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Global Standards for Supply Chain Data Visibility

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management



Objectives

- To raise awareness of and sensitize stakeholders to GS1 standards for health care
- To understand the relevance of GS1 standards across the health care supply chain
- To understand the relevance of GS1 standards to enabling pharmaceutical traceability

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Foundations of Global Standards

Public Health Supply Chains Are Challenged by ...

- Poor data visibility, because items and products are identified in non-standard ways
 - Proprietary identification numbers that are reassigned at various points in the supply chain
 - Identification that is inconsistent across procurement agencies and supply chain stakeholders to the end user
- Lack of standardization in processes and operations, because of inconsistent packaging labels
 - Multiple barcodes
 - Different types of barcodes
 - No barcodes

... WHICH RESULT IN RISK TO SUPPLY CHAIN SECURITY.

GS1 Standards in the Health Care Value Chain

- GS1 standards are enabling health care providers to uniquely identify products, patients, caregivers, assets, and locations for transparent processes across the health care value chain
- Global standards — a common language for identification, data capture, and data exchange — are the basis for global trade, verification, and traceability
- Use of GS1 standards in health care supports traceability of products from the manufacturer to the patient, contributes to detect counterfeit products, helps to prevent medication errors, enables effective recalls, and supports clinical processes

Lack of Standards in Daily Life Is Inefficient and Annoying



Content Source: GSI Global Office

In Health Care, It Is Inefficient and Dangerous!



- Multiple bar codes on one package: Which one to scan?
- Different types of bar codes: inconsistent, incompatible.
- No bar code: Need to bar code, repackage, relabel.

Content Source: GSI Global Office

Our Reality Is That We Operate in a Global Environment



Source: APEC Toolkit

So, How Are Global Standards Relevant?

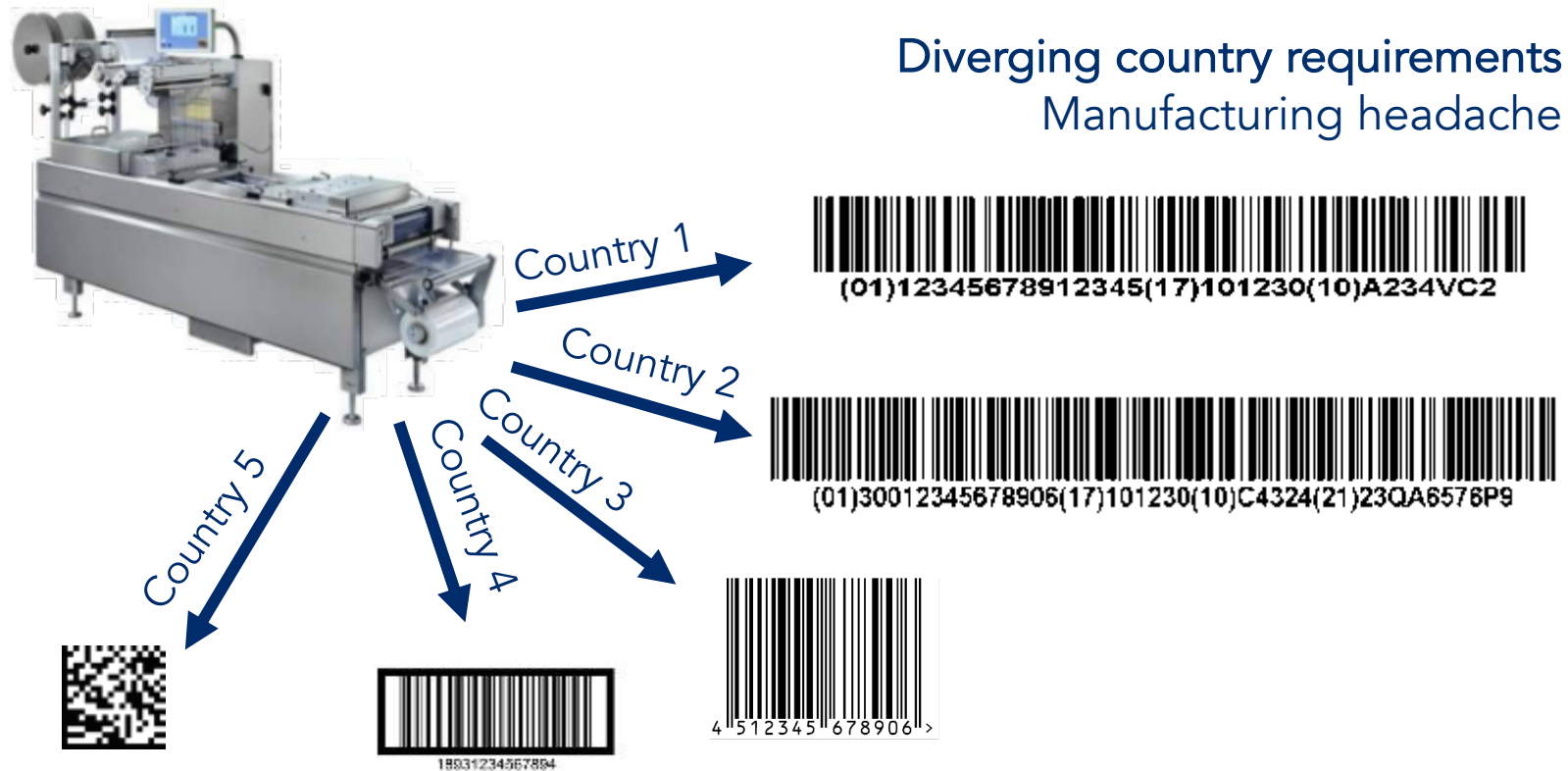
- National identification and classification structures do exist, but to interact with external trading partners (e.g., manufacturers, distributors, procurement agents, donors, export clients), you need to speak a common language.
- Within a country, global standards enable interoperability across disparate systems in a sector by having one reference code to associate items or products across different stakeholder groups.



Content Source: GSI Global Office

GS1 Global Standards Introduction

The Need for Global Standards in Health Care



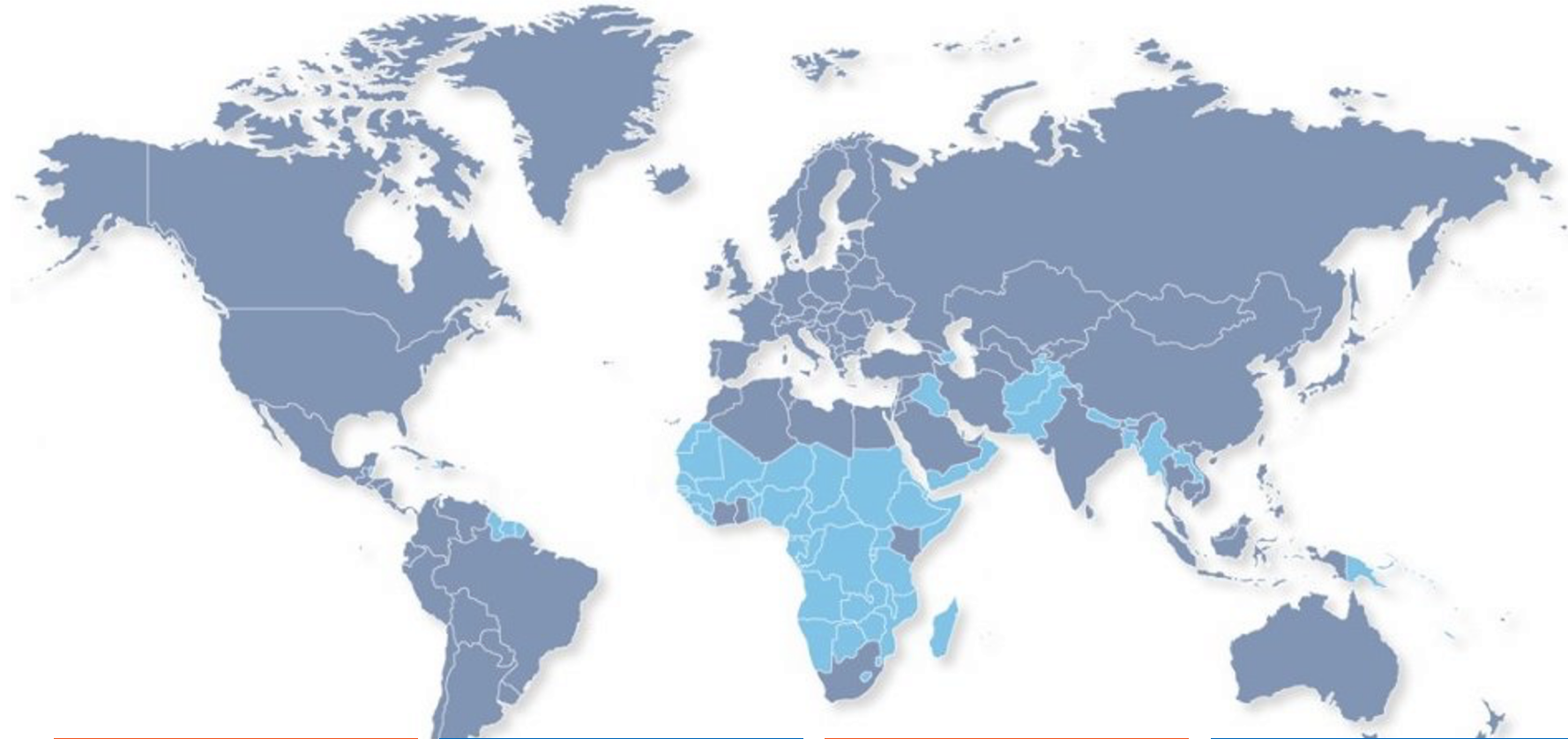
“CUSTOMIZED ACTIONS MEAN COSTS!!

Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering. Otherwise, complexity and cost will continue to raise.”

— Senior executive, MD company

Content Source: GSI Global Office

GS1 — an International Standards Organization



1 million

More than 1 million companies worldwide use GS1 standards.

150 countries

25 industries are served across 150 countries.

6 billion

Barcodes are scanned more than 6 billion times per day globally.

115 MOs

115 member organizations around the world.

Content Source: GS1 Global Office

GS1 has Recognized Non-Governmental Organization Status by the United Nations

UNITED NATIONS  NATIONS UNIES
DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS
Office for ECOSOC Support and Coordination – NGO Branch
DC1-1480, 1 UN PLAZA, NEW YORK, N.Y. 10017
Tel: (212) 963-8652 • Fax: (212) 963-9248
www.un.org/ecosoc/ngo

1 August 2011

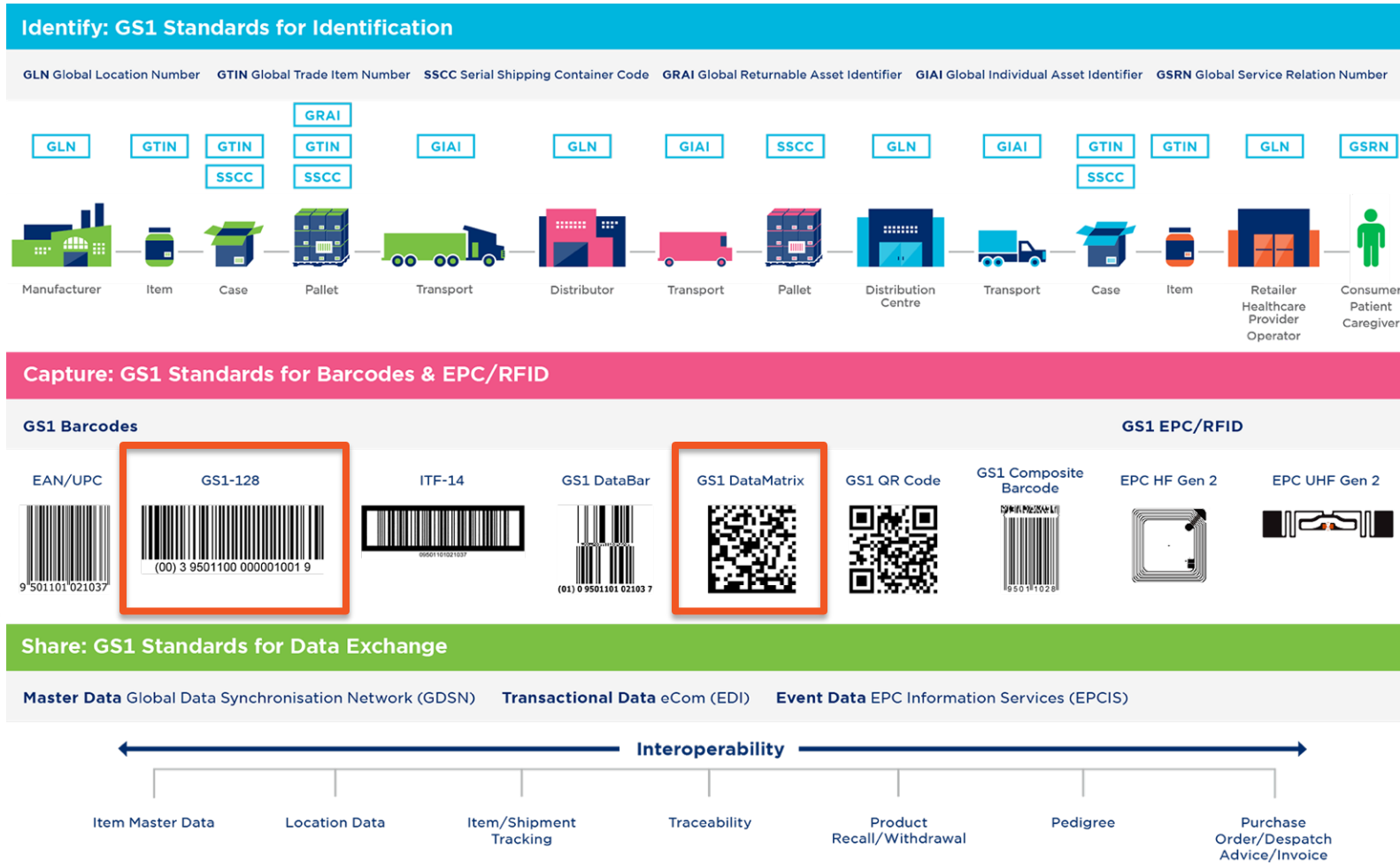
Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant **Special** consultative status to your organization “GS1”. On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.

Content Source: GS1 Global Office

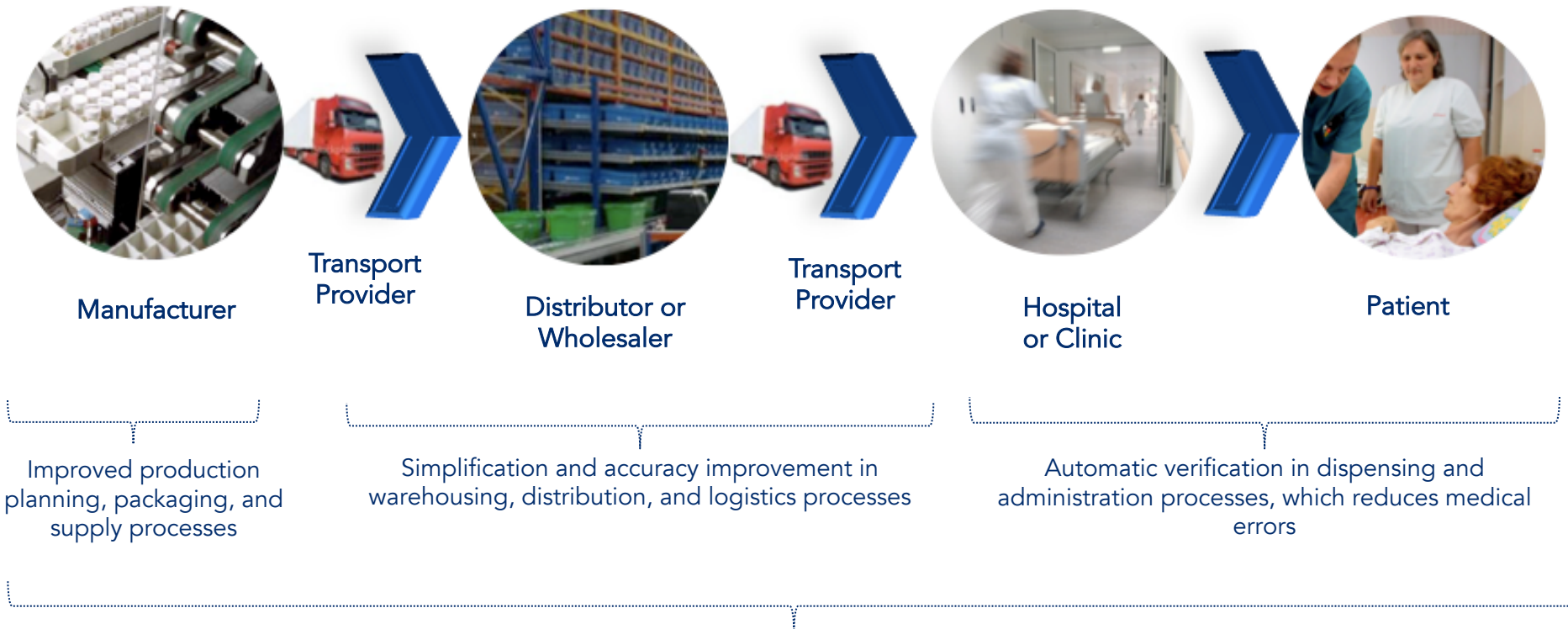
GS1 Standards for Health Care

Automatic Identification and Data Capture (AIDC)



Content Source: GS1 Global Office

GS1 Standards Across the Entire Supply Chain



- More accurate and efficient supply chain management
- Enabling traceability and authentication (counterfeiting, product recalls, etc.)
- Enabling regulatory compliance
- **Improving patient safety and supply chain efficiency!**

Content Source: GS1 Global Office

Product Labeling and Identification

Automatic Identification & Data Capture (AIDC)

AIDC refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement).



The Vision of AIDC for Health Care

EVERY item has
ONE set of key identification data carried in
ONE data carrier
that is able to be scanned by EVERYONE
at every key process step ...



Content Source: GSI Global Office

Barcode Scanning in the Supply Chain Improves Data Quality

Manual vs. automated data entry

1 keystroke (input) error in every 300-500 keystrokes

versus

1 error in 350,000 on the low end
(linear symbology)







to

1 error in 10,500,000 on the high end
(2D/Matrix symbologies)



Content Source: GSI Global Office

Position — GS1 DataMatrix vs. GS1 QR Code

GS1 Healthcare 2D Data Carrier Recommendation Summary		
GS1 Keys for:	 GS1 DataMatrix	 GS1 QR Code
a) Trade Item Identification <ul style="list-style-type: none"> • GTIN • GRAI • GIAI • SSCC* 		
b) Other Identification use cases <ul style="list-style-type: none"> • GLN • GDTI • GSRN • ...etc. 		
<p>*NOTE: This paper discusses use of GS1 2D/Matrix Data Carriers and does not alter present policy on use of 1D/Linear. At present SSCC is only used with the GS1-128 1D/Linear Data Carrier. SSCC is included above for future use when applicable.</p>		

Content Source: GS1 Global Office

The Foundation: GS1 Identification Keys

- Unique
- Non-significant
- International
- Secure
- Foundational



Global Trade Item Number (GTIN)
Item Identifier



Serial Shipping Container Code (SSCC)
Logistics Unit Identifier



Global Location Number (GLN)
Location Identifier

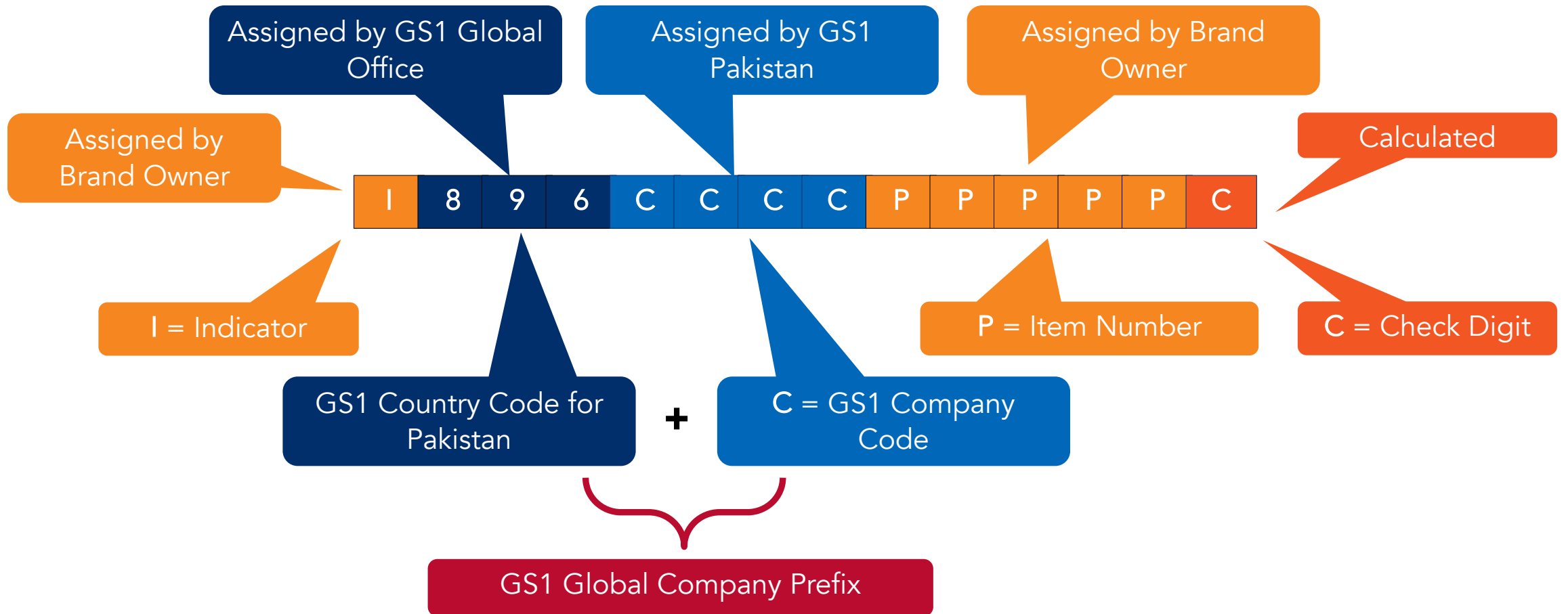
And there are more ...

Content Source: GS1 Global Office

Global Trade Item Number (GTIN)

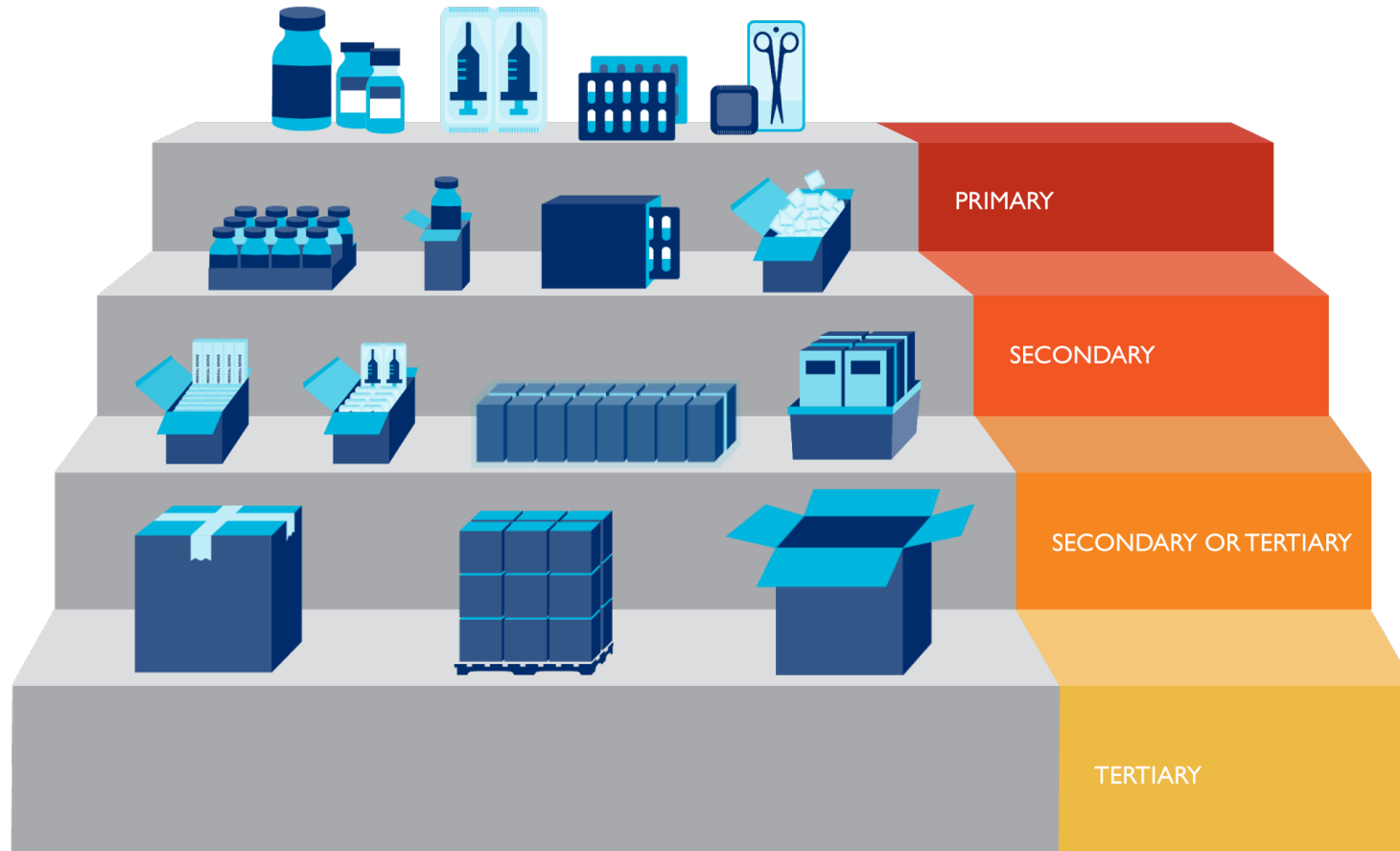
- Used to identify **any item** upon which there is a need to **retrieve pre-defined information** that may be **priced, ordered, or invoiced** at any point in any supply chain.
- GTIN is an umbrella term for all GS1 “trade item” identification numbers.
- A GTIN may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure, but **GTIN-14 is becoming more common for health care.**

Anatomy of a GTIN-14 ... an Example



Content Source: GS1 Global Office

Different Trade Item Packaging Levels Require Different GTINs



Content Source: GSI Global Office

Additional GS1 Application Identifiers (AI)

- Enable encoding of additional information other than the product identification into a barcode
- The GS1 General Specification includes 100+ AIs for various use cases and sectors
- In health care, these are the four most used data elements:

01	GTIN
10	Batch/Lot Number
17	Expiration Date
21	Serial Number

Note: Other than certain efficiency recommendations within the GS1 General Specifications, the order of AIs is not significant and should not be mandated.

Item Identification and Select Other Item Information Must Be Captured in a Data Carrier

GS1 128-Linear Barcode



(01) 10222222333334(17) 091231(10) A1345B(21) 1234



GTIN-14

Expiry Date

Batch Number

Serial Number

(01) 20887511007346
(17) 150331
(10) A1B2C3D4E5
(21) 123456789


GS1 2D DataMatrix Barcode

The Globally Harmonized Approach

Example from secondary pack

Data Matrix — Coding proposal derived from GS1 standards

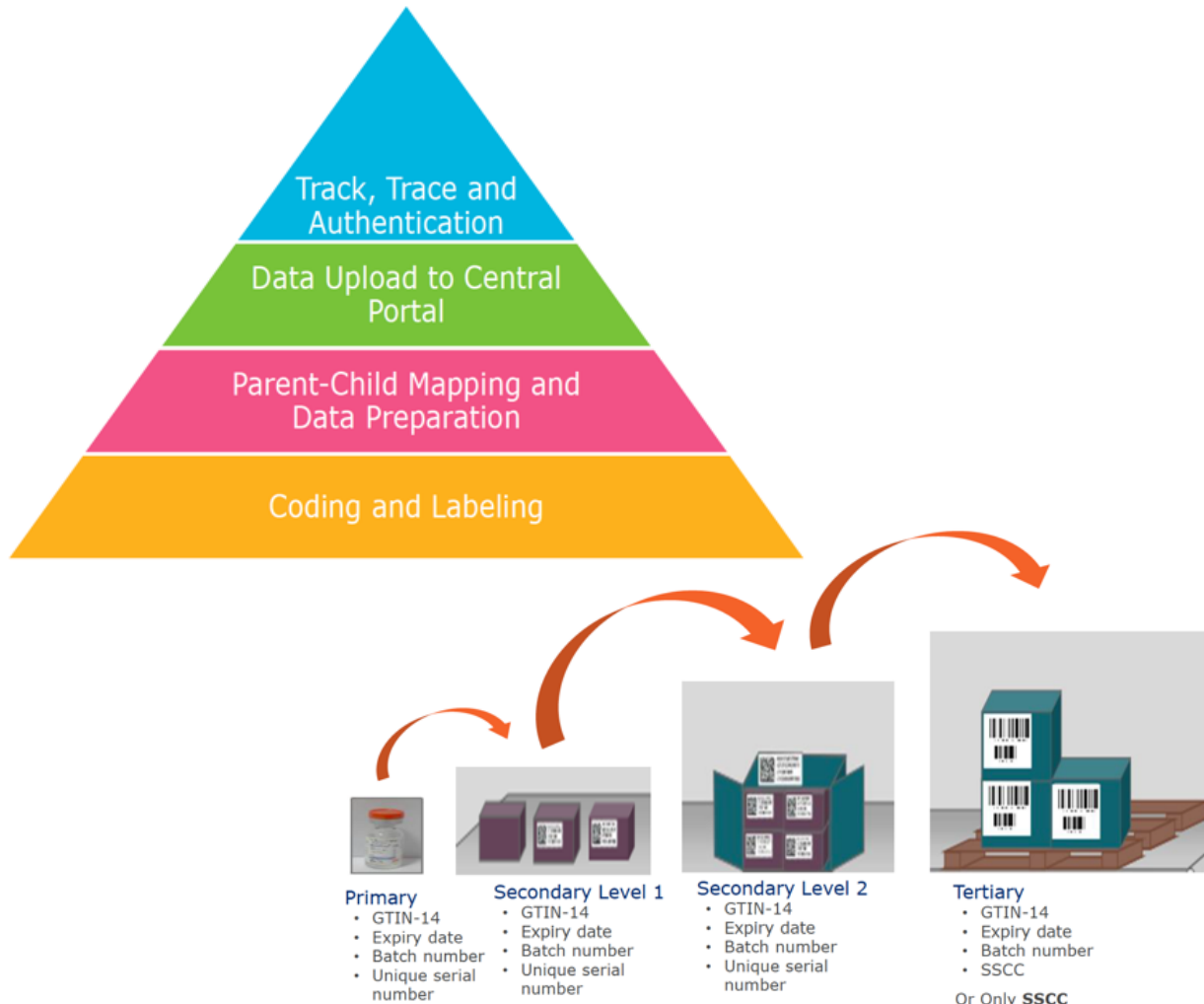
- Global Product Code assigned by manufacturer (GTIN): 14 digits
- Unique serial number (randomized): up to 20 alphanumeric characters
- Expiry date: 6 digits (YYMMDD)
- Batch number: up to 20 alphanumeric characters

GTIN: (01) 08699546010011	
Batch: (10) TRT08E3	
Expiry: (17) 151228	
S/N: (21) 583053774154	



Content Source: GSI Global Office

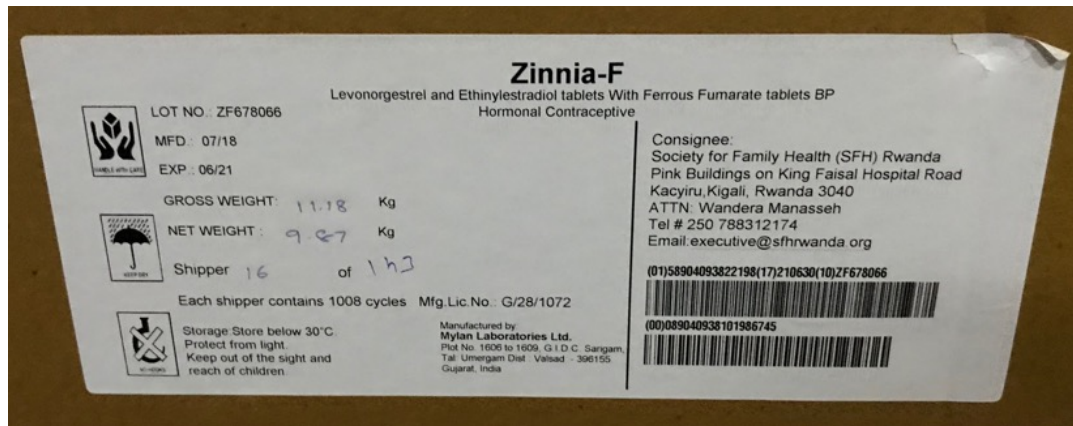
Government of India Export Requirement for Pharmaceuticals



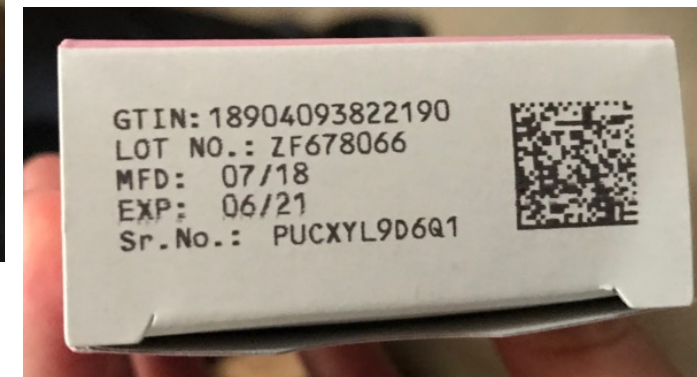
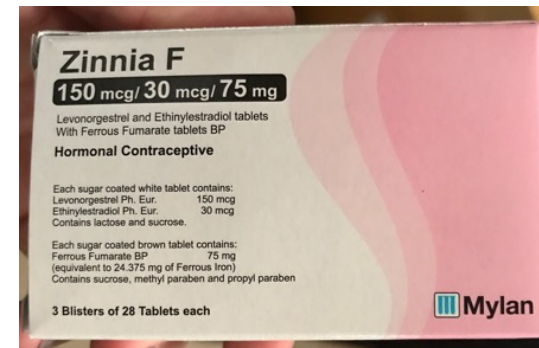
- India Director General for Foreign Trade seeks to ensure quality and protect brand image of pharmaceutical products exported from India.
- With effect from 10 January 2015, all drugs with manufacturing date on or after 10 January 2015 can be exported only if both the tertiary and secondary packaging carry barcoding as applicable.
- This means that pharmaceuticals imported from India already should be compliant!

As a Result, Many Trade Items in Countries Are Already Compliant

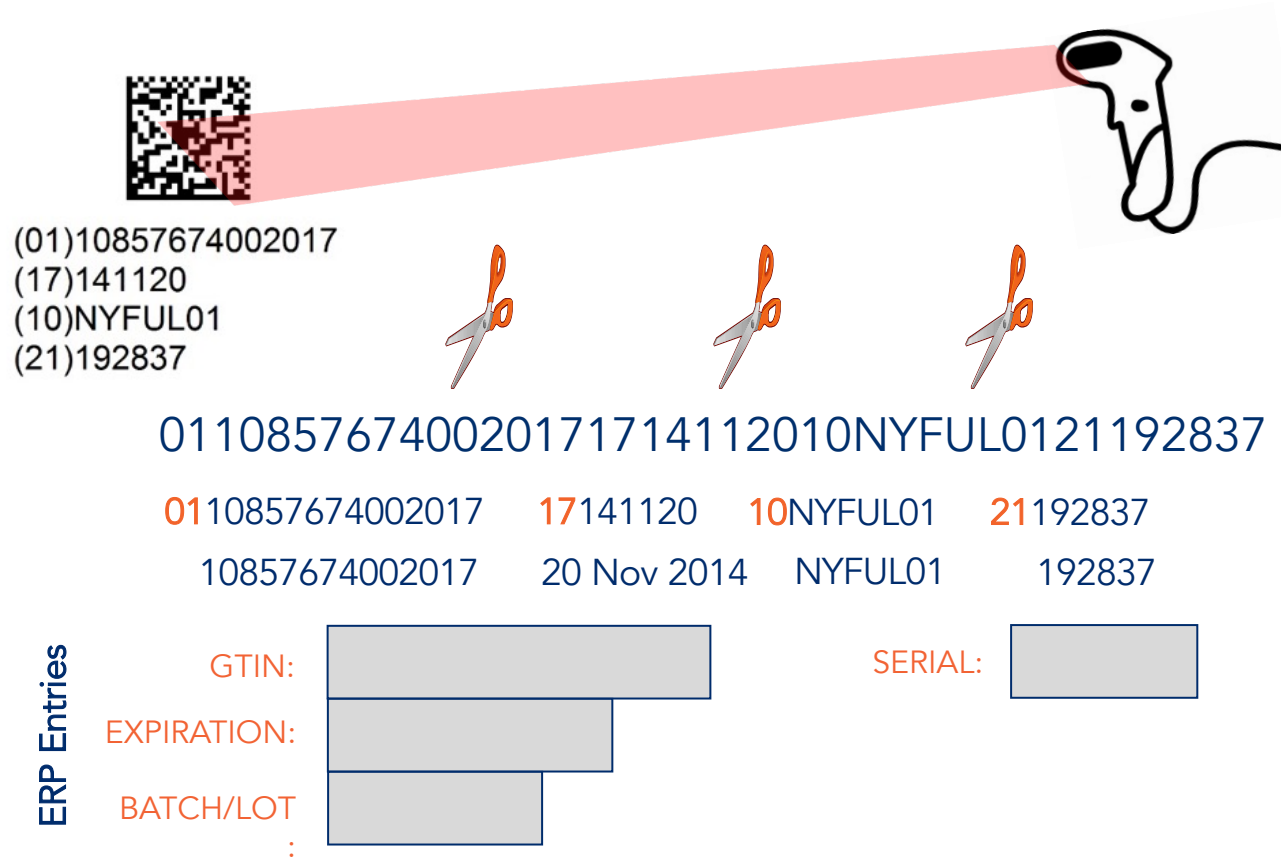
Tertiary Pack Examples



Secondary Pack Examples

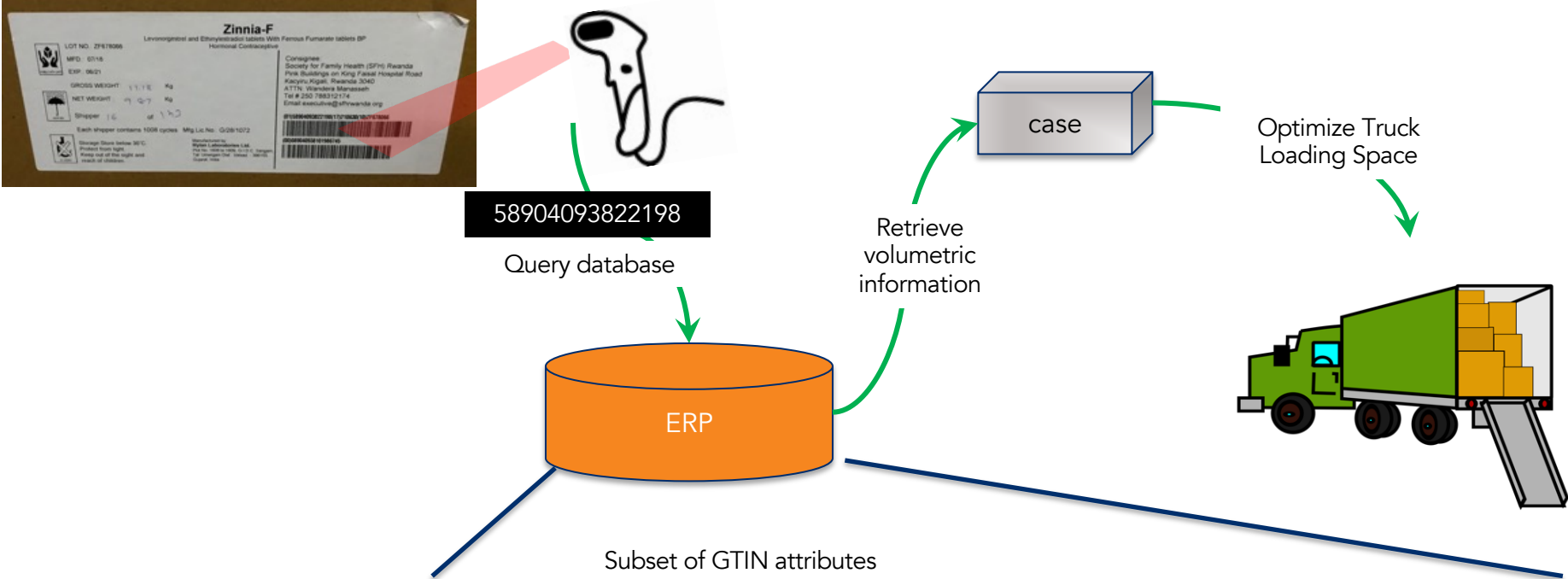


Scanning and Identification Keys in Action



Content Source: GSI Global Office

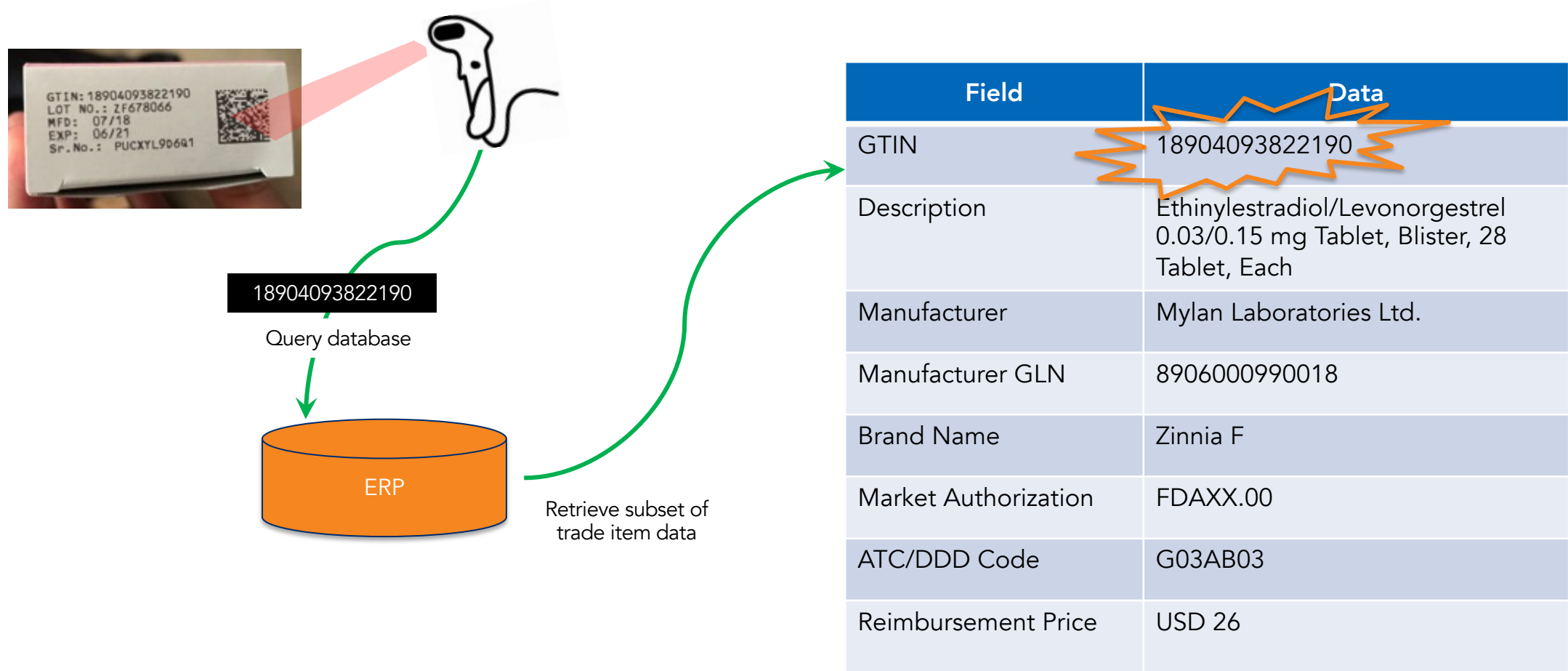
Product Master Data Enables Use of GTIN (ex. Central Medical Stores)



GTIN Number	Central Medical Stores Product Code	Description	Shelf Life	UOM	Length	Length UOM	Width	Width UOM	Height	Height UOM
58904093822198	FP00XX	Ethinylestradiol/Levonorgestrel 0.03/0.15 mg Tablet, Blister, 28 Tablet, Case [Mylan] [Zinnia F]	36	CS	0.50	m	0.30	m	0.15	m

*simplistic and illustrative
Content Source: GSI Global Office

Product Master Data Enables Use of GTIN (ex. Facility)

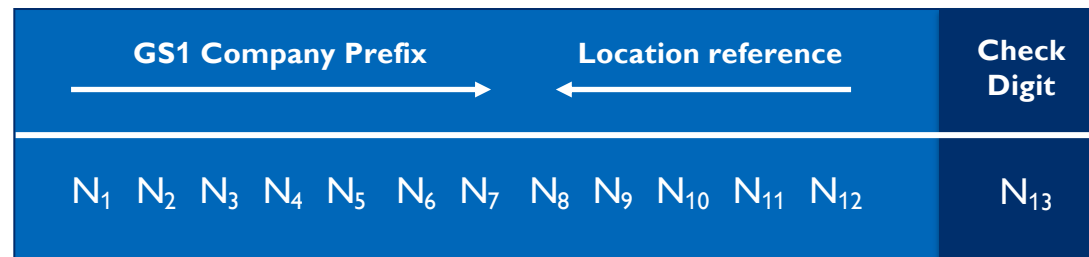


*simplistic and illustrative

Content Source: GSI Global Office

Global Location Number (GLN)

- The GLN is used to identify physical locations and legal entities
- GLNs are used when there is a need to retrieve pre-defined information to improve the efficiency of communication with the supply chain
- GLNs are a prerequisite for data sharing using the GS1 standard
- The GLN is constructed as follows, and can be from the same company prefix as the GTIN:



Content Source: GS1 Global Office

GLNs in Barcodes

- In business operations, GLNs are meaningless if they are not associated with a particular function or purpose.
- The specific AI indicates the particular function of the location number that is represented in the bar code symbol, e.g.:
 - (AI 410) “Ship to – Deliver to” GS1 GLN
 - (AI 411) “Bill to – Invoice to” GS1 GLN
 - (AI 414) GS1 GLN to identify a physical location
 - (AI 415) GS1 GLN of the invoicing party
- **GLNs are used in regulations on traceability!**
 - Argentina, Turkey, Egypt, etc.

The GLN in Use ... an Example

Company Prefix 60312345



Warehouse

GLN: 60301234500001



Clinic

GLN: 6031234500065



Pharmacy

GLN: 6031234500017



Community Health Post

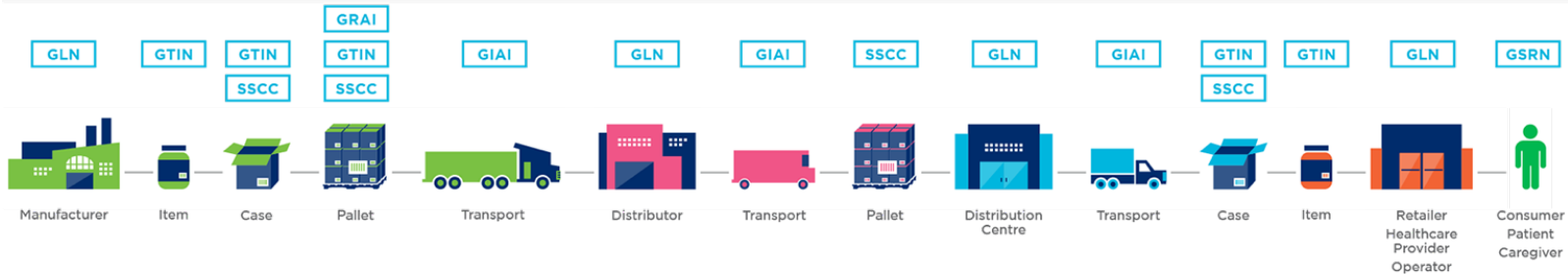
GLN: 6031234500005

Master Data Management

GS1 Standards for Sharing Supply Chain Data

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 & EPC/RFID

GS1 Barcodes

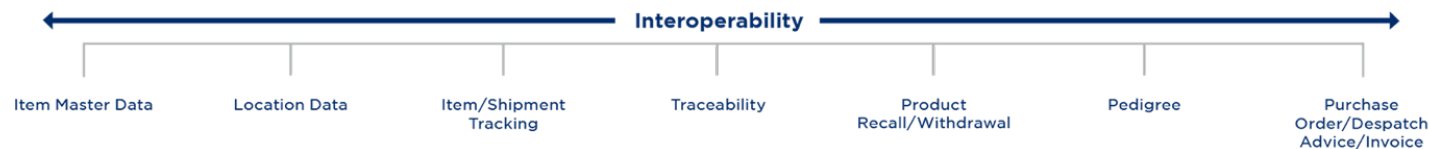


GS1 EPC/RFID



Share: GS1 Standards for Data Exchange

Master Data Global Data Synchronisation Network (GDSN) **Transactional Data** eCom (EDI) **Event Data** EPC Information Services (EPCIS)






Content Source: GS1 Global Office

Three Kinds of Shared Data in Health Care Supply Chains

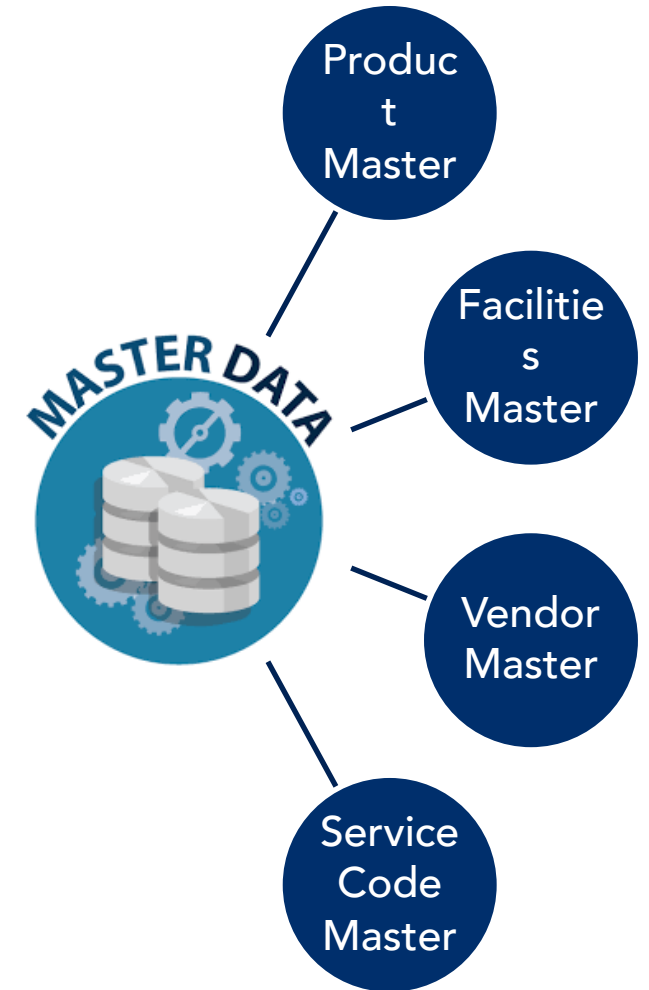


SUPPLY CHAIN INFORMATION DATA TYPES

	DEFINITION	EXAMPLES OR DESCRIPTION
 MASTER DATA	<p>ITEM: product identifiers and associated descriptive attributes</p> <p>LOCATION: facility (legal entity) identifiers and associated descriptive attributes</p>	<p>ITEM: Manufacturer, brand name, item description, unit of measure, net content, shelf life</p> <p>LOCATION: Address, contact information, role</p>
 TRANSACTION DATA	<p>Information about production, planning ordering, delivering, paying, and other transaction-related processes that occur through the supply chain</p>	<p>Order quantity, units sold, stock on hand, forecasted units, price</p>
 EVENT DATA	<p>Information about the physical movement and status of products as they move through the supply chain</p>	<p>Commissioning, shipping, receiving, decommissioning</p>

What Is Master Data?

- Item-, entity-, or location-related data that is created by the owner of that item or entity.
- The data that is needed by the recipient to perform operational and commercial processes.
- Product-related data or characteristics are referred to as ATTRIBUTES.
- Unique reference numbers* are the keys that are used to access master data across multiple systems, applications, or processes.
- Hierarchies are the magic behind health care analytics — the ability to define roll-up and drill-downs of information.

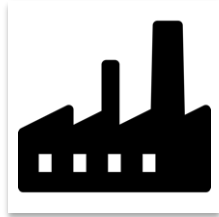


*For items, Global Trade Item Number (GTIN)
*For entities, Global Location Number (GLN)
Content Source: GSI Global Office

Where Do We Use Master Data?



✓ Planning



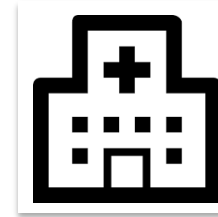
✓ Manufacturing



✓ Logistics



✓ Warehouse



✓ Clinic



✓ Pharmacist



✓ Procurement



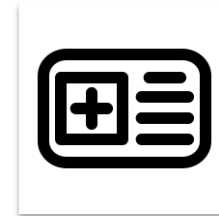
✓ Regulatory



✓ Customs



✓ Distribution



✓ Insurance

Data Errors in Health Care

U.S. Department of Defense Study

% of Total Data Error	Manufacturer	Distributor	GPO	Health Care Provider
Missing Middle Levels of Packaging	15-20%	1-4%	20-25%	15-25%
Hard "Packaging Quantity" Errors	1%	1%	2%	2-5%
Unit of Measure Confusion/Misuse	2-6%	1-3%	2-5%	Unknown
Missing Packaging — Not Middle Level	3-8%	3-8%	3-7%	5%
Manufacturer Name Problems	NA	2-5%	1-4%	30%
Obsolete Products	1-4%	2-5%	1-8%	5-15%
Missing Product Brand Names	2-5%	5-10%	5-10%	20-25%
Incomplete Item Descriptions	5-15%	3-12%	5-15%	10-20%
Wrong Customer Unit Prices	Unknown	1-2%	NA	1-2%
Customer Paid More Than Lowest Contract Price	NA	Unknown	NA	3-6%

Source: https://www.gsl.org/docs/healthcare/events/291105/KG_HUG_301105.pdf

The Cost of Data Errors



Catalog Disparities

- Incorrect Item Data: 30%
- Costs: US\$60 to \$80 per error to correct
- Time Lost: 25 minutes/SKU/year

75,000
10,000
41,500
6,000
10,000
1,044
(150,000)
Total Assets \$ (1)

Invoice Errors

- 60% invoices with errors, of which, 43% have deduction costs
- To Correct: US\$40 to \$400 to reconcile

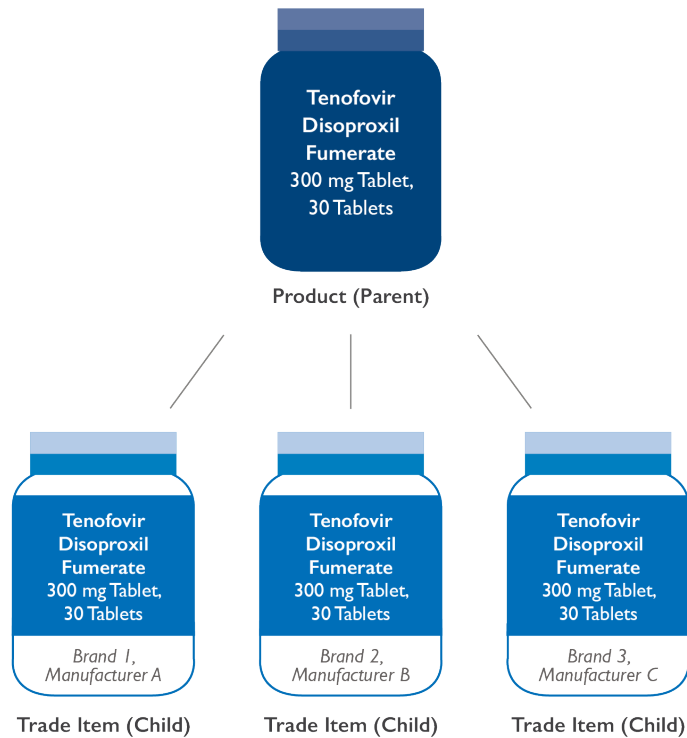


Lost Business

- Product Roll-in: About 4 weeks
- Lost Sales: 3.5% due to inaccurate data

- Source: Supply Chain Management Review — Synchronization: a cure for bad data.(INNOVATIONS: New ways of thinking about supply chain management)
- Link to GDSN cases studies: <http://www.gs1.org/standards/gdsn/case-studies>

Products vs. Trade Items



Product

An object with a defined set of attributes or characteristics

Trade Item

Individual instances of a product with some unique characteristics (e.g., manufacturer, brand name, pack configuration/design)

Why differentiate?

Managing price, quality, distribution, and recalls needs to happen at the item level

What Is Master Data Management (MDM)?

- MDM is, at its most basic, the process of linking identity data and reference data across multiple IT systems into a single, consistent point of reference. That single point of reference could be an item, location, or patient code.
- A more formal, all-encompassing definition of master data management is this:
 - MDM comprises the processes, governance, policies, standards, and tools that consistently define and manage the critical data of an organization to provide a single point of reference.
- Managing codes or identifiers is the foundation of MDM. If you can't do that well, you won't be able to succeed in the complex task of managing reference data.
- MDM seeks to ensure that an organization does not use multiple versions of the same reference data in different application systems or parts of its operations.
- Global Health Supply Chain Program–Procurement and Supply Management (GHSC-PSM) project Product Master Data Reference Guide:
<https://www.ghsupplychain.org/PMDMReferenceGuide>

Important! MDM is not an IT function. It is a business strategy that can be optimized with the appropriate use of enabling technologies.

Source: [Health Catalyst](#)

Why Do We Care About MDM?

- Large organizations with a multitude of processes and systems to process transactions are often faced with the challenge of not having a “Source of Truth” for their master data.
- Data is an enterprise asset that is used to make strategic decisions across the supply chain, from registration to service delivery.
- **80 percent of data in transactions is master and reference data.**
- Alignment of master data is the basis for trade and traceability.

*William El Kaim 2016

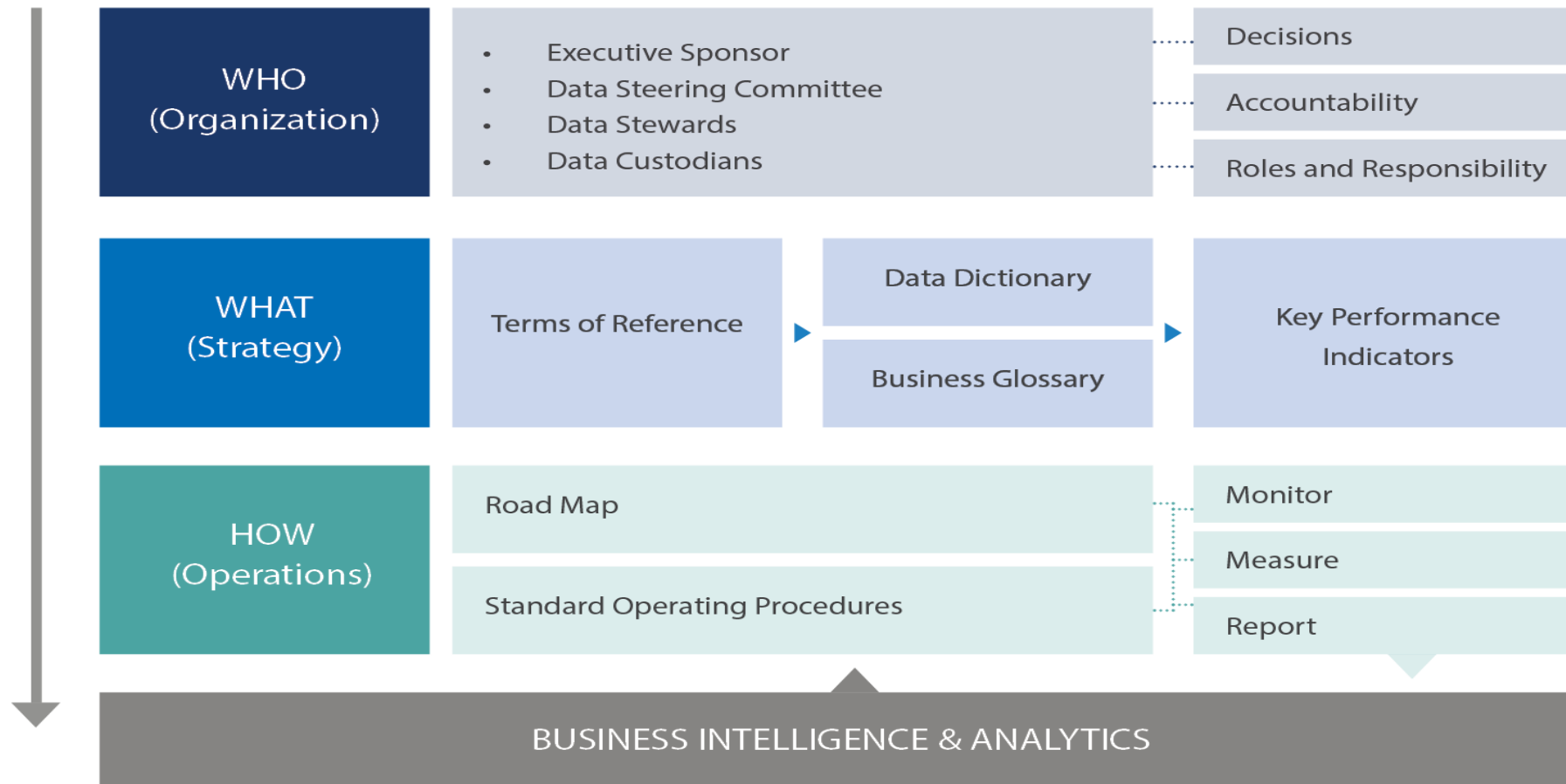
Foundational Pillars of an MDM Program



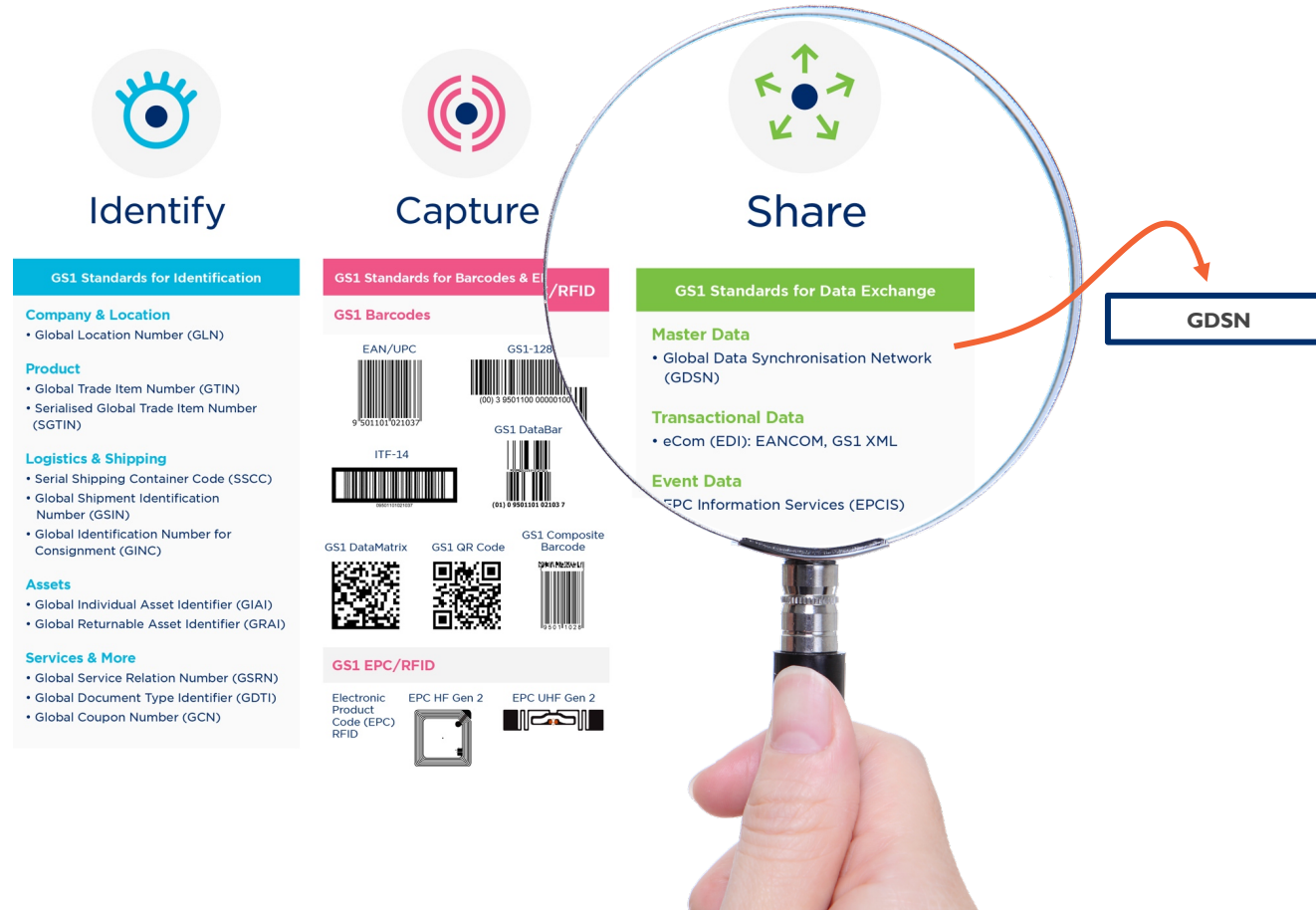
Data Governance	Data Architecture	Data Quality Mgt.	Data Storage and Operations	Data Security	DI&I
<ul style="list-style-type: none"> - Data Governance Organization - Data Governance Strategy - Data Governance Operations 	<ul style="list-style-type: none"> - Master Data Terminology Strategy - Reference Data Model 	<ul style="list-style-type: none"> - Data Quality Strategy - Data Quality Audits - Data Validation Rules and Reasonability Checks 	<ul style="list-style-type: none"> - Data Operations and Configuration Management - Data Lifecycle Management - Data Auditing, Logging, and Reporting 	<ul style="list-style-type: none"> - Privacy, Access Control, Authentication - Data Sharing Agreements 	<ul style="list-style-type: none"> - Platform Architectural Approach - Architectural Standards - Integration and Data Sharing - Historical Data, Archiving, and Retention

Product Master Data Management Reference Guide: <https://www.ghsupplychain.org/PMDMReferenceGuide>

Product MDM Governance Framework



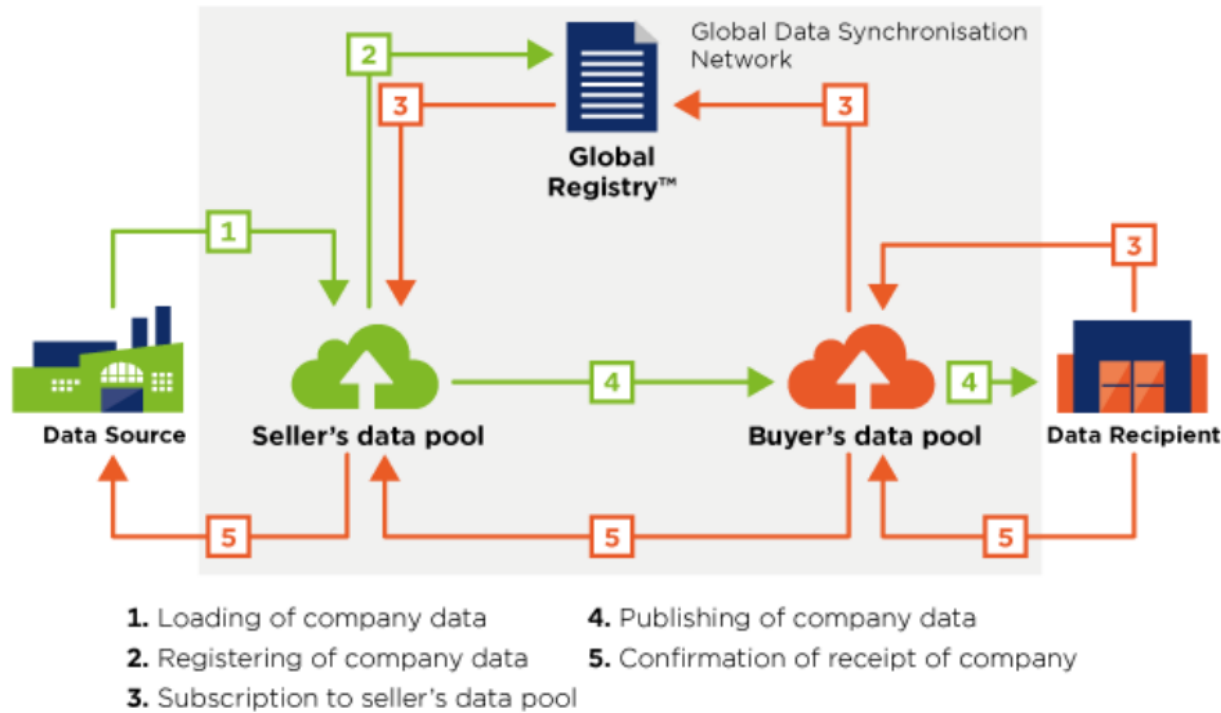
GS1 Master Data Standards



Opportunities for Global Data Synchronization Network (GDSN)

- Single source of truth on master data: the supplier!
- Get a consistent set of attribute data from all trading partners
- Near real-time updates if product data changes
- Opportunity to receive registration (marketing authorization) information in a standard and consistent manner
- GHSC-PSM will have the same identifying data as United Nations Populations Fund (UNFPA), Global Fund, and others, improving cross-agency procurement analytics

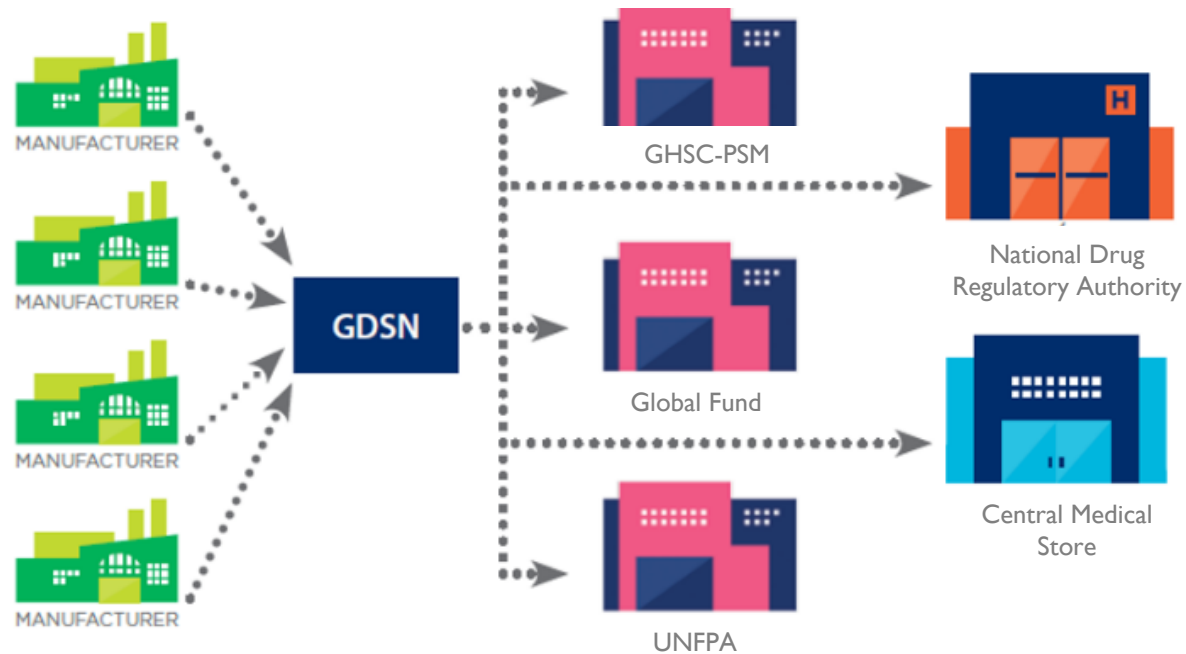
The GDSN Is the GS1 Standard for Master Data Exchange



- 39 certified GDSN data pools
- 2.1+ million health care products
- 3,500+ suppliers
- Published to 96 target markets

The GDSN Opportunity for Global Health

GS1 Global Data Synchronisation Network™ (GDSN®)

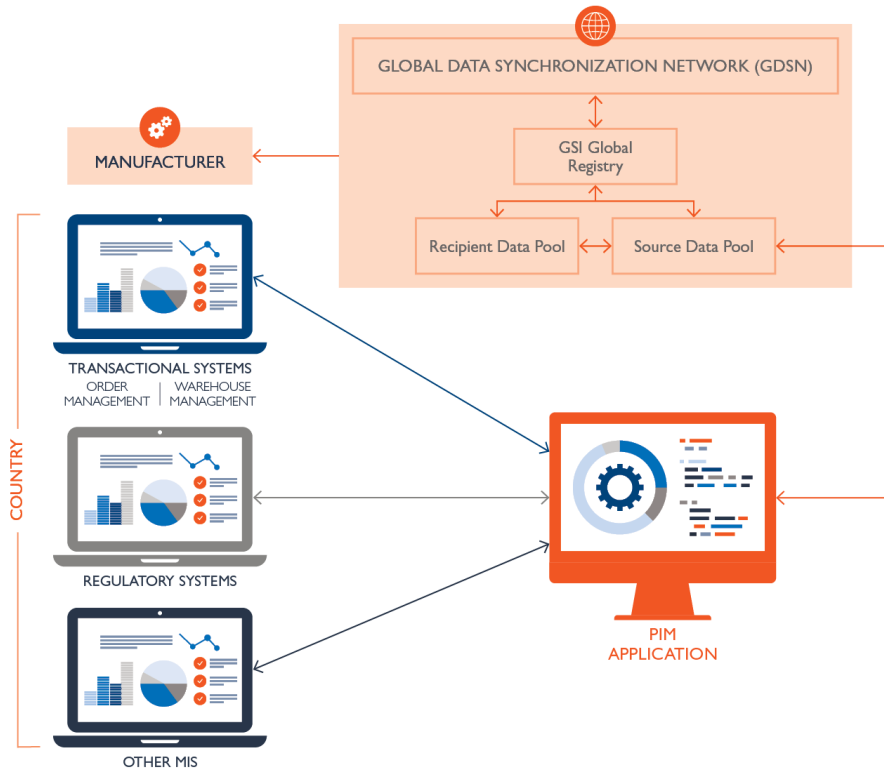


Manufacturers are able to provide data to all kinds of databases and all kinds of customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.

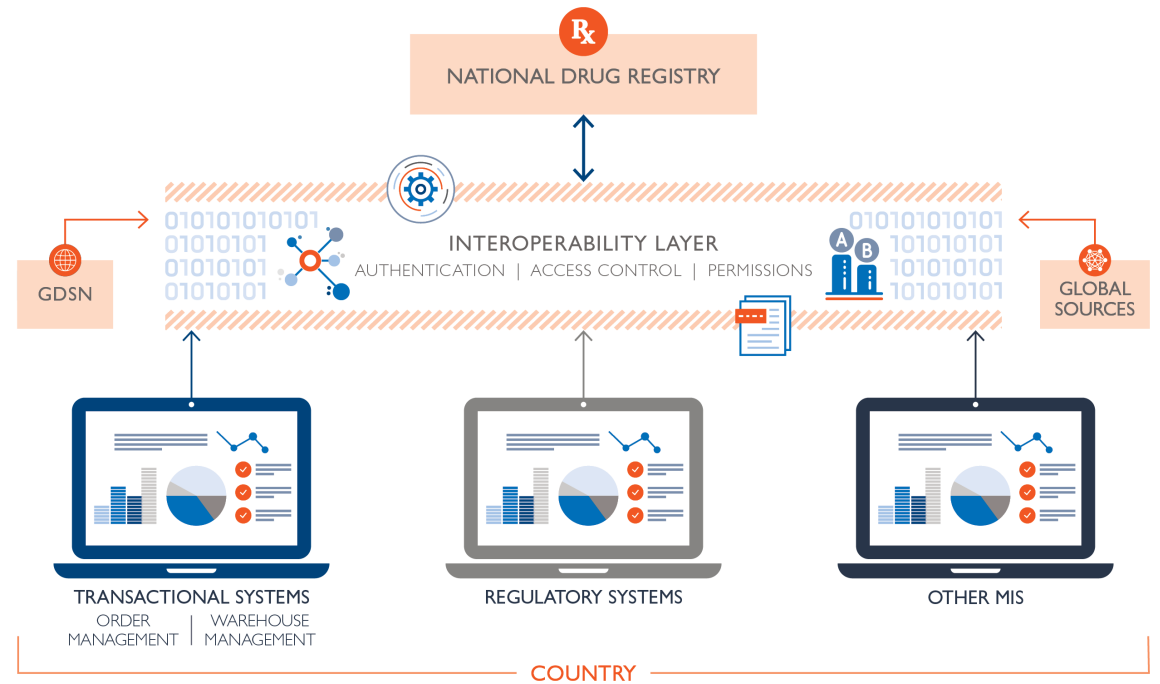
Data Integration and Interoperability (DI&I)

DI&I Platform Architectural Approach

DI&I Integration and Data Sharing



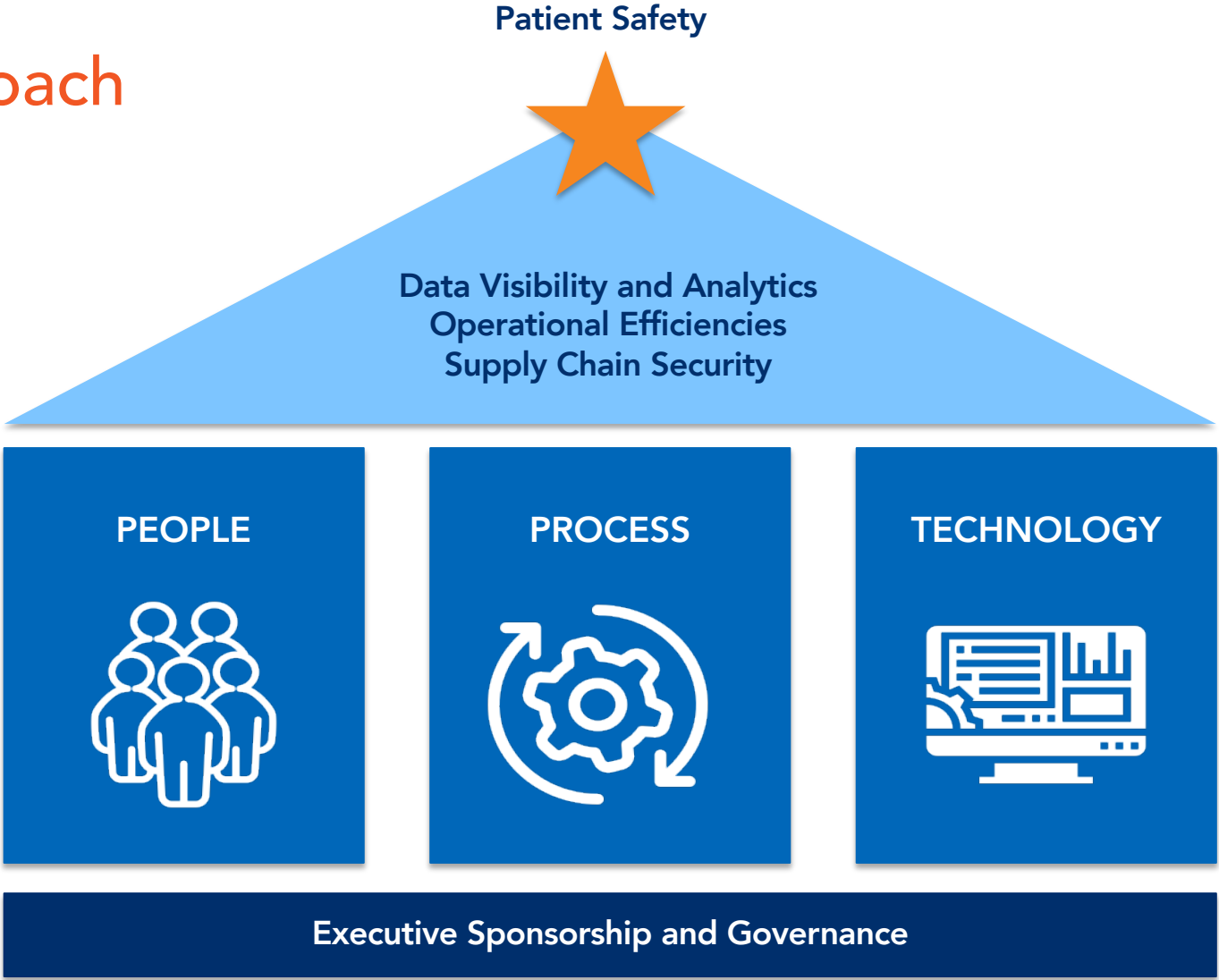
DI&I Architectural Standards



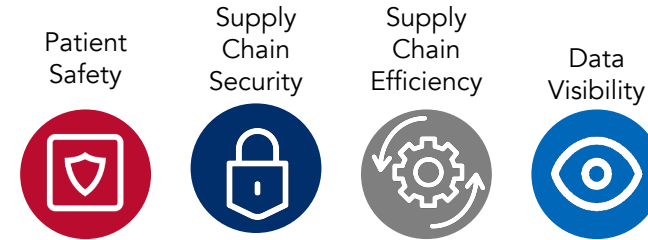
DI&I Historical Data, Archiving, and Retention

Traceability Overview

Holistic Approach



GS1 Standards Support a Number of Supply Chain Objectives



Objective Category	Objective Description	Patient Safety	Supply Chain Security	Supply Chain Efficiency	Data Visibility
ADDRESS	SF or stolen product detected in the legitimate supply chain	Yes	Yes	No	No
	Theft or diversion of products from the legitimate supply chain	No	Yes	No	No
	SF or stolen product that is obtained by the patient/end user	Yes	No	No	No
IMPROVE	Accuracy and efficiency of procurement operations	No	No	Yes	No
	Efficiency of "reverse" logistics processes (e.g., those used for returns, recalls)	Yes	No	Yes	Yes
	Visibility of product "status" (e.g., expiry, recalls)	Yes	No	Yes	Yes
	Efficiency of inventory management and distribution	No	No	Yes	Yes
	Efficiency of payment and payment monitoring processes	No	Yes	No	Yes
	Pharmacovigilance and control of treatment outcomes	Yes	No	No	Yes
ENABLE	Visibility into where the product is within the supply chain	No	Yes	Yes	Yes
	Visibility to decrease or eliminate reimbursement fraud	No	Yes	No	Yes
	Harmonized trade/customs clearance procedures for pharmaceutical products	No	No	Yes	Yes

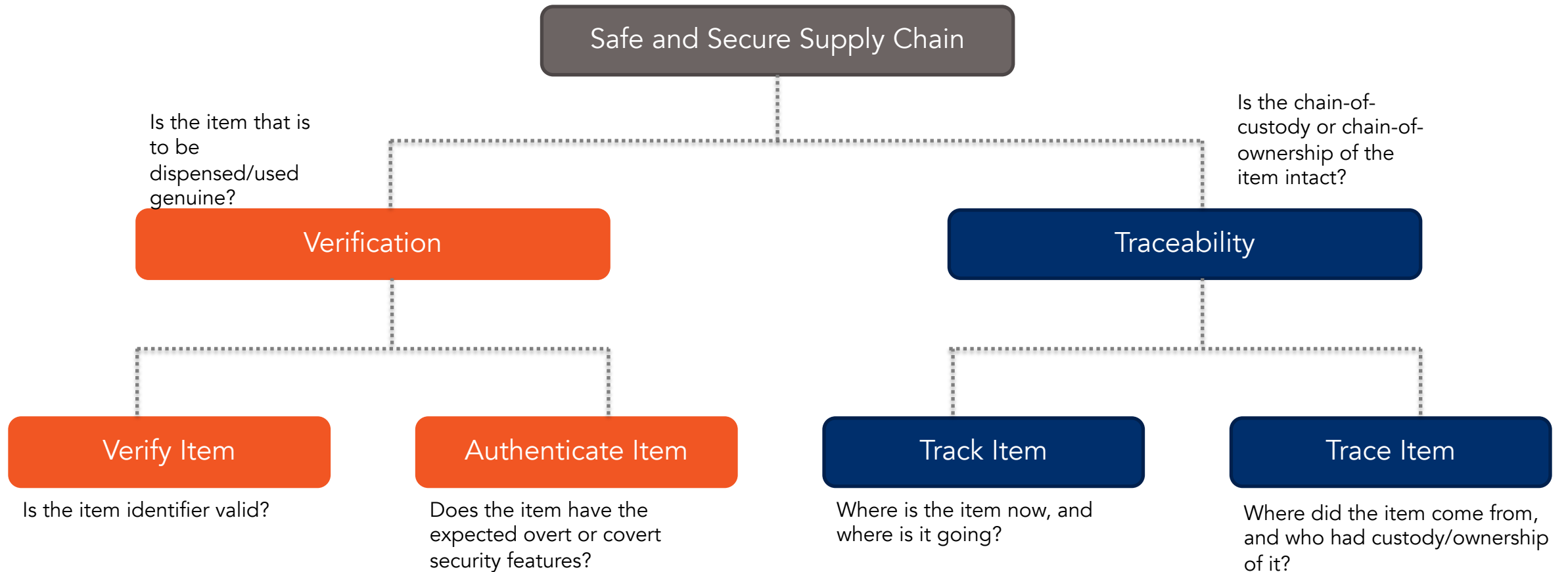
Content Source: GS1 Global Office

GS1 Standards Enable Traceability of Items in the Supply Chain

Feature	GTIN	GTIN + Batch/Lot	GTIN + Serial Number
Low-precision identification	X		
Medium-precision identification		X	
High-precision identification			X
Item exists in multiple locations at the same time	X	X	
Item exists in only one location at the same time			X
Enables inventory control		X	X
Enables anti-substandard and falsified (SF) measures			X
Enables product recall	All units of a given GTIN	All units of a given GTIN + batch/lot	Specific unit with a matching GTIN + serial number

Content Source: GSI Global Office

Different Approaches to Achieving These Objectives

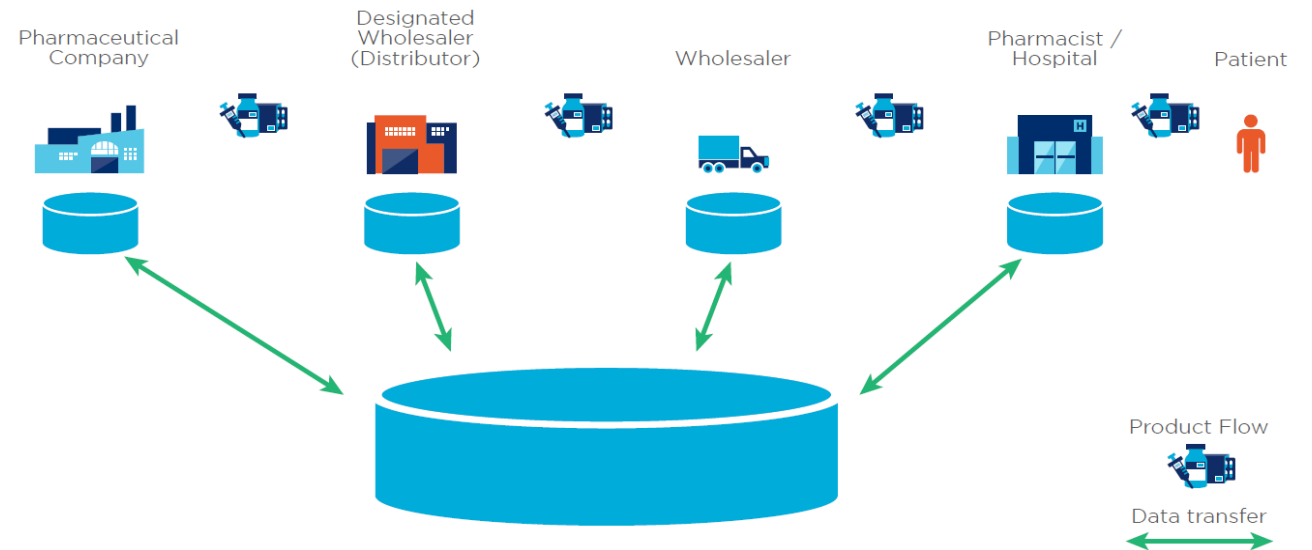


Content Source: GSI Global Office

Understanding Traceability

Traceability is the ability to **track forward** the movement through specified stage(s) of the extended supply chain and **trace backward** the history, application, or location of the

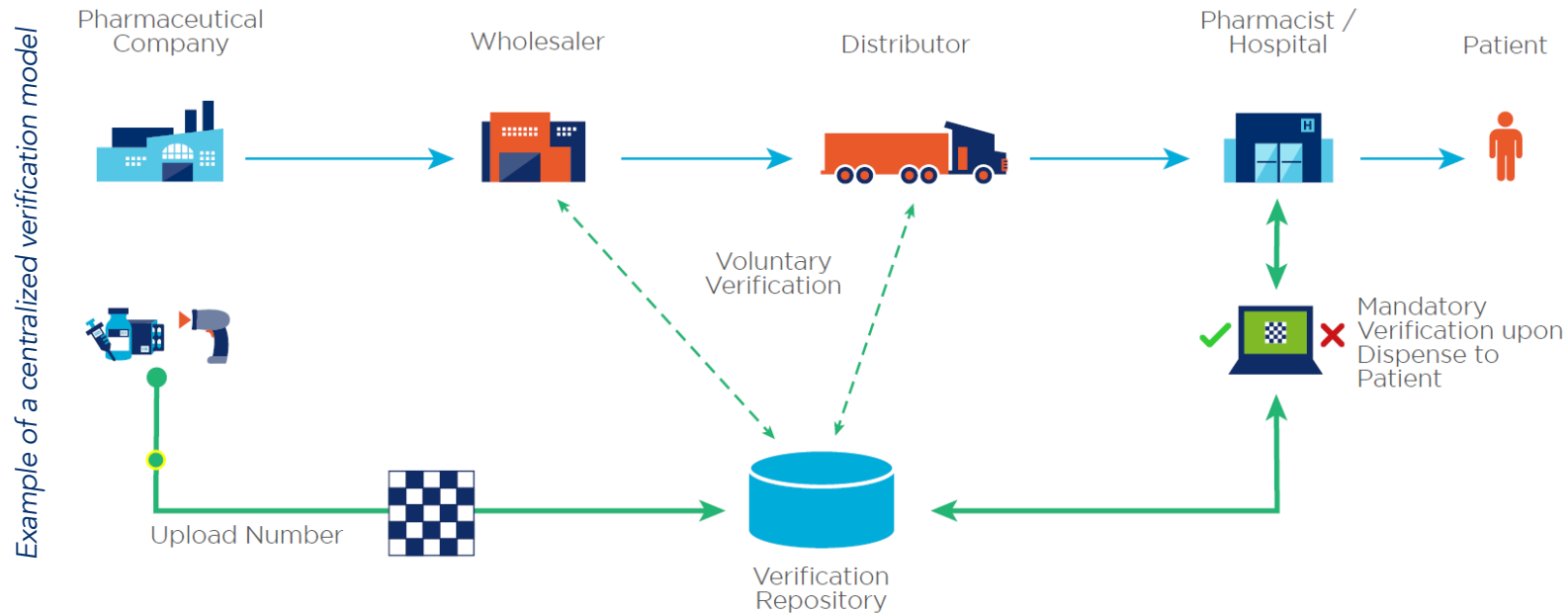
item under consideration. The scope of a traceability implementation will depend on the maturity and vision of a specific implementation. Traceability can be implemented at the batch/lot or at the serialized trade item level. In either case, fundamental to traceability is the concept that, **in parallel with the flow of the physical product, there has to be a flow of information about the product!**



Example of a centralized traceability model

Content Source: GSI Global Office

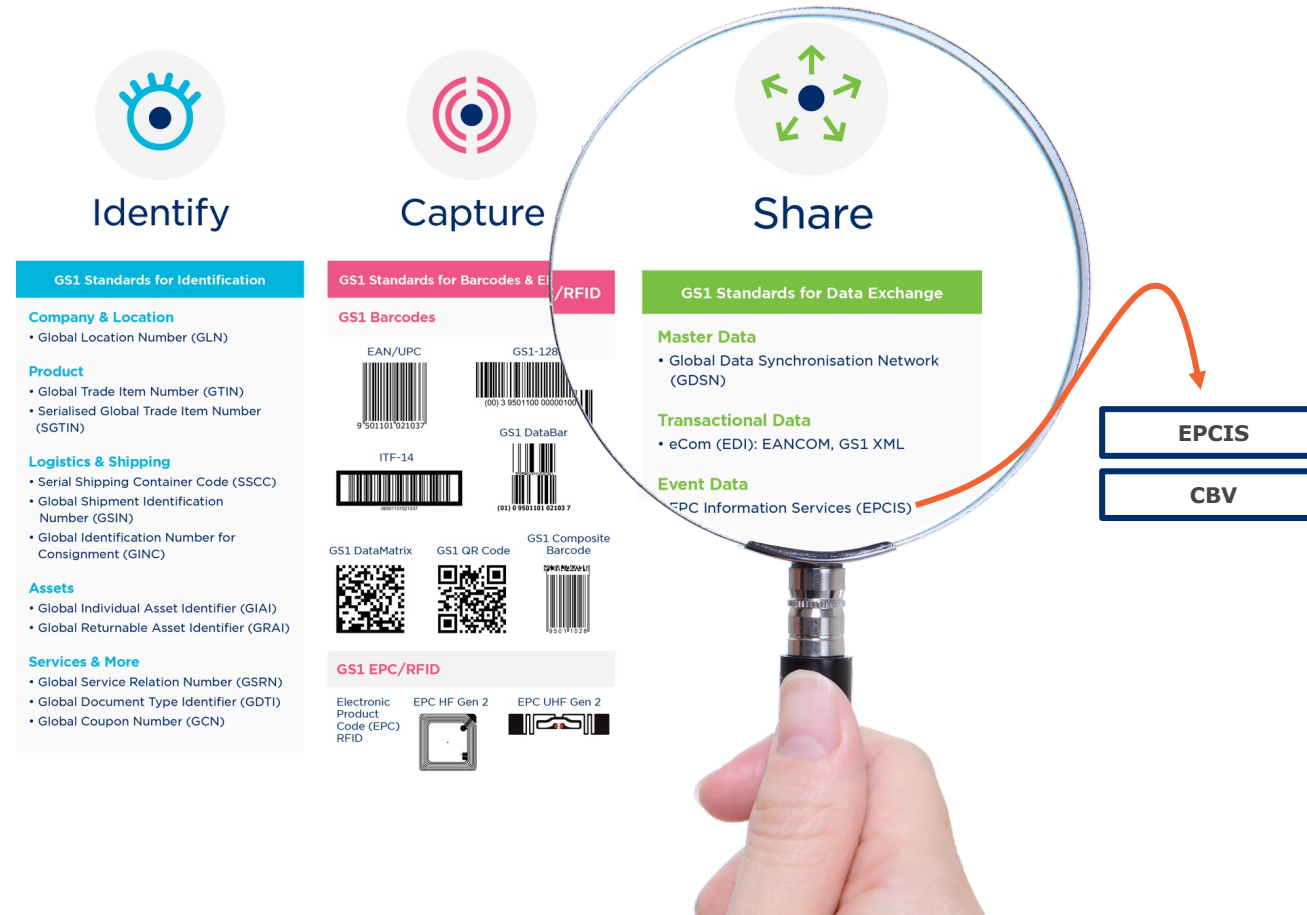
Understanding Verification



Product verification refers to checking at any single point in the supply chain that the unique identifier that is printed on the item is assigned by the product manufacturer. Countries can implement verification as part of a traceability mandate or as a [point-of-dispense](#) (e.g., check at a service delivery point) and/or [point-of-use](#) (e.g., check by the consumer or the patient) model at an end point in the supply chain.

Content Source: GSI Global Office

Electronic Product Code Information Services (EPCIS): A GS1 "Share" Standard




Content Source: GS1 Global Office

What Is EPCIS?

- A GS1 standard that enables trading partners to share information about events — physical movement and status of products — through the supply chain.
- It does not replace enterprise resource processing (ERP), warehouse management system (WMS), or Track-and-Trace system; it is a complementary layer that offers interoperability between disparate systems.
- EPCIS is intended to be used in conjunction with the GS1 Core Business Vocabulary (CBV) standard. The CBV provides definitions of data values that may be used to populate the data structures defined in the EPCIS standard.
- The use of the standardized vocabulary provided by the CBV standard is critical to interoperability and to provide for querying of data by reducing the variation in how different businesses express common intent.

EPCIS Is an Open GS1 and ISO Standard

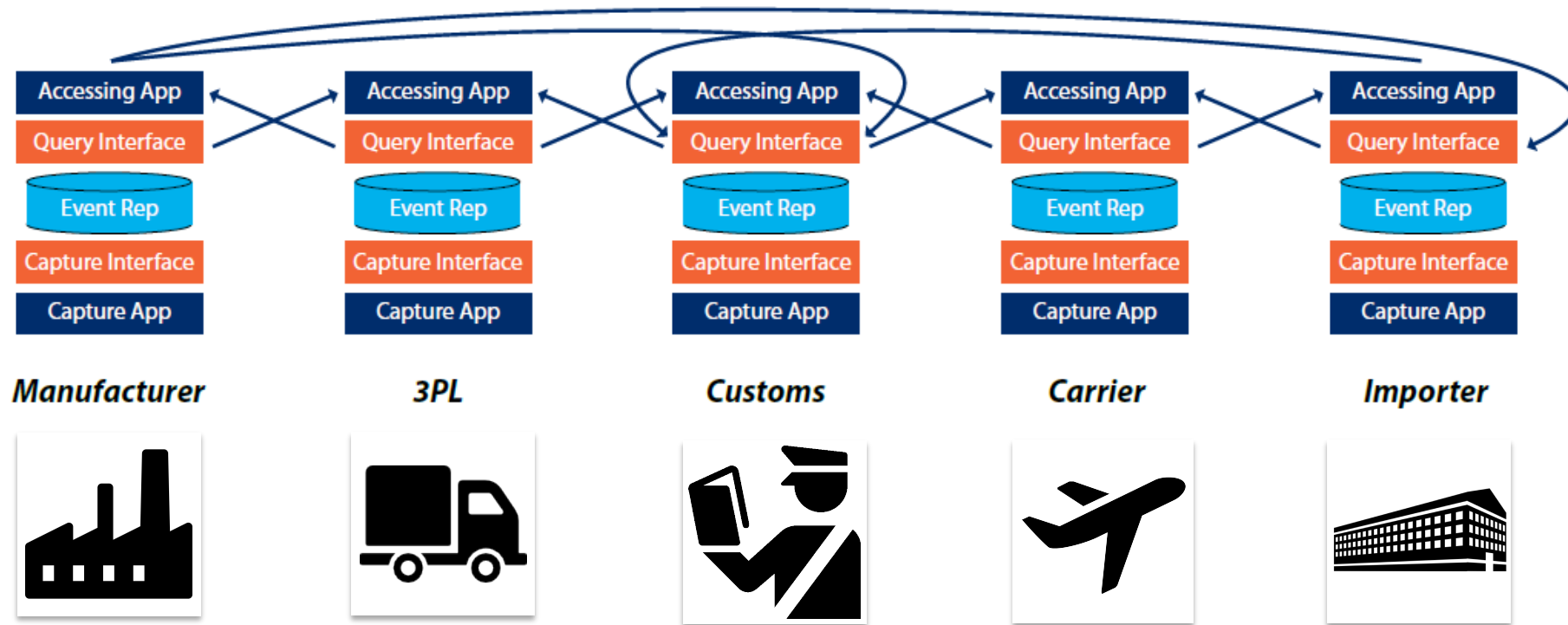
- Defines framework data model and interfaces for sharing data
- Enables services and solutions for supply chain visibility
- Data-carrier-neutral: works with Barcodes and/or RFID
- Approved as ISO/IEC 19987 
- EPCIS is an open standard, not a product or service for sale
- U.S. Federal Drug Administration draft guidance points to EPCIS as a way to **interoperably** exchange pharmaceutical traceability data
- GS1 keys identify the what and where of visibility events.

Sharing Information on Events

- **WHAT** objects are the subject of event?
 - *Individual objects (SGTIN) or groupings (GTIN + Lot/batch)*
- **WHEN** did this event take place?
 - *Date, time, time zone*
- **WHERE** did this event take place?
 - *GLN of physical location and object's subsequent whereabouts*
- **WHY** did this event take place?
 - *Business step, disposition, source/destination information*

All captured in an EPCIS repository!

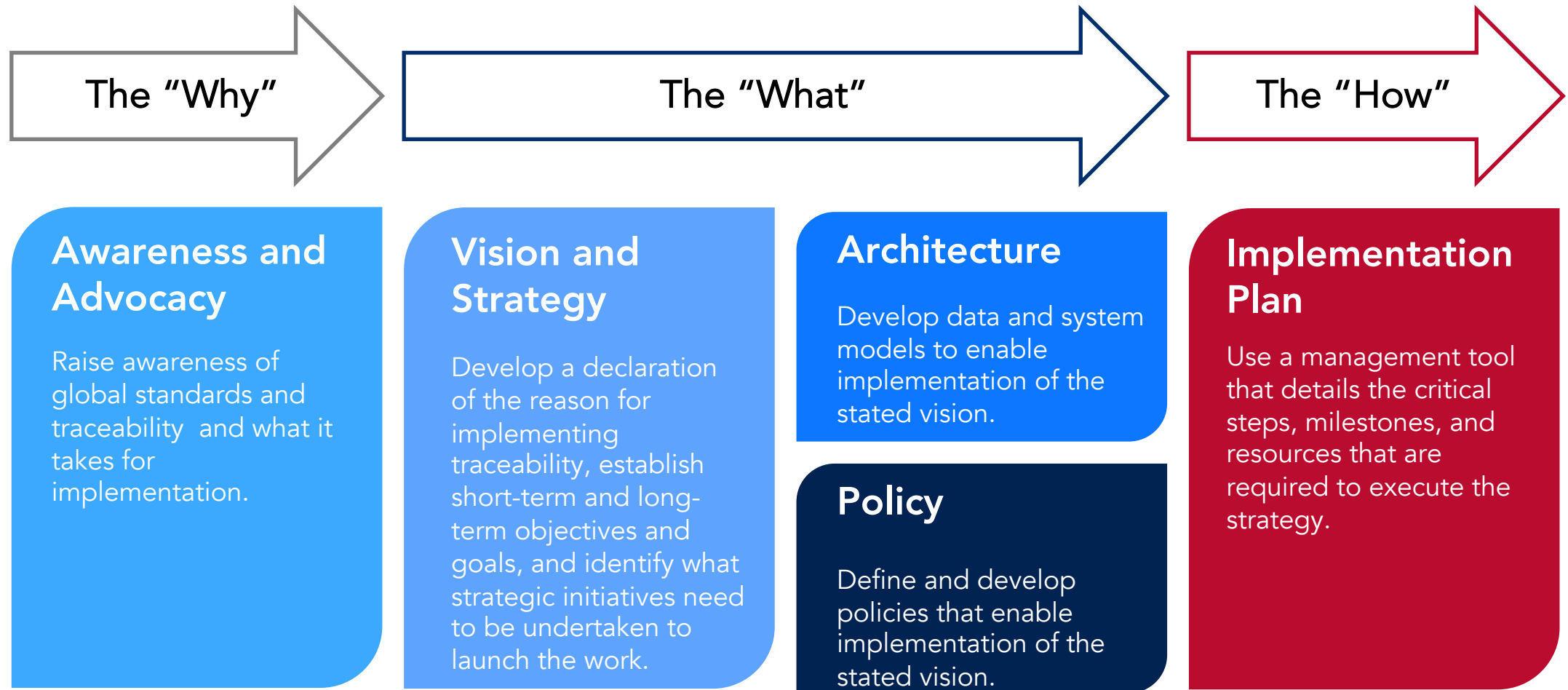
EPCIS End-to-end Data Visibility



EPCIS enables tracking and tracing AND easy sharing of event data in real-time among trading partners upstream and downstream.

Content Source: GSI Global Office

GHSC-PSM's Global Standards and Traceability Planning Framework

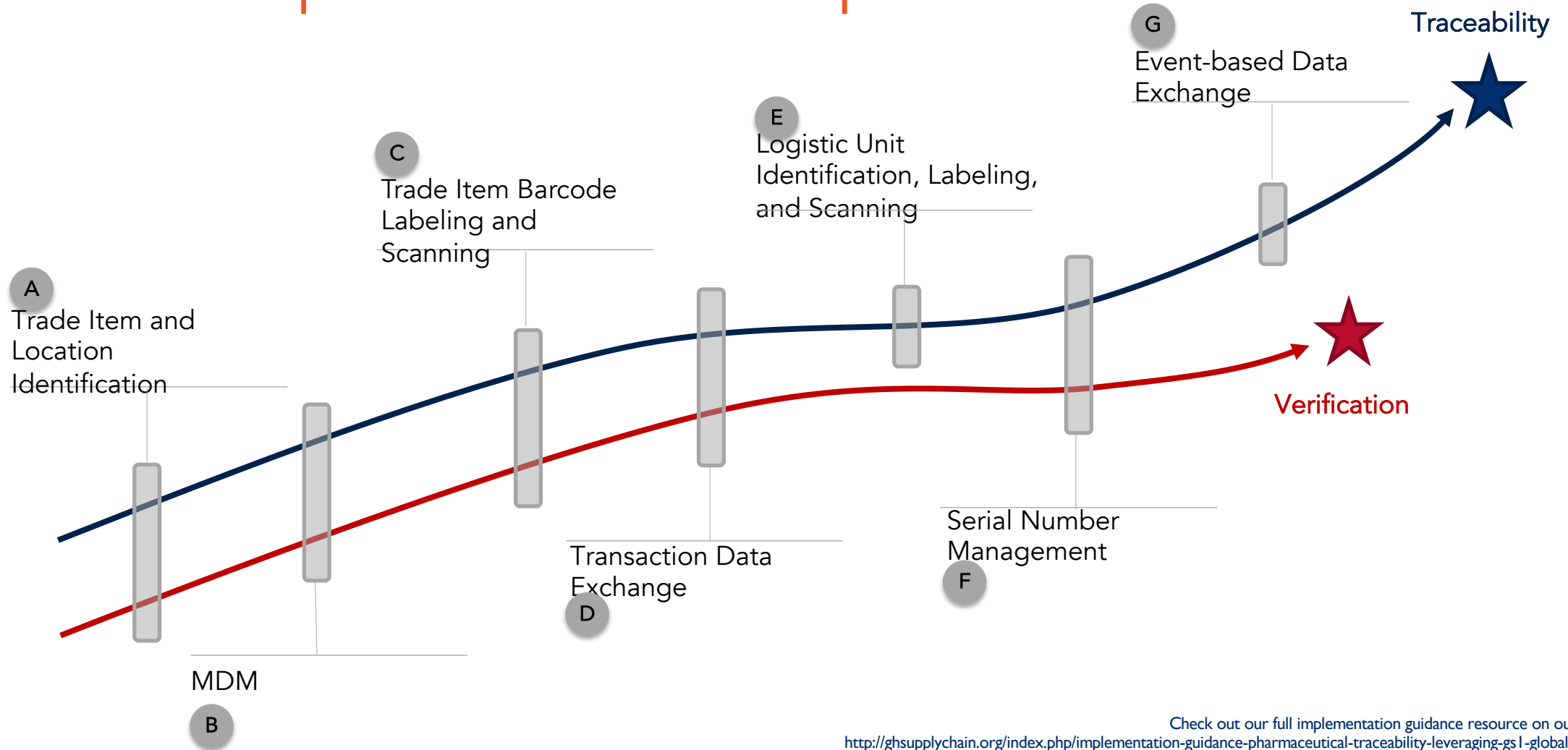


Check out our full implementation guidance resource on our website:

<http://ghsupplychain.org/index.php/implementation-guidance-pharmaceutical-traceability-leveraging-gs1-global-standards>

*Illustrative example only.
Each country will develop an implementation plan based on their vision and strategy.*

Illustrative Implementation Roadmap



Check out our full implementation guidance resource on our website:
<http://ghsupplychain.org/index.php/implementation-guidance-pharmaceutical-traceability-leveraging-gs1-global-standards>

What Does It Take? A Holistic Approach that Includes ...



Governance & Advocacy



Regulatory & Policy



Supply Chain Operations



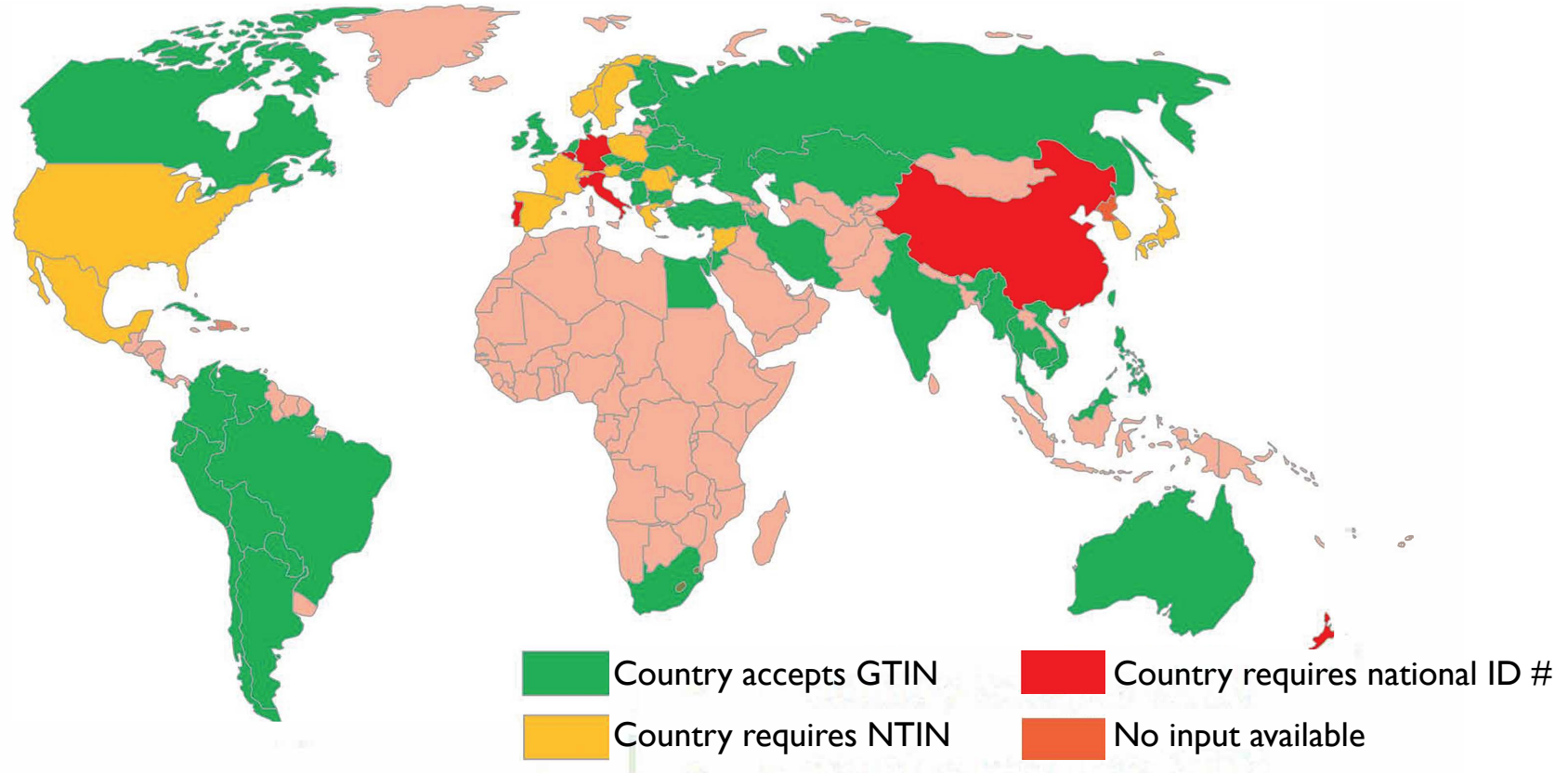
Systems & Technology



Service Delivery

GS1 Standards Around the World

Global Identification of Pharmaceuticals



Source: GSI Canada (as of July 2020)

United States Agency for International Development (USAID) GHSC Technical Assistance Footprint



August 2020

Tanzania Pilot

“Improves my work by reducing time used to count the stock during receiving or dispatching of vaccines.”

“Reduces the emergency trips, which is usually caused by inadequate vaccine record keeping.”

“The improvement of quality of data could be significant when assessing movement of stock (time) from higher levels to low levels.”

Overview

- Proving the benefits of barcoding for vaccines has been launched in region of Arusha with one vaccine from Pfizer
- Project led by PATH and supported by GAVI

Initial Findings

- Labor savings foreseen across various business processes:
 - Tracking stock movement, counting, expiry date management, and ordering (50-60%)
 - Demand planning, data cleansing, and synchronization (2-5%)
 - Reverse logistics associated with the location, identification, return, and receipt of recalled health commodities (2-4%)

Source: Presentation Brian Taliesin, PATH at GSI Healthcare Conference in Dubai, April 2016. Further reading: [LINK](#)

Nicaragua Pilot

Overview

- Main objective was to evaluate the benefit of barcode scanning on vaccine tracking and visibility
- Pfizer vaccine with GTIN, lot number, and expiry date in 2D DataMatrix
- On three different levels: from central store to regional to local
- Ministry of Health wants to extend to ALL vaccines

Results

- Adjustments reduces to 1:233 transactions
- 68 percent reduction in time needed for one transaction
- 100 percent stock visibility at all levels of the system
- Improved security with central data repository



Source: Presentation Rehana Wolfe, Pfizer at GSI Healthcare Conference in Berlin, April 2017. Further reading: [LINK](#)

Kenya — 2014 — Tender Kenya Medical Supplies Agency Barcoding Requirement



Status: Agreement between GS1 Kenya and Kenya Medical Supplies Agency

Scope: Medical commodities

Planned requirements

- Packaging level: secondary
- Data carrier: Re-labelling by Kenya Medical Supplies Agency with GS1 barcodes

Open point(s)/upcoming developments

- Ministry of Health is driving discussions to establish a traceability solution, focusing on post-market surveillance
- Ongoing discussions in the national assembly about the formation of the Food and Drug Authority

Source: Presentation Rehana Wolfe, Pfizer at GSI Healthcare Conference in Berlin, April 2017. Further reading: [LINK](#)

Rwanda

Scoping Regulation



Status: Rwanda national vision and strategy for pharmaceutical traceability endorsed by Minister of Health in June 2019

Scope: Pharmaceuticals

Planned requirements

- Requirements to be fully aligned to GS1 standard
- Stakeholder endorsement of the centralized track-and-trace model
- Planned implementation of a national product catalog for product master data in 2020

Open points/upcoming developments

- Terms of reference developed for the Traceability Steering Committee and supporting working groups
- Currently developing a phased traceability costed implementation plan
- In 2020, seek to establish of traceability architecture based on the chosen model; ongoing discussions around interoperability across existing systems in country

Presented at GSI Healthcare Conference Nigeria September 2019

Nigeria Implementation



Status: Vision and strategy for traceability developed

Scope: Pharmaceuticals

Planned requirements

- Ongoing stakeholder engagement
- Ongoing assessment of current regulations and opportunities to incorporate GS1 standards
- Planned implementation of a national product catalogue for product master data in 2020

Open points/upcoming developments

- Seeking approval of a four-year Nigeria Pharmaceutical Traceability Work Plan, which comprises a four-phased approach to traceability: enabling environment (governance and policy); MDM; AIDC implementation; and serialized traceability.

Presented at GSI Healthcare Conference, Nigeria, September 2019

Malawi

Developing Vision and Strategy



Status: Vision and strategy for traceability developed and under stakeholder review

Scope: Pharmaceuticals

Planned requirements

- Ongoing assessment of current regulations and opportunities to incorporate GS1 standards
- Planned implementation of a national product catalog for product master data in 2020

Open points/upcoming developments

- Seeking revision and input on the vision and strategy document for pharmaceutical traceability
- Focus on assessing current state of regulations, processes, data, and technology to inform future state and implementation plan

Presented at GSI Healthcare Conference Nigeria September 2019

Zambia

Policy & Implementation



Status: Vision and strategy for traceability developed and under stakeholder review

Scope: Pharmaceuticals

Planned requirements

- Ministry of Health/ICT seeks to implement national drug registry in 2021, assessing opportunities to use GLN in facility/vendor registries

Open points/upcoming developments

- Received stakeholder feedback on vision and strategy for pharmaceutical traceability; under final review and will seek endorsement from Ministry of Health
- Medical Stores Limited currently implementing internal barcoding system and seeking opportunities to leverage GS1 data carriers from manufacturers
- Opportunity to reassess regulatory frameworks in support of driving standardization
- Zambian Medicine Regulatory Authority has also drafted a policy to include GLNs as a requirement at the point of submission for registration of dossiers that are awaiting signoff by the minister

Presented at GSI Healthcare Conference, Nigeria, September 2019

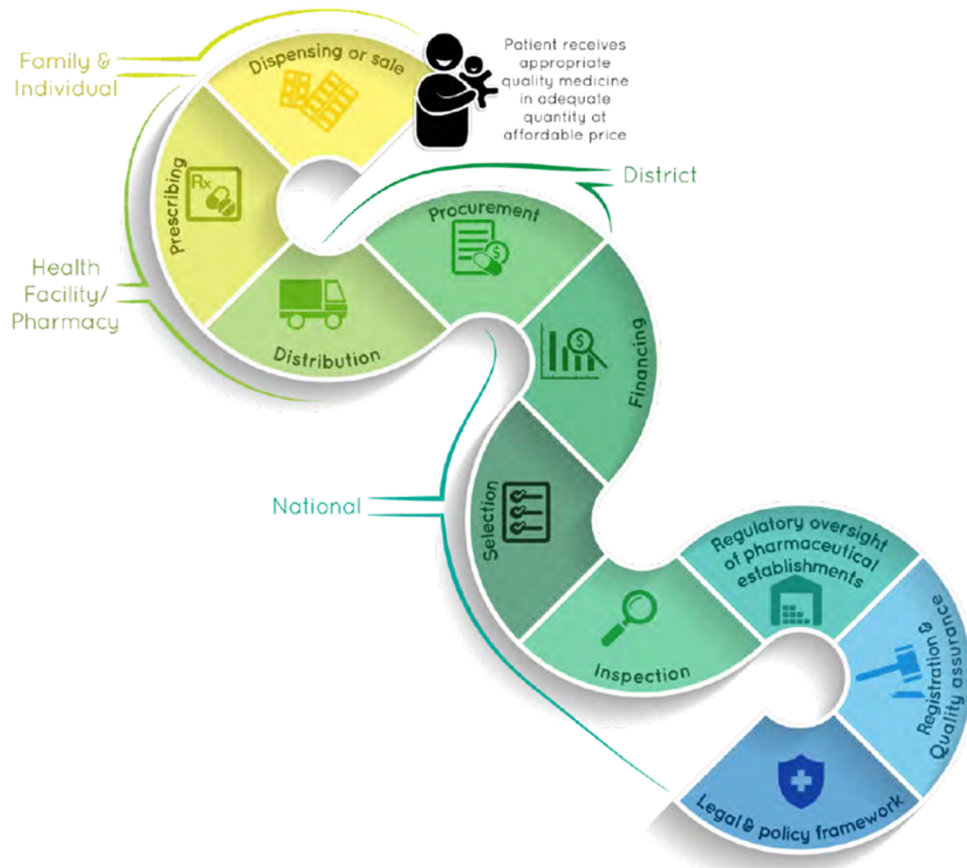
Use Case: Ethiopia

Slides from Mr. Teddy Berihun, Senior Health Information Systems Advisor, USAID Ethiopia during GS1 Healthcare Conference in Lagos, 2019





The focus of Ethiopia's regulatory system and supply chain is to consistently get quality products to people



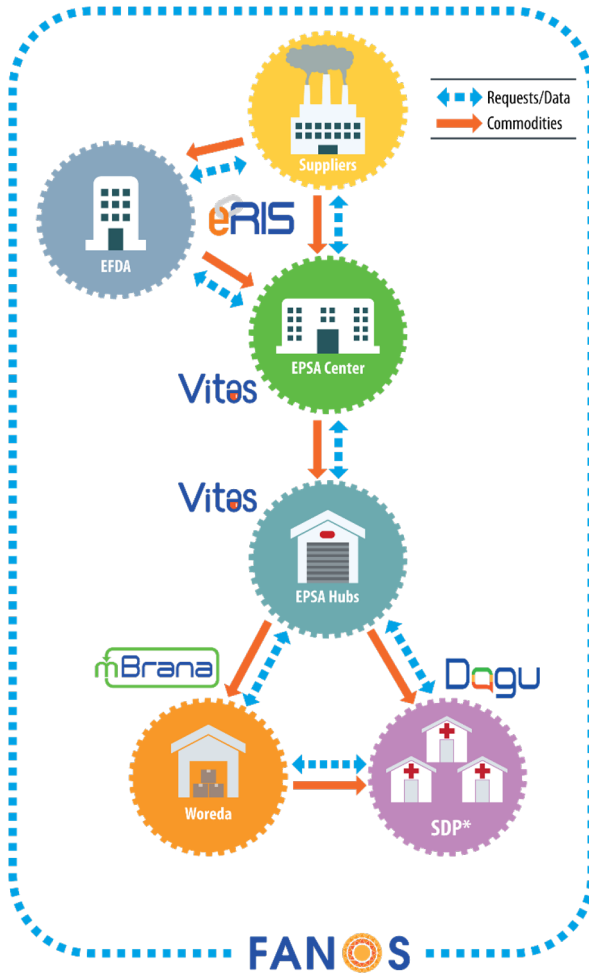
Infographic Credit: Global Financing Facility

“Much of the [world’s] burden of **disease** can be prevented or cured with **known, affordable technologies**. The problem is getting **drugs, vaccines, information** and other forms of prevention, care or treatment—**on time, reliably, in sufficient quantity and at reasonable cost**—to **those who need them.**”

— World Health Organization



A suite of information systems support the exchange of information throughout the supply chain



* Service Delivery Points (hospitals, clinics, health posts)

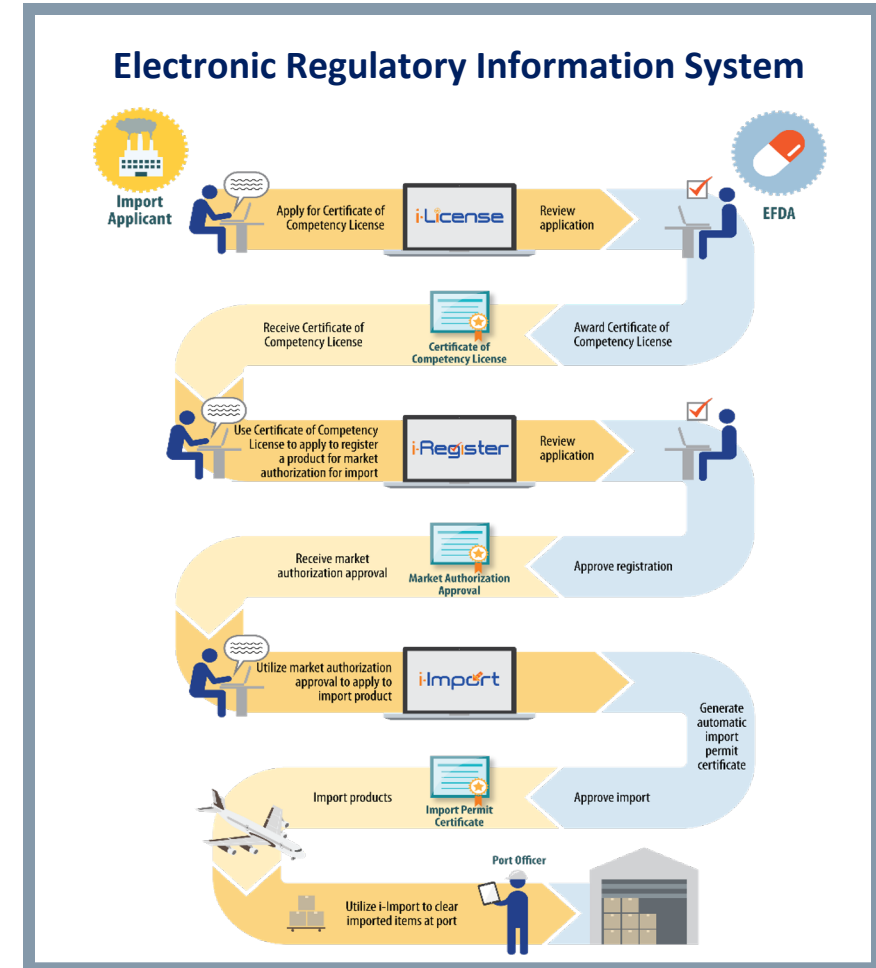
An overview of Ethiopia's supply chain:

- **110+ million** Ethiopians
- **21,000+** unique health commodities
- **3,900+** facilities and **18,000+** health posts
- **194+** unique importers
- **837** unique supplier license holders
- Value of drugs approved for import by local importers **USD 225,744,174**

A suite of information systems support the exchange of information throughout the supply chain

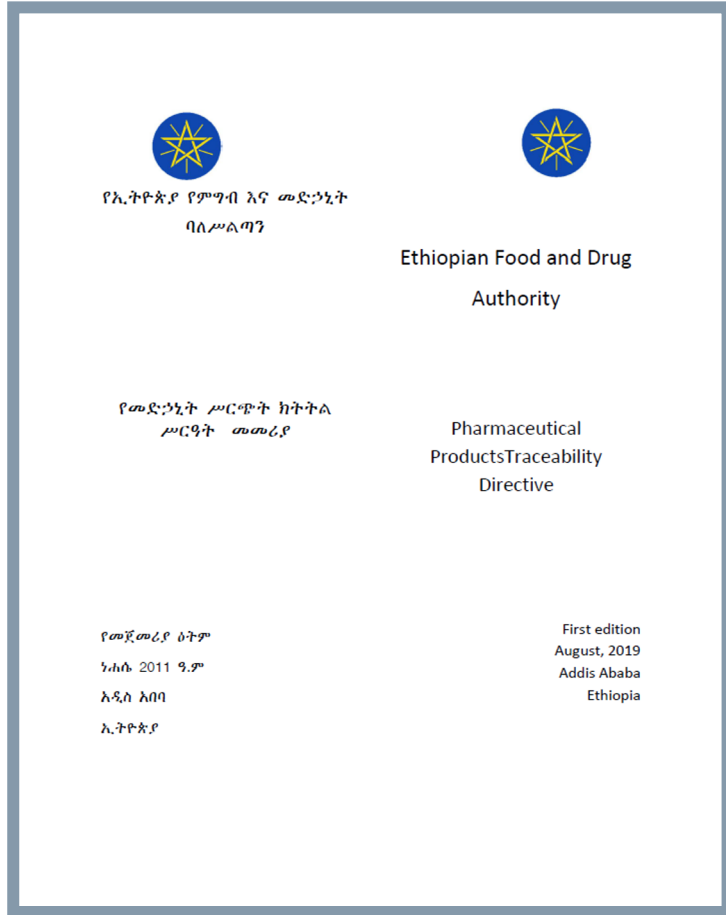
EFDA is building a technology infrastructure with the **Electronic Regulatory Information System (eRIS)** that support end to end supply chain visibility to provide one unbroken chain of action and information:

- **i-License** – used to apply for a certificate of competency to register and import products.
- **i-Register** – used to manage the market authorization process where an applicant seeks to register a medical product.
- **i-Import** – used to manage the import process for medical products, once registered in Ethiopia.





In addition to technology, traceability is being supported by policy



Pharmaceutical Products Traceability Directive:

1. To protect the public from falsified, substandard, unregistered, expired, recalled or otherwise harmful pharmaceuticals
2. To improve efficiency in the pharmaceutical supply chain regulation
3. To develop a system in which the identification, authentication and traceability of a pharmaceutical product is guaranteed from manufacturers to importers, wholesalers, healthcare providers and retail outlets, and other points of dispense, and;
4. To enforce the mandatory requirements and the implementation of identification, authentication and traceability of pharmaceutical products.



Scope of the *Pharmaceutical Products Traceability Directive*

- All pharmaceutical products registered in Ethiopia which are intended for human use; and
- All supply chain actors involved in the physical movement of pharmaceutical products, including but not limited to:
 - Manufacturers
 - Importers
 - Wholesalers
 - Healthcare providers
 - Retail outlets and other points of dispensing





The *Pharmaceutical Products Traceability Directive* is being implemented in four phases

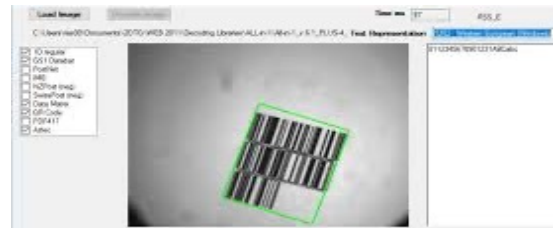
Phase 1

Unique identification (GS1) + labelling requirements



Phase 2

Share standardized master product and location data



Phase 3

Batch traceability



Phase 4

Serialization/traceability of unique items



GTIN 00314141999995
SN 10000000234
EXP 25 JAN 2015
LOT 987654321GFEDCBA

McKinsey Quantifies Supply Chain Issues in Health Care



The McKinsey report, “Strength in unity: The promise of global standards in healthcare,” highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in health care.

The report is available at
<http://www.gs1.org/healthcare/mckinsey>

Huge Cost Savings and Patient Safety Benefits When Adopting a Single Global Standard in Health Care

- “Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities.”
- “Rolling out such standards-based systems globally could prevent tens of billions of dollars’ worth of counterfeit drugs from entering the legitimate supply chain.”
- [We] “estimate that healthcare cost could be reduced by \$40 billion-\$100 billion globally” with the implementation of global standards.
- “Adopting a single set of global standards will cost significantly less than two” — between 10 percent and 25 percent lower cost to stakeholders.

Source: McKinsey report, “Strength in unity: The promise of global standards in healthcare,” October 2012

Ultimately, It's All About ...

Credit: Maggie Hallahan



Photo credit: Wendy Tactuk, courtesy of CapacityPlus and IntraHealth International



... PATIENT SAFETY!

Resources

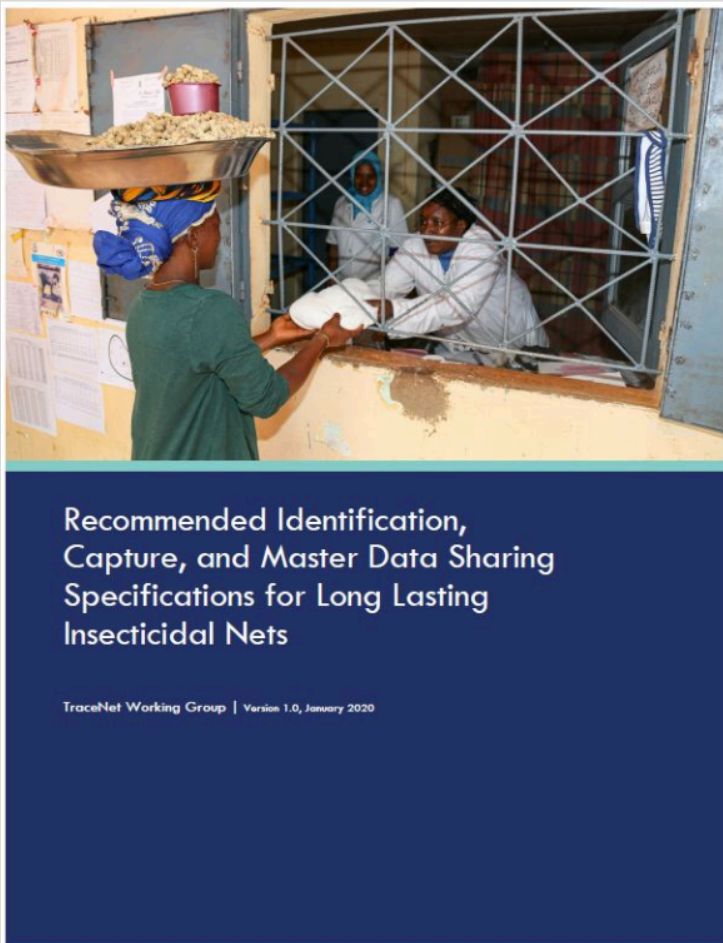
Joint Donor Guidance on Data Standards for Suppliers



- Document is endorsed by Global Drug Facility (Stop Tuberculosis), Global Fund, UNFPA, United Nations Development Programme, and USAID/GHSC-PSM
- Collective group of agencies referred to as *international procurement agencies*
- Guidance on identification, data capture, and data sharing aligned with global standards
- Agency-specific timelines for implementation are included in Annex C
- Currently disseminated by respective agencies to suppliers through their own channels

Available: <http://ghsupplychain.org/index.php/global-standards-technical-implementation-guideline-global-health-commodities-v21>

Recommended Identification, Capture, and Master Data Sharing Specifications for Long-Lasting Insecticidal Nets



- Currently circulated on social media (Twitter, LinkedIn, etc.)
- Document covers new standards for identification, data capture, and data sharing to which long-lasting insecticidal nets manufacturers will be held accountable

Available: <http://ghsupplychain.org/TraceNet-Recommendations>

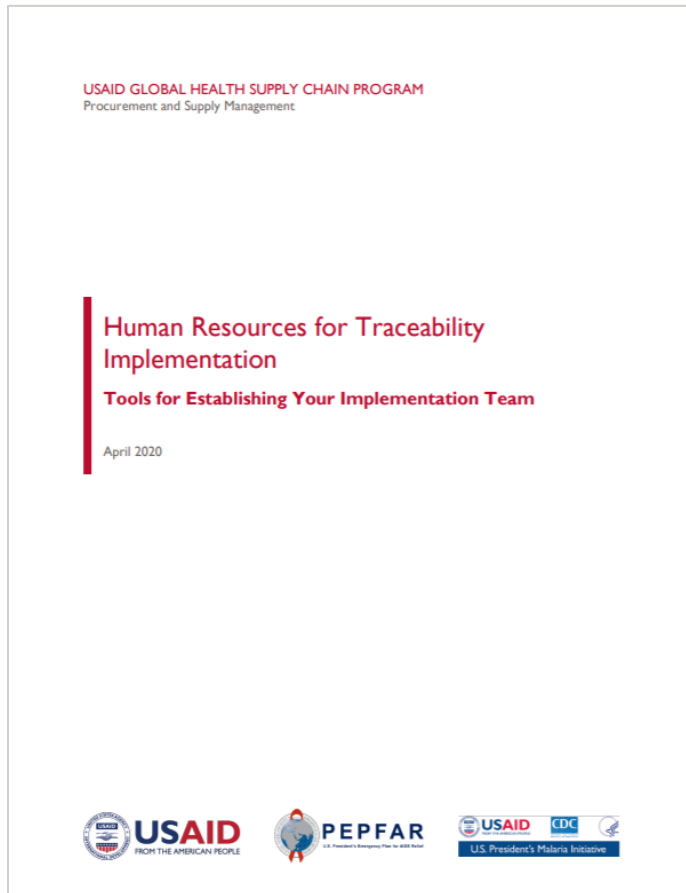
Product Master Data Management Reference Guide



- Guidance on the identification, sharing, and management of accurate product information throughout the product lifecycle in the supply chain.
- Accompanied by a Product MDM Toolkit.
- Contains normative references to standards and good practices of product MDM with a specific focus on GS1 global standards for health care supply chains.
- More information at <http://ghsupplychain.org/globalstandards>

Available: <https://www.ghsupplychain.org/PMDMReferenceGuide>

Human Resources for Traceability Implementation



- The following tools have been designed for country programs and national authorities to adopt and adapt in resourcing in-country traceability implementation strategies:
 - Notional organizational diagram
 - Primary responsibilities and required skill set for the roles identified in the notional organizational diagram
 - Detailed job descriptions for traceability project manager, regulatory specialist, and supply chain MDM specialist roles
- Available in English and French

Available: <https://www.ghsupplychain.org/GlobalStandardsRoleDescriptions>

GS1 Supply Chain Information System (SCIS) Requirements

- The following tools have been designed for country programs that seek to procure SCISs that are compliant with GS1 standards:
 - GS1SCIS Requirements, including functional and technical requirements that form the basis for how specific SCIS provide GS1 capabilities
 - The GS1 SCIS Requirements Narrative that introduces the SCIS Requirements and how they can be used as a starting place for specific procurements across the SCIS spectrum



USAID
FROM THE AMERICAN PEOPLE

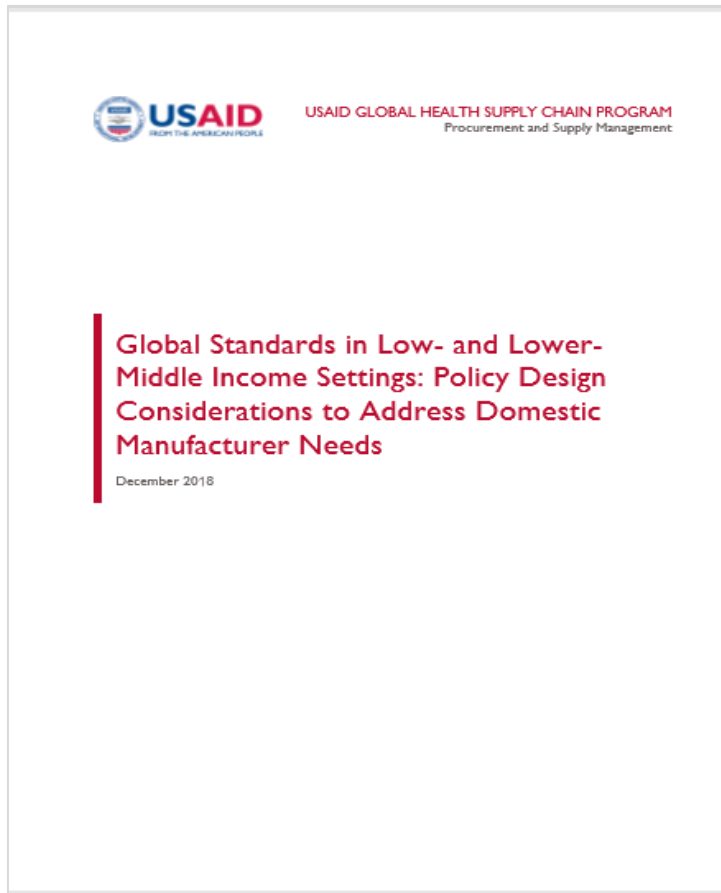
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

GS1 SCIS Requirements Narrative

Version 1, July 2020

Available: <http://www.ghsupplychain.org/GS1SCISReqs>

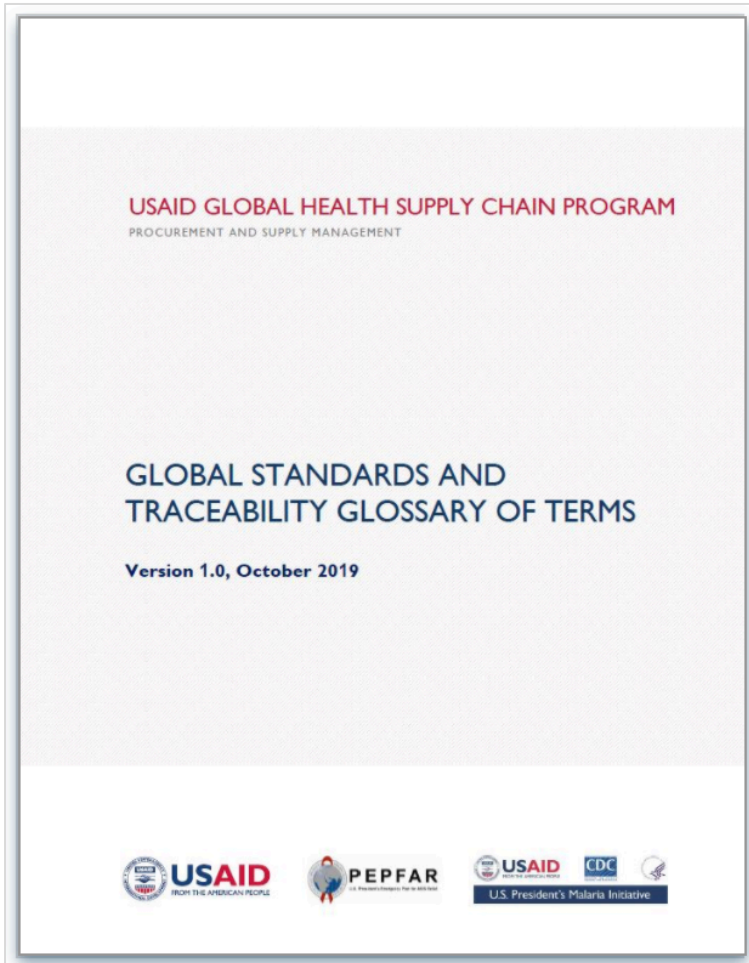
Global Standards in Low- and Lower-Middle Income Settings: Policy Design Considerations to Address Domestic Manufacturer Needs



- Provides guidance and strategic considerations for national-level policymakers in low- and lower-middle income settings who are developing policies for pharmaceutical traceability to address the needs of domestic pharmaceutical manufacturers.
- Utilizes a case study approach to provide considerations for legislative design for traceability implementation.
- Explores people, process, and technology impact on local manufacturers on traceability implementation.

Available: https://www.ghsupplychain.org/sites/default/files/2019-09/Global_Standards_Business_Case.pdf

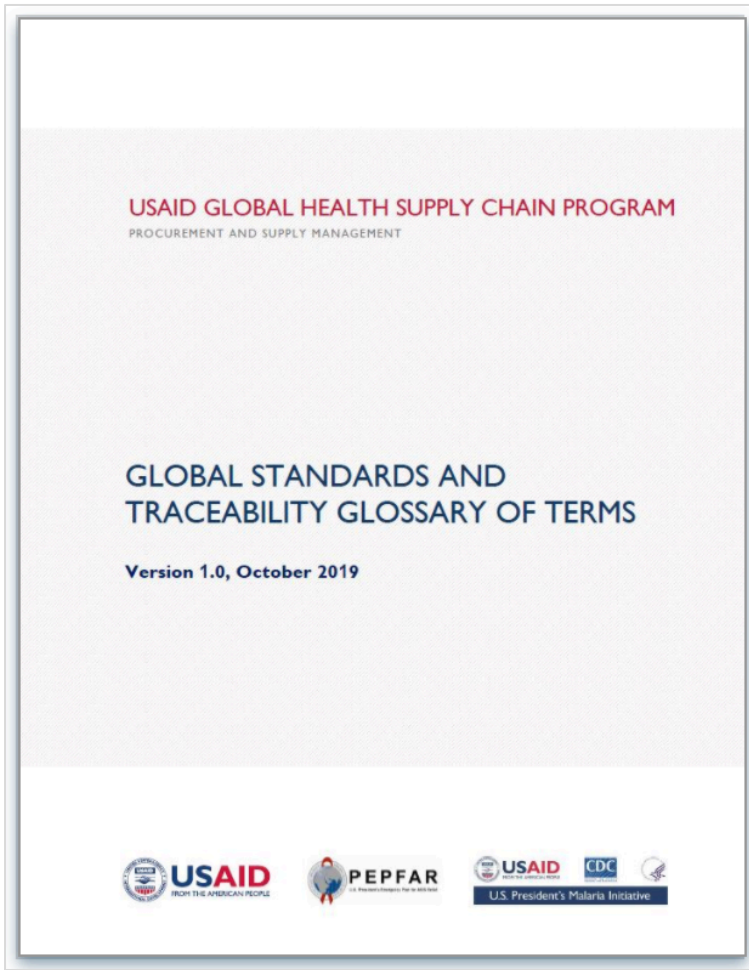
Business Case for the Implementation of Global Standards



- Document presents the business case for adoption and implementation of global standards product identification, location identification, and product master data.
- Discusses the current approach to product identification, party/location identification, and MDM in the global health supply chain.
- Provides guidance on identification, data capture, and data sharing that is aligned with global standards.

Available: https://www.ghsupplychain.org/sites/default/files/2019-09/Global_Standards_Business_Case.pdf

Global Standards and Traceability Glossary of Terms

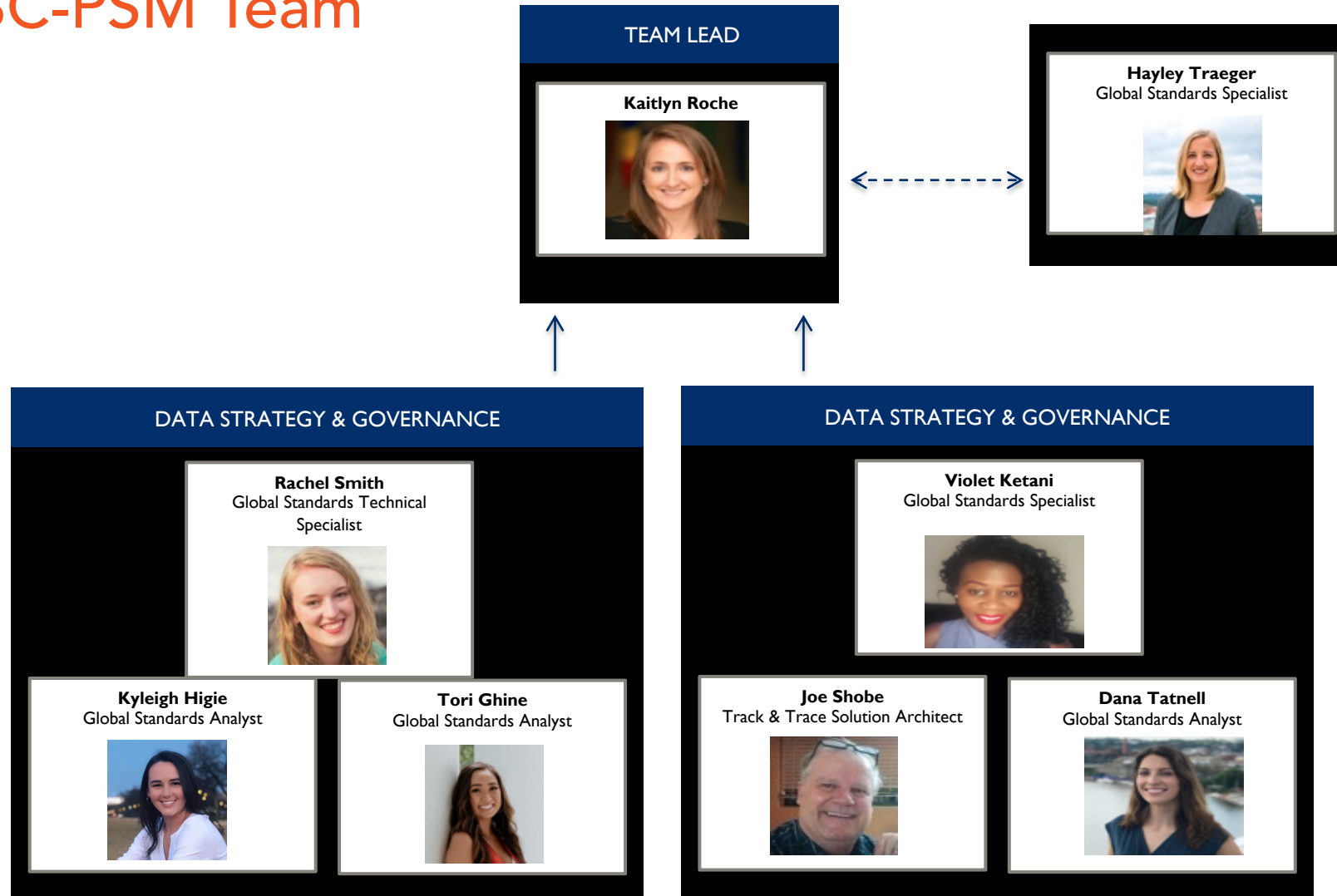


Term	Definition
automatic identification and data capture (AIDC)*	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.
barcode*	A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.
barcode verification*	The assessment of the printed quality of a barcode based on International Organization for Standardisation (ISO)/International Electrotechnical Commission (IEC) standards using ISO/IEC-compliant bar code verifiers.
batch/lot*	The batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
brand owner*	The Organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the GTIN.
classification	A form of cataloguing, or identifying, products that can be defined as a process for grouping products into categories based on an understanding of the essential properties and relationships between them. A classification system is used to group like products such as medical devices versus pharmaceutical drugs. Example classification systems are UNSPSC, GPC, eClass, and ATC.
check digit*	A final digit calculated from the other digits of some GS1 identification keys. This digit is used to check that the data has been correctly composed. (See GS1 check digit calculation.)
concatenation*	The representation of several element strings in one barcode.
data architecture	Data architecture is composed of models, policies, rules, or standards that govern how data is stored, managed, and utilized in an information system.
data governance	The development, execution, and supervision of policies, programs, and practices that standardize, collect, control, protect, deliver, and enhance the value of data and information assets.
data synchronization	The process of maintaining the consistency and uniformity of data instances across all consuming applications and storing devices.
Data Matrix*	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
Global Location Number (GLN)*	The GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.
Global Trade Item Number* (GTIN)*	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and check digit.
GS1	A neutral, not-for-profit, global Organization that develops and maintains the most widely used supply chain standards in the world.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

Available: <https://www.ghsupplychain.org/glossaryofterms>

GHSC-PSM Team



This deck is supported by materials prepared by GS1. GS1 is a not-for-profit organization that develops and maintains global standards for business communication.

The USAID GHSC-PSM project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security.

We support USAID programs and presidential initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, and population and reproductive health commodities.

Acronyms

Acronym	Definition	Acronym	Definition
AI	GS1 application identifier	GPO	Group Purchasing Organization
AIDC	automatic identification and data capture	GTIN	global trade item number
CBV	core business vocabulary	MDM	master data management
DI&I	data integration and interoperability	SCIS	supply chain information system
EPCIS	electronic product code information services	SSCC	serial shipping container code
ERP	Enterprise resource processing	UOM	Unit of measure
GDSN	global data synchronization network	UNFPA	United Nations Population Fund
GHSC-PSM	USAID Global Health Supply Chain Program–Procurement and Supply Management project	USAID	United States Agency for International Development
GLN	global location number	WMS	warehouse management system