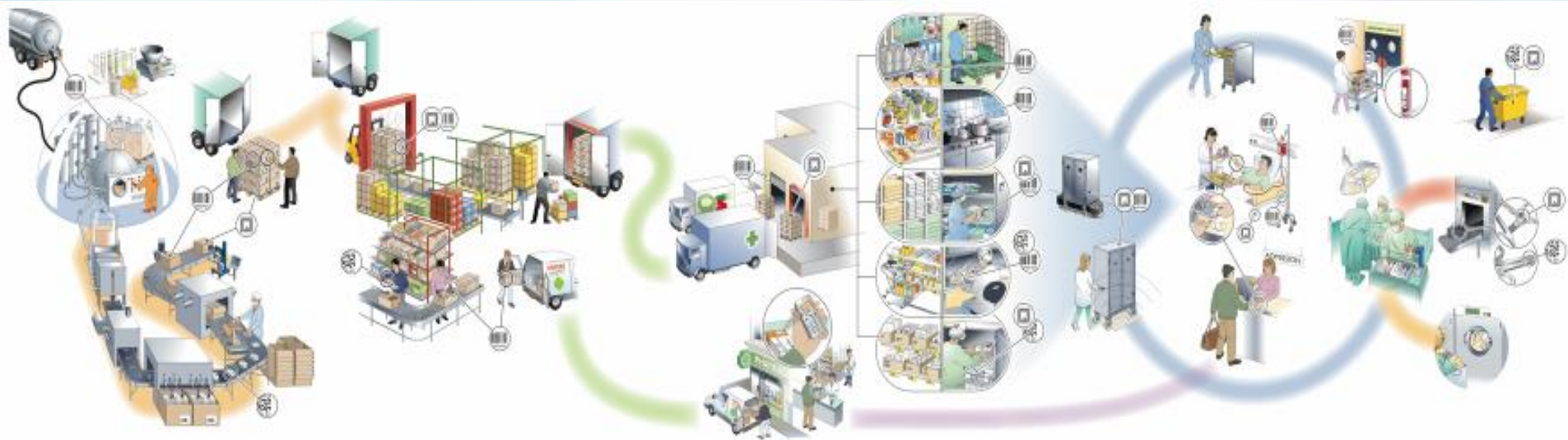


Information Flow



Physical Flow of Goods: To Connect Supply Chains and Industries

User Driven: Global Healthcare



GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing **patient safety, operation** and **supply chain efficiencies**.

Our vision:



GS1 Healthcare envisions a future in which the healthcare sector achieves **harmonised implementation** of **global standards** in **business and clinical processes** enabling **interoperability**, optimal **quality** and **efficiency** of healthcare delivery to **benefit patients**



Patient Safety



supply chain
security &
efficiency



traceability



product data

Healthcare Traceability



Barcode is not just for Retail, but also other industries...

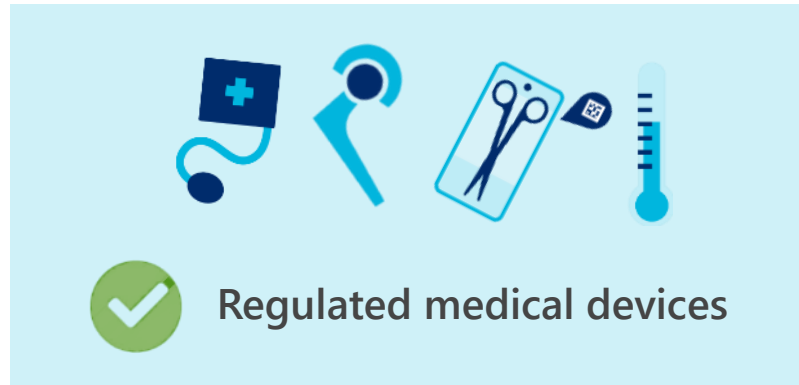
HEALTHCARE

Application for Regulated Healthcare Medical Devices

Unique Device Identification (UDI) System

A system to provide **single, globally harmonised identification of medical devices** through distribution & use, requiring the label of devices to bear a globally unique device identifier based upon standards, and also linked to a jurisdiction-specific **public UDI database**.

Unique Device Identification (UDI)

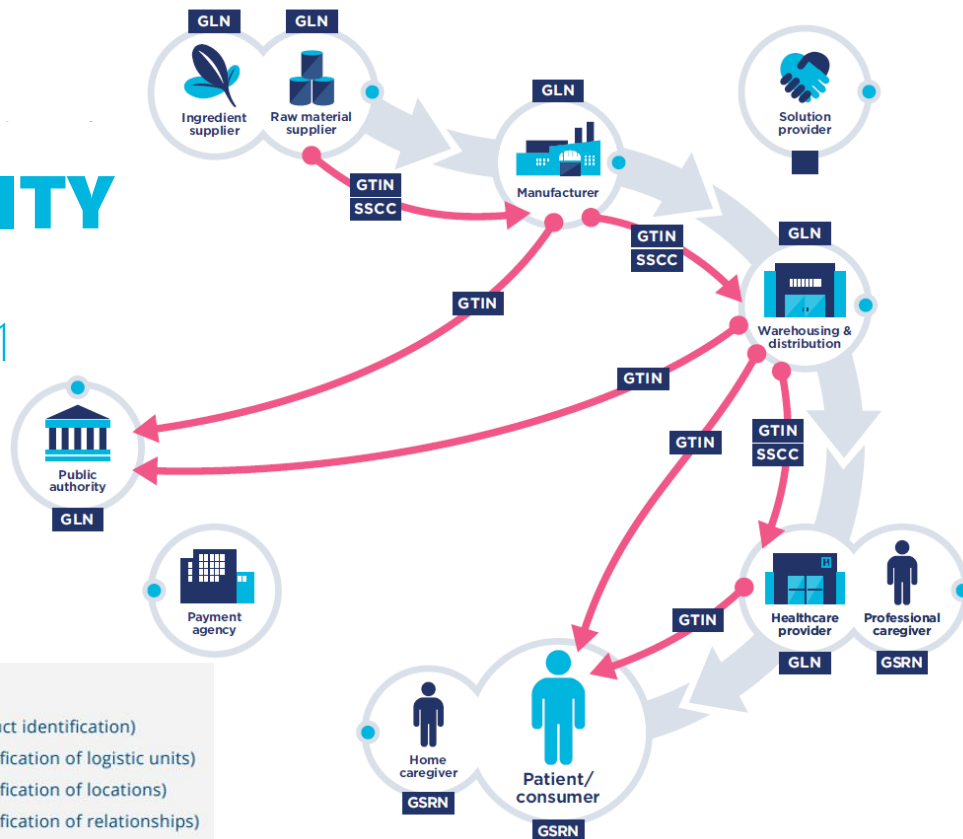


- The United States Food and Drug Administration (**FDA**), the **European Commission** & other regulators have developed UDI regulations for Medical Devices and In Vitro Diagnostic (IVD) Devices
- **GS1** is an **UDI Issuing Agency/Entity** based on many regulations worldwide, in particular US, EU, China, South Korea, Saudi Arabia

Enable End-to-End

VACCINE TRACEABILITY

from Supplier until
Recipient using GS1
Identification Keys



GS1 standards legend

GTIN	Global Trade Item Number	(product identification)
SSCC	Serial Shipping Container Code	(identification of logistic units)
GLN	Global Location Number	(identification of locations)
GSRN	Global Service Relation Number	(identification of relationships)

AstraZeneca

Covid-19 Vaccine Package
with GS1 DataMatrix



The vaccines supply chain



Often the supply chain is broken

- Vaccines are expired or not stored correctly
- Vaccines are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled

Vaccine Traceability



- The benefits of global standards not only in ensuring an effective supply chain, but also in effectively applying vaccines and **keeping the link between patient and the vaccine they received**. The last will be very critical to **capture possible side effects, safeguard the correct second dose** with the same vaccine if needed, and also to ensure data flow and analysis on immunisation coverage.



GS1 Recommendations



Vaccine ID

- Identification and labelling of vaccines

Vaccine Registry

- Developing a registry of immunisation

Patient/Caregiver

- Leveraging patient and caregiver identification

Traceability

- Establishing a traceability system

Adopt global standards

- better inventory control to avoid counterfeits and lost

Global healthcare initiatives

- Follow proven best practises

GS1 DataMatrix



Square



Rectangle



GS1 DataMatrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:

- Allowing the encoding and marking of a greater amount of data within a smaller space
- Enabling direct part marking of trade items where labels may not be practical (small medical / surgical instruments)
- Providing error detection and correction capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

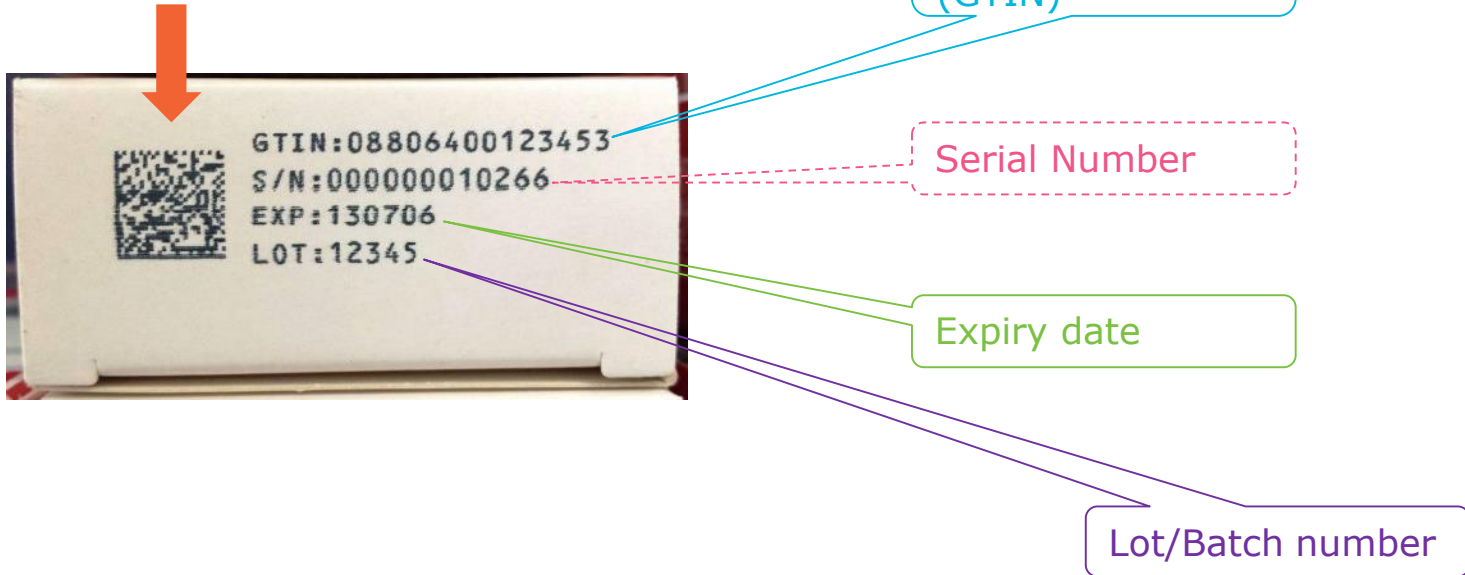
Marking vaccines with **GS1's DataMatrix Vaccine identification information** (like product identifier, lot number, and expiration date) is essential for health care providers to administer vaccines with confidence and improve the supply chain. For this reason, the **WHO** recommends that all vaccines be identified with this data in a standardized barcode.

Global trend: IDENTIFY

4 identification data elements







GS1 DataMatrix





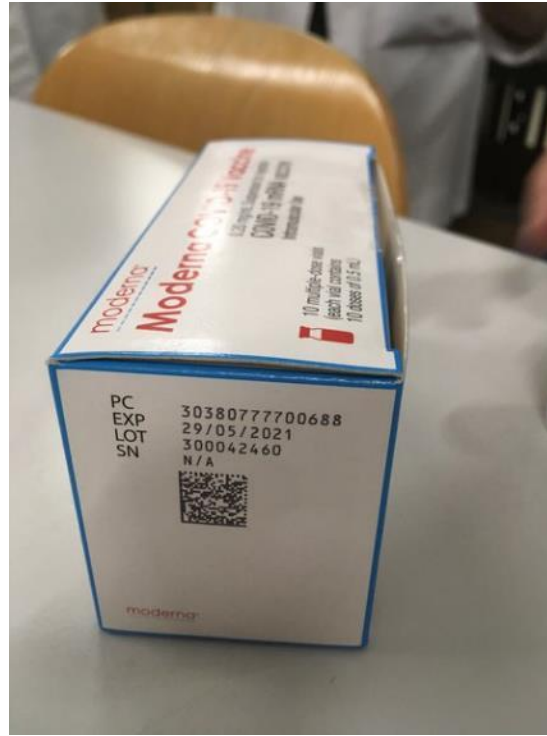
HA intends to require pharmaceutical products to be labelled in such a way as to facilitate the transfer of product identification information, the expiration date/ the best before date and the batch number from the product to the tracking system at Sales Pack Level.

Packaging Hierarchy	Example	HA Terms	HA requires an Identifier ?	HA requires a bar code ?	Required type of bar code	Remarks
Primary Packaging	A pill in blister cell 	Base Unit	No	No	NA	Not in scope
Secondary Packaging	2 blisters in 1 box 	Sales Pack	Yes, HA requires GTIN to identify a Sales Pack. Example of GTIN: 4891668000018	Yes	GS1 Data Matrix	1) HA refers the identifier to "Unique Product Identifier" 2) Enforced by 2021 (TBC)
Case	20 boxes in 1 Case 	Carton	No	Yes	GS1-128	Done since 2012 by local suppliers or logistic providers
Logistic Unit	Pallet of 8 cases 	Pallet	Yes, HA requires SSCC to identify a logistic unit. Example of SSCC: 148916680000000000	Yes	GS1-128	Done since 2012 by local suppliers or logistic providers

GS1 DataMatrix on COVID Vaccines



Moderna COVID Vaccine



GS1 DataMatrix on COVID Vaccines



AstraZeneca
COVID Vaccine

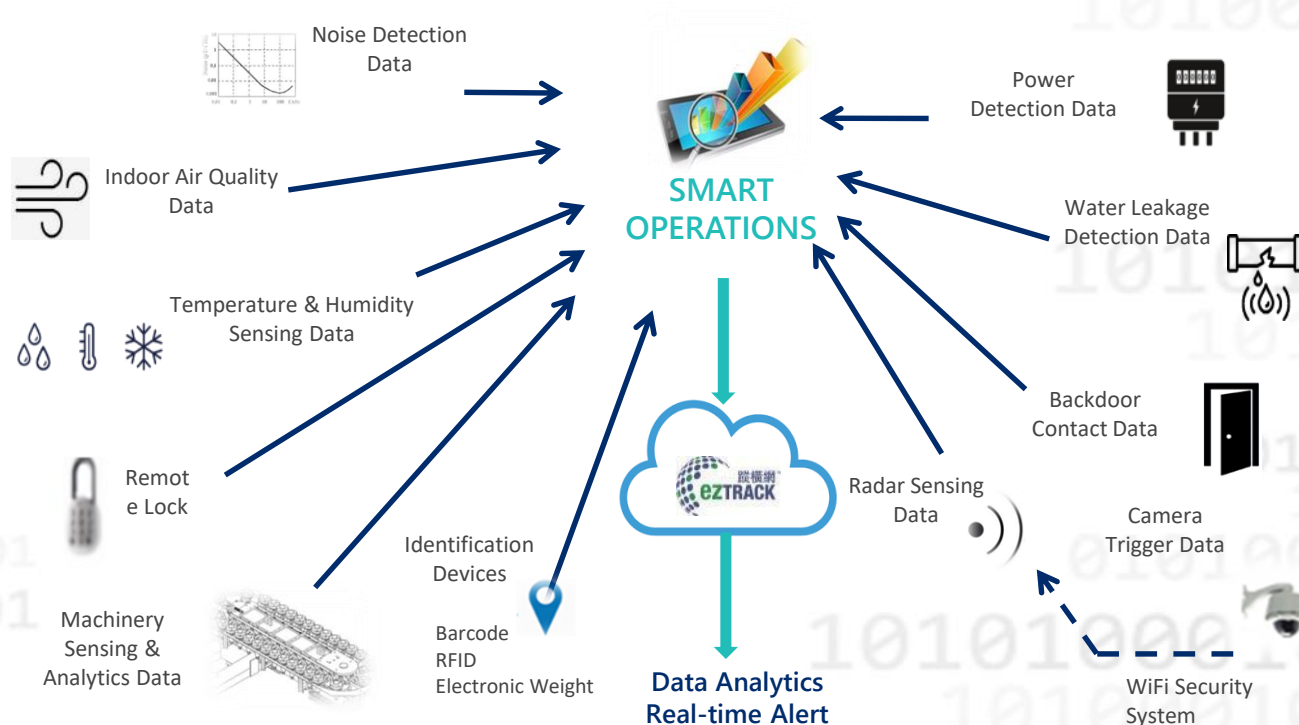


Smart Cold Chain Management

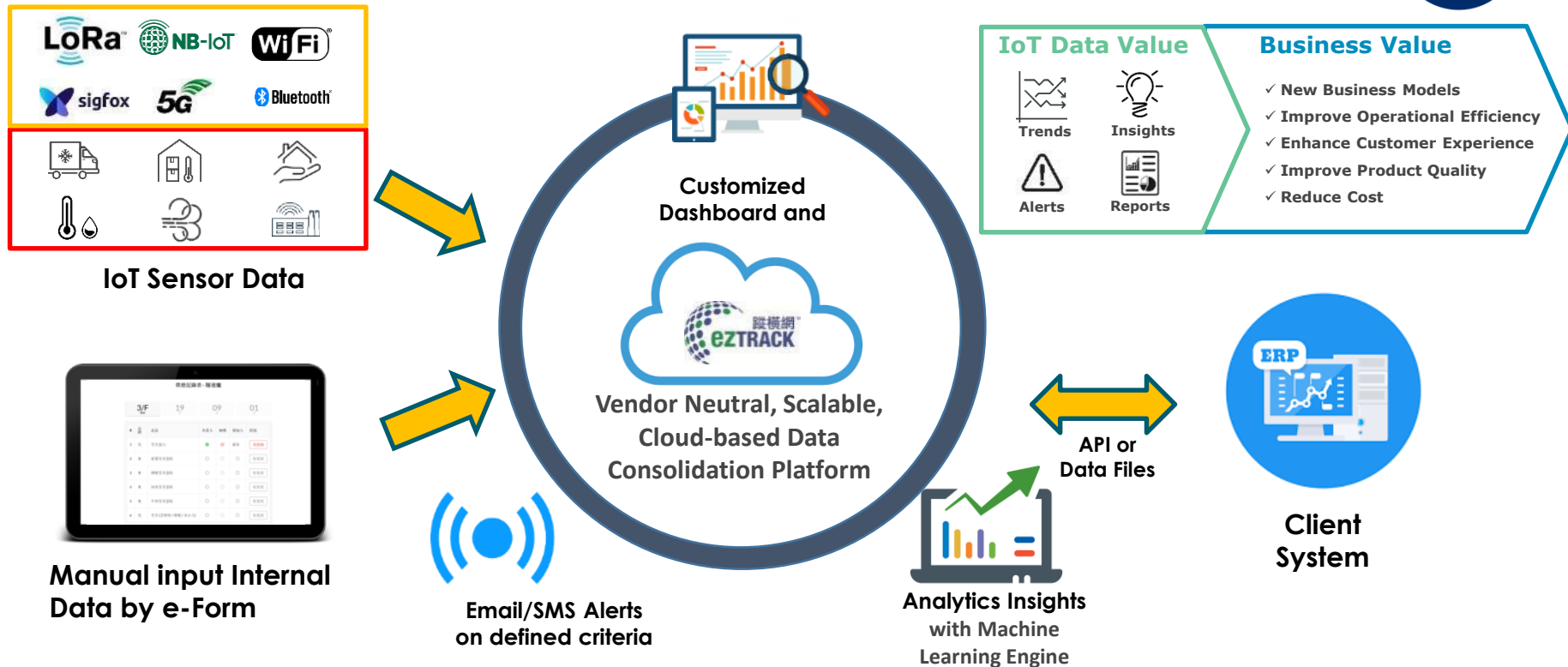


GS1HK **SMART OPERATIONS SOLUTIONS**

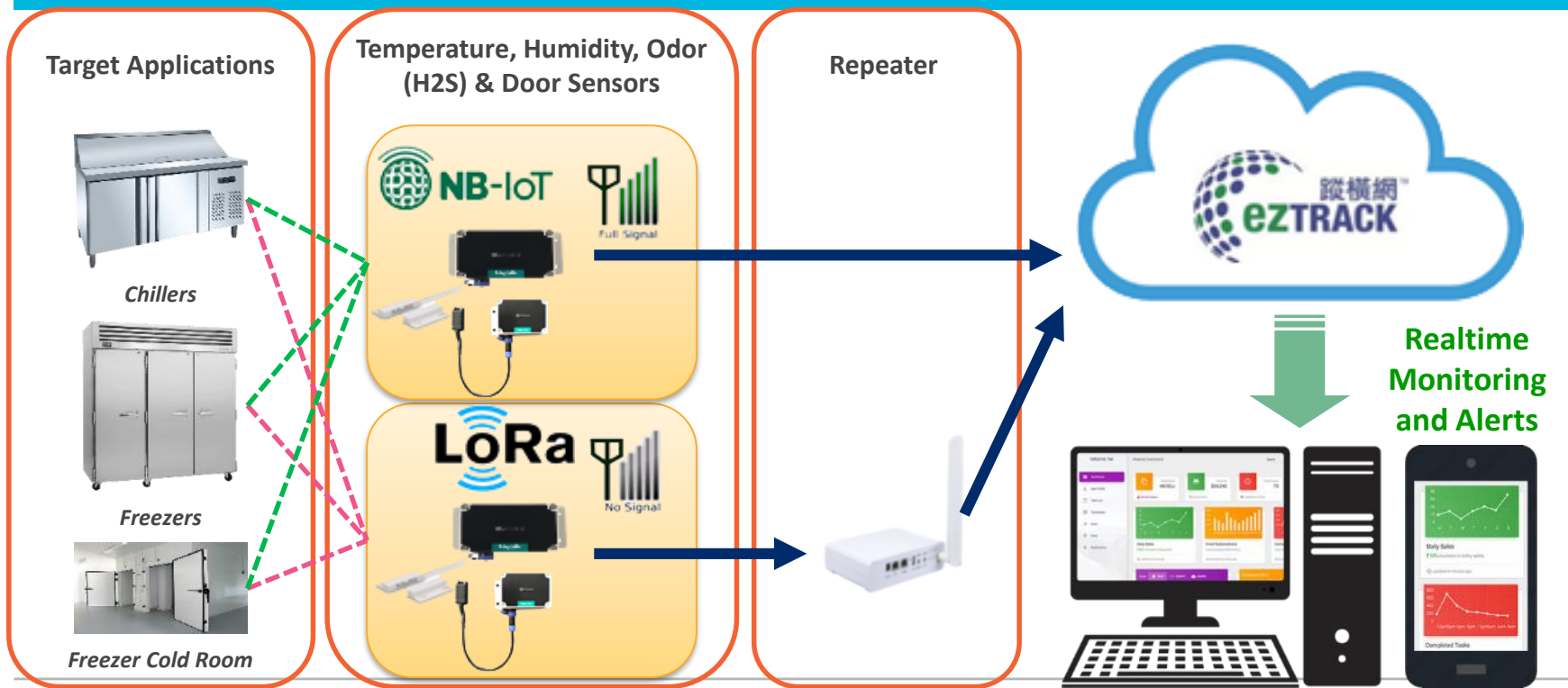
Improve Efficiency & Maximize Productivity



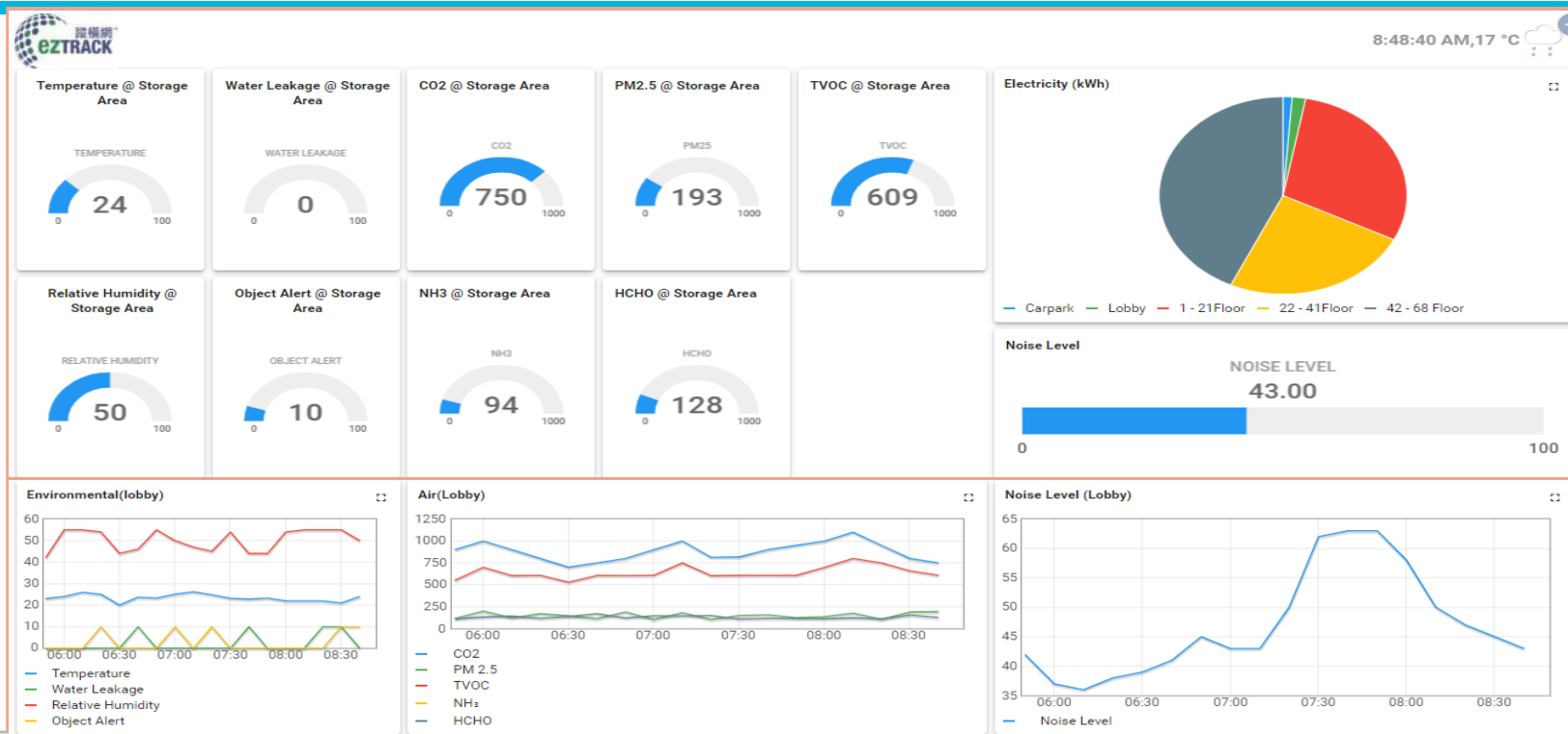
GS1HK Smart Operation **Data Network**



Smart Cold Chain Solution



Smart Cold Chain Solution



Global Adaptation





Global Standards adaptation

United States

- drug identification and labeling for the COVID-19 vaccines

- A 2D barcode containing the National Drug Code (NDC) embedded in the GTIN
- The lot number
- A placeholder expiration date on secondary level packaging

Russia

The COVID-19 vaccines will fall under the scope of the current system of medicines traceability based on a DataMatrix, with GTIN and related identification attributes.

Turkey COVID-19 Vaccine Traceability Solution



COVID19 vaccines have been serialized in Turkey using **GS1** standards. Traceability ensures that vaccines reach the right end-user/patient with a transparent pharma supply chain.

https://www.linkedin.com/posts/visiott_visiott-track-and-trace-solutions-activity-6757585513286275072-riuw/



a personalized data matrix code application
for coronavirus vaccines.

Current Status on Vaccine Traceability



The following publications support the need to move towards unique identification and barcoding of vaccines using global standards:

- **The Vaccine Presentation and Packaging Advisory Group (VPPAG) of the WHO** recommended barcodes on all packaging levels, except for primary packaging. **GS1** standards and associated specifications are used to encode the GTIN, lot number and expiry date
- **Gavi, the Vaccines Alliance and UNICEF** requiring all vaccines procured by the alliance to carry a **GS1** barcode symbol on the secondary packaging level by latest 31 December 2021 in support of vaccines track and trace
- **UNICEF** has requested use of **GS1** barcodes in their recent tender for COVID-19 vaccines.

World Health Organisation (WHO) VPPAG



- **Vaccine Presentation and Packaging Advisory Group (VPPAG) for improvements of vaccines packaging**
- Created bar code subgroup in 2011 as barcoding becomes prevalent for medicinal products to improve inventory visibility and patient safety in developed markets
- How to leverage barcodes for the vaccines supply chain in developing markets
- Chairs: Rich Hollander (Pfizer/IFPMA), Daniel Thornton (GAVI)

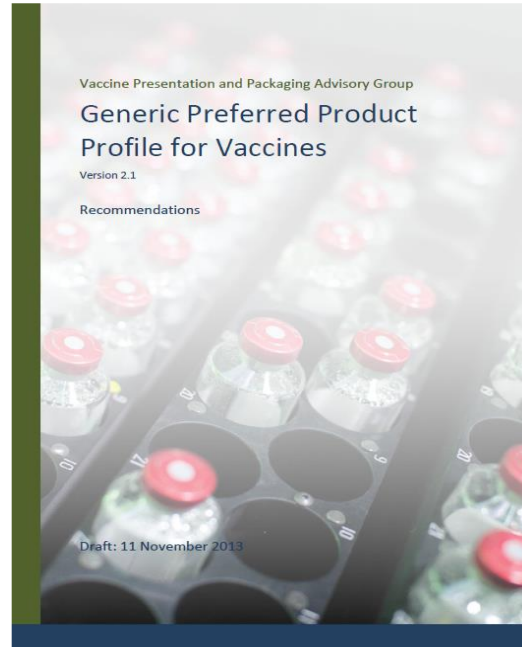


WHO VPPAG recommendations



- 2019 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes on all packaging levels used by manufacturers, with the exception of primary packaging
- GS1 standards and associated specifications are being used to encode the Global Trade Item Number (GTIN), lot number, and expiry date

[http://www.who.int/iris/bitstream/10665/148168/1/WHO IVB 14.10 eng.pdf](http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf)





- **Assessing the programmatic suitability of vaccine candidates for WHO prequalification** (PSPQ v2) published at http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf

Barcodes

**Planned for transition to critical criteria in next revision

- Bar codes are recommended on all packaging levels used by manufacturers, with the exception of primary packaging, and should conform to GS1 standards and associated specifications.
- Bar code data should include the Global Trade Item Number (GTIN), lot number, and expiry date.(VPPAG)

The WHO VPPAG guideline – some details



- Released in April 2019
- In scope secondary and tertiary packaging – **not** primary and **not** logistic units
- GTIN plus lot number plus expiry date (**not** serialisation)
- Data carrier: GS1-128 or GS1 DataMatrix



11 April 2015

VPPAG Bar Code Implementation Technical Guideline

	Current Value
Document Title	VPPAG Bar Code Implementation Technical Guideline
Date Last Modified	11 April 2015
Document Issue	Release Version 1.0
Document Status	Final for Release
Document Description	Technical guideline for the identification and marking of vaccines purchased through WHO, UNICEF, Gavi, The Vaccine Alliance

GAVI announcement: vaccine manufacturer GS1 compliance



- Starting 1st October 2019, for vaccine tenders backed by **Gavi** financing and issued by **UNICEF**, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021.

The screenshot shows the UNICEF website with the header "unicef for every child" and navigation links: WHO WE ARE, WHAT WE DO, WHERE WE WORK, PRESS CENTRE, STATISTICS, and BLOGS. A message states: "We're building a new UNICEF.org. As we swap out old for new, pages will be in transition. Thanks for your patience – please keep coming back to see the improvements." The main content area is titled "Supplies and Logistics" and features a sidebar with links: Supply home, About Supply, For suppliers and service providers, Procurement Services, Strengthening supply chains, Immunization, Health emergency supplies, HIV, Malaria, Medical devices, and Supplies for children. The main article is titled "GAVI announcement: vaccine manufacturer GS1 compliance" and is highlighted with a red border. The article text reads: "Starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021." Below this, it states: "Gavi, the Vaccine Alliance is supporting countries to improve vaccine visibility and traceability from manufacturer to beneficiary, contributing to our efforts to secure quality assured vaccines delivered to the right place, in the right quantities, at the right time to all children and adolescents." Further down, it mentions: "UNICEF and the World Health Organization (WHO) have recognized the benefits of the use of harmonized global or international identification and serialization standards on vaccines to improve visibility and traceability. Since 2015, UNICEF has recommended the use of GS1 standards on the secondary package of vaccines. Gavi, the Vaccine Alliance is planning to require GS1 data and barcode standards on the secondary package to improve product identification, labeling, and data exchange within the immunization supply chain. Starting 1st October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021. An implementation roadmap will be developed in consultation with partners in the coming months." To the right of the article are links: Share This, RSS feed, Printer friendly, and Email this article. Below these is a section titled "Children need your help" with a photo of a child and a "DONATE NOW" button.

unicef
for every child

WHO WE ARE WHAT WE DO WHERE WE WORK PRESS CENTRE STATISTICS BLOGS

We're building a new UNICEF.org.
As we swap out old for new, pages will be in transition. Thanks for your patience – please keep coming back to see the improvements.

Supplies and Logistics

Supply home
About Supply
For suppliers and service providers
Procurement Services
Strengthening supply chains
Immunization
Health emergency supplies
HIV
Malaria
Medical devices
Supplies for children

GAVI announcement: vaccine manufacturer GS1 compliance

Starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021.

Gavi, the Vaccine Alliance is supporting countries to improve vaccine visibility and traceability from manufacturer to beneficiary, contributing to our efforts to secure quality assured vaccines delivered to the right place, in the right quantities, at the right time to all children and adolescents.

UNICEF and the World Health Organization (WHO) have recognized the benefits of the use of harmonized global or international identification and serialization standards on vaccines to improve visibility and traceability. Since 2015, UNICEF has recommended the use of GS1 standards on the secondary package of vaccines. Gavi, the Vaccine Alliance is planning to require GS1 data and barcode standards on the secondary package to improve product identification, labeling, and data exchange within the immunization supply chain. Starting 1st October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021. An implementation roadmap will be developed in consultation with partners in the coming months.

Share This
RSS feed
Printer friendly
Email this article

Children need your help

Children worldwide need your help right now. Please donate what you can today.

DONATE NOW

https://www.unicef.org/supply/index_103734.html

COVID-19 Vaccines with GS1 Standards



Comprehensive papers that describe the current status and relate to GS1 standards are (non-exhaustive list):

- [Deloitte White Paper](#) :
Securing trust in the global COVID-19 supply chain
- [Article in Elsevier](#):
How to ensure we can track and trace global use of COVID-19 vaccines
- [Article in Elsevier](#):
The role of manufacturers in the implementation of global traceability
- [Article in Vaccines](#):
Emerging manufacturers engagements in the COVID-19 vaccine research, development and supply



Minimizing supply chain hiccups, advancing interoperability

“COVID-19 vaccines and therapeutics, plus associated medical devices and consumables, present an urgent need for a system of traceability built around globally identified products. The not-for-profit global standards organization **GS1** has developed the most widely utilized supply chain standards”





Key take away

The Healthcare supply chain is global

After the COVID-19 pandemic healthcare stakeholders will concentrate on optimizing processes for a better and safer future

Manufacturers who want to export into the world will need to implement GLOBAL standards

Let's work together to improve patient safety – with a simple scan!

Thank you!

Safer, more efficient care starts with a simple scan!