



Implementation of Global Standards for Traceability in Global Health

Lack of standards in daily life is inefficient and annoying...



..in healthcare, it is inefficient and dangerous!



Inconsistent identifiers necessitate slow and manual mapping exercises

System Type	Item ID	Item Name for 2-Rod Implant(s)
Country A - Warehouse Management System	PRH0010	Jadelle 2x75mg rods, Pack of 10 Pairs
Country A - Internal Stock Report	FP003700	Jadelle implant (levonorgestrel 75mg) (Piece)
Country A - LMIS	NA	Jadelle, Implant set
Country B - Drug Register	3085	Indoplant (Contraceptive Implant) / Levonogestrel 75mg
	4439	Zarin Sino II Implant / Levenorgestrel 75mg
Country B - LMIS	RH0025	Trocar, Sterile For Jadelle Insertion / Pack of 10
	RH0005	Levonogestrel Implant Contraceptive 10 rods, 750mcg/rod, Sub-dermal / 1 Implant
Procurer A	100130GYV01S03W (English/Spanish), 100130GYV01S08P (English/French)	Levonorgestrel 75 mg/Rod w/ Trocar, 5 Year Efficacy, 2 Rod Implant, 1 Each [Bayer] [Jadelle] / English/Spanish
	103915GYV01S2C7 (English/French) 103915GYV01S2CA (English/Portuguese) 103915GYV01S2CB (NAFDAC) 103915GYV01S2CC (Tailored PIL) 103915GYV01S2CD (Zambia Registration)	Levonorgestrel 75 mg/Rod w/ Trocar, 3 Year Efficacy, 2 Rod Implant, 1 Each [Shanghai Dahua] [Levoplant]
Procurer B	LNG_IMPL_75MG	Levonorgestrel 75mg x 2
Donor Coordination Tool	1001	Levonorgestrel 75mg/rod, 2 Rod Implant, 3 Year Efficacy
	1002	Levonorgestrel 75mg/rod, 2 Rod Implant, 5 Year Efficacy

Manual entry causes delays and mistakes

Manual vs automated data entry

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

versus

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

...to...

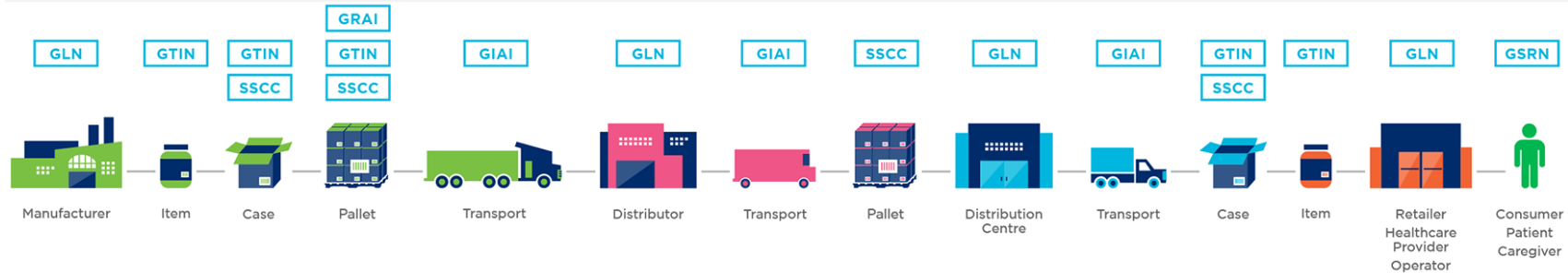
1 error in 10,500,000 on the high end (2D/Matrix symbologies)



GS1 is a system of global standards to enable traceability

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

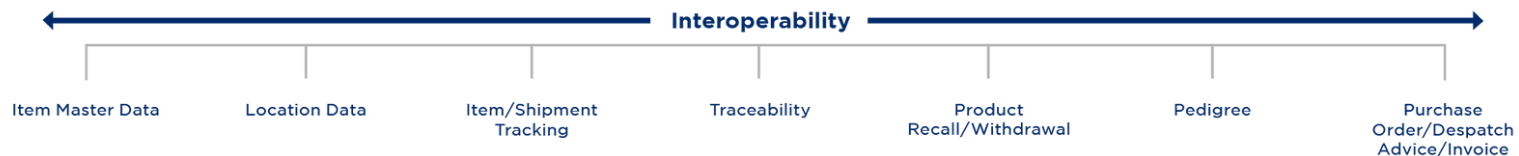
GS1 Barcodes



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)





What do we seek to achieve through implementing global data standards?

Vision

To enable identification of every item procured at every point in the supply chain, through administration to the patient

Goal

To enable a secure and efficient supply chain from source through to service delivery

Objectives

- To enable end-to-end data visibility and traceability
- To identify and implement supply chain efficiencies
- To ensure supply chain security
- To increase patient safety

Implementing traceability is a complex endeavour



Governance & Advocacy



Regulatory & Policy



Supply Chain Operations



Systems & Technology



Service Delivery



GHSC-PSM's leadership in global standards & traceability



Global Supply Chain

Mandated standard identification, labeling, and master data synchronization for all pharmaceuticals, medical devices, sterile kits, and reagents



Donor Coordination

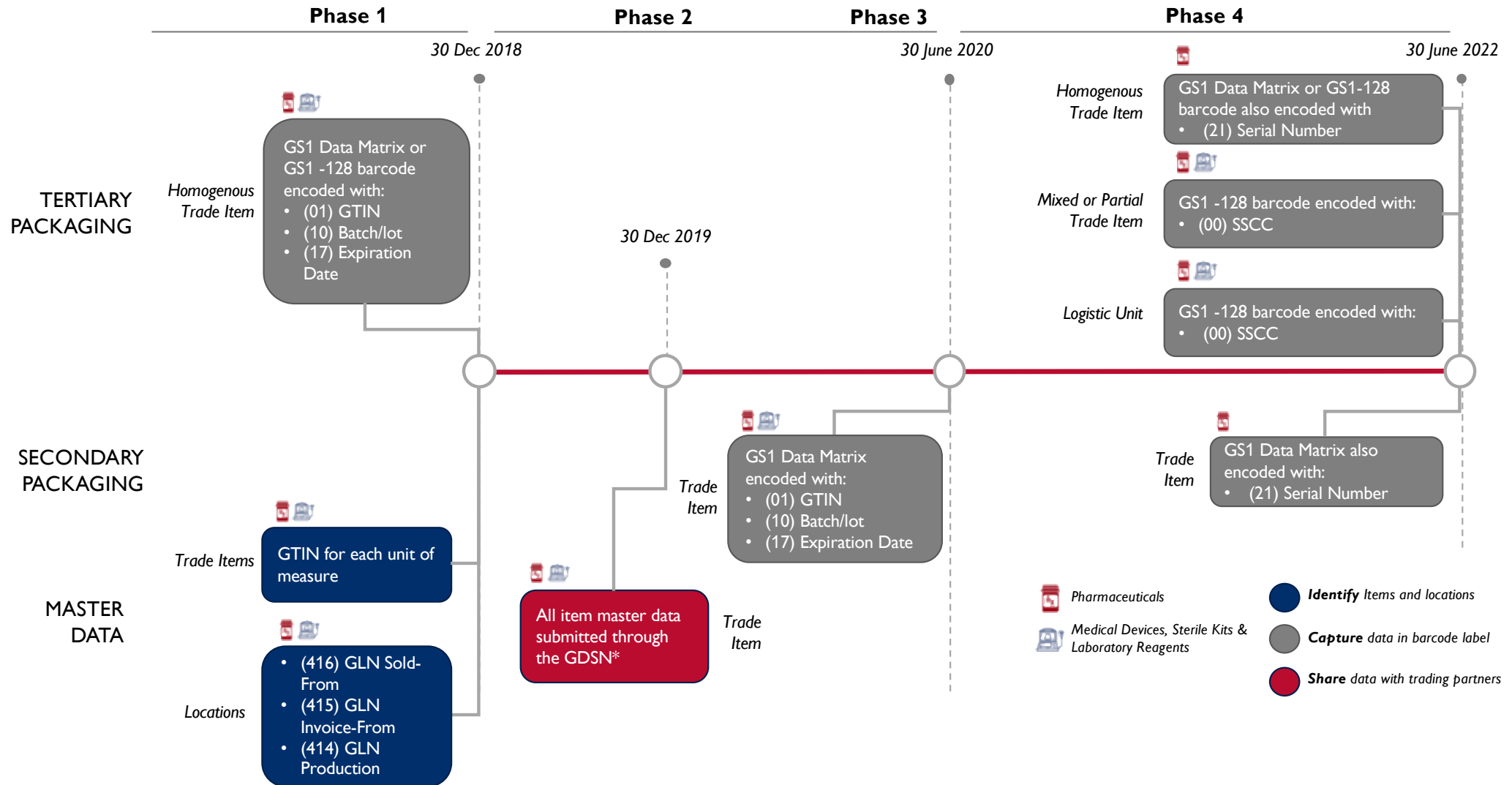
Convened a global health donor working group to build consensus and align requirements between procuring organizations



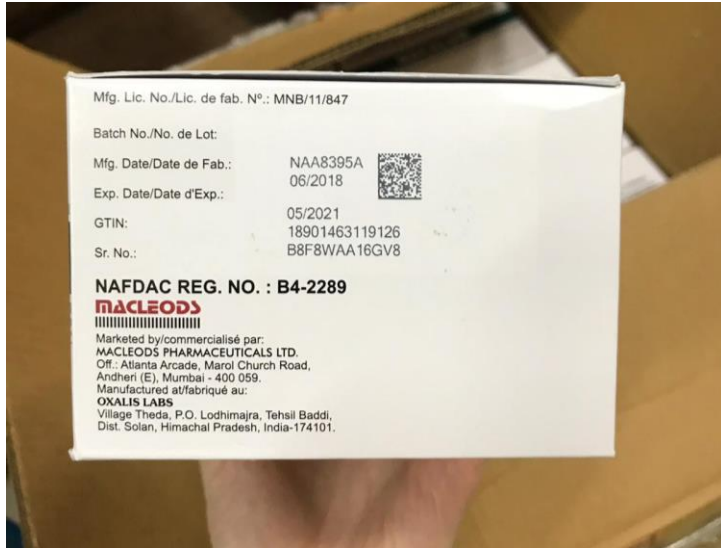
Country Implementation

Developed a set of frameworks and tools to aid stakeholders in planning and implementing a successful traceability vision

Compliance requirements in the USAID/GHSC-PSM supply chain

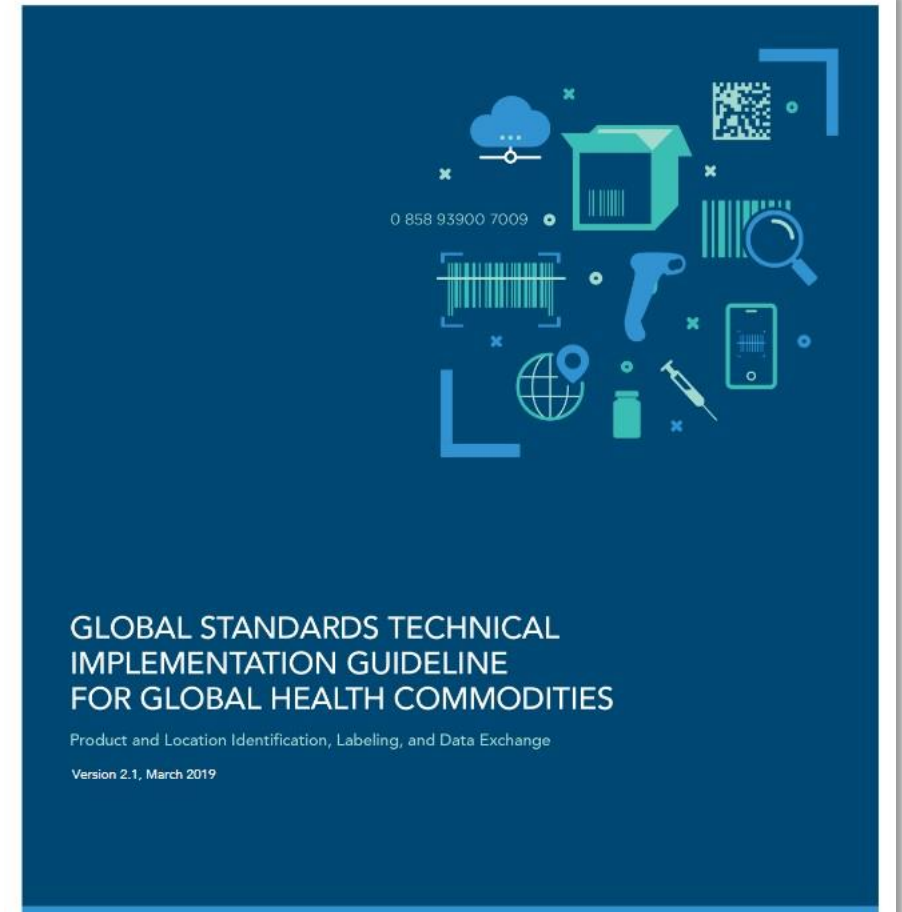


Standardized identifiers available on product today



Joint donor guideline

- Single primary reference document for technical requirements to meet requirements for implementation of global standards for product and location identification, labeling, and data exchange
- Endorsed by the Global Drug Facility/StopTB, Global Fund, UNDP, UNFPA, and USAID



Stop TB Partnership
GLOBAL DRUG FACILITY

TheGlobalFund

UNFPA

UN
DIP

USAID
HEALTHY PEOPLE, HEALTHY PLANETS

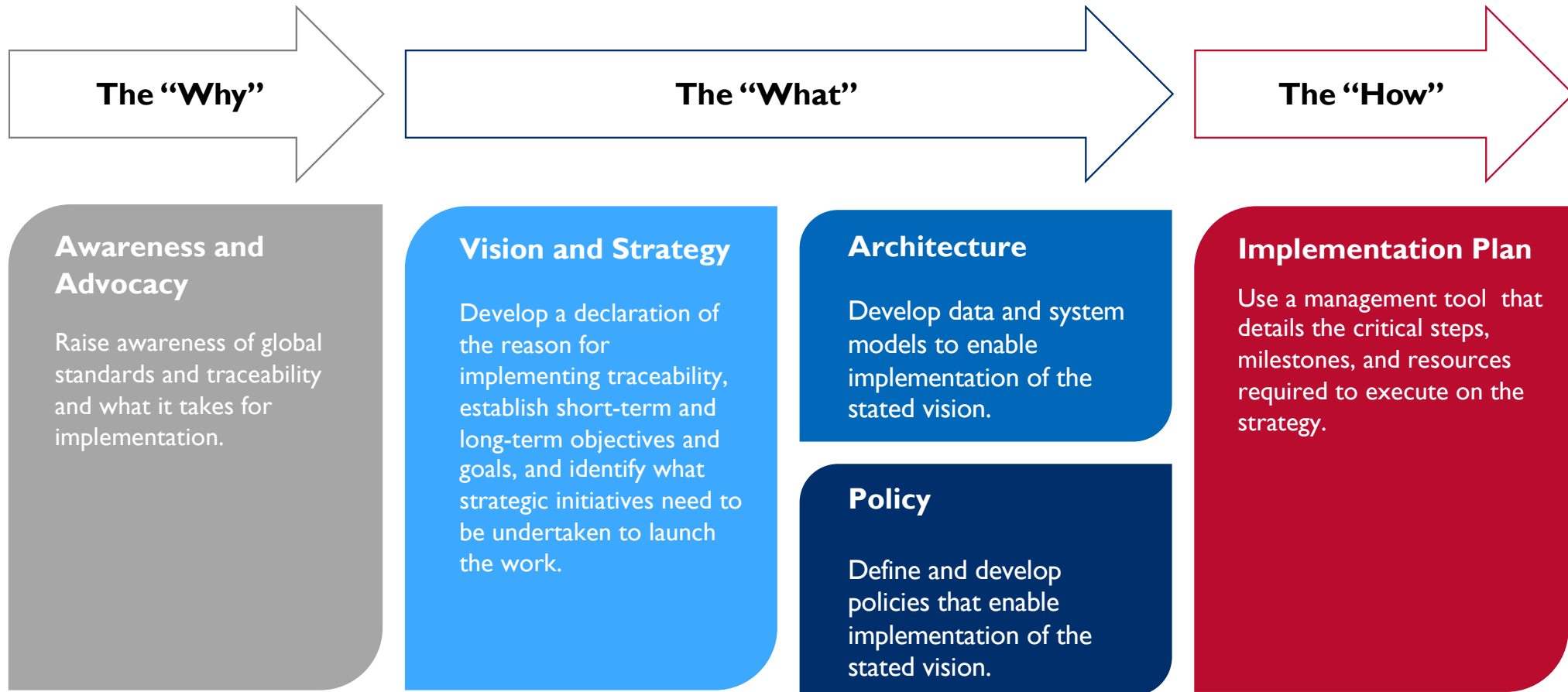
PEPFAR
U.S. President's Emergency Plan for AIDS Relief

USAID
U.S. President's Malaria Initiative

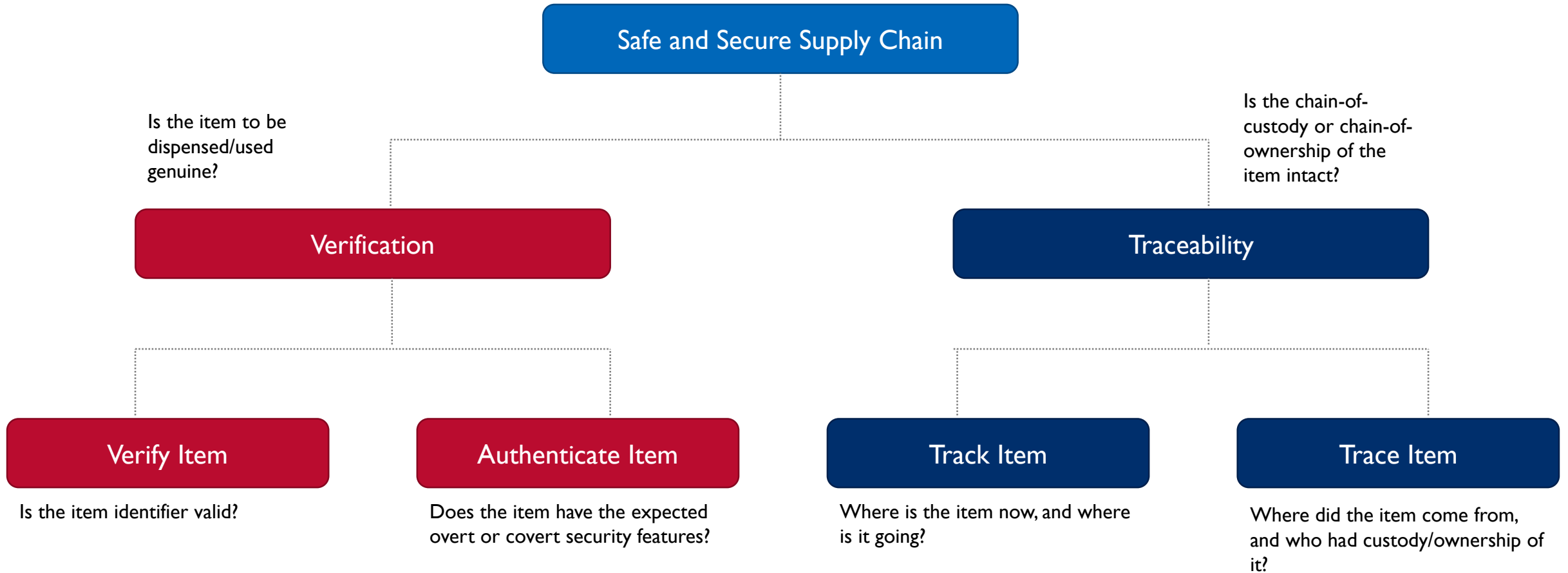
International procurement agency timelines – pharmaceuticals & vaccines

Agency	Phase 1	Phase 2	Phase 3	Phase 4
Global Drug Facility	31 Dec 2019	31 Dec 2019	30 Jun 2020	30 Jun 2022
The Global Fund	31 Dec 2019	31 Dec 2019	30 Jun 2020	30 Jun 2022
UNDP	Voluntary but preferred			
UNFPA	31 Dec 2019	31 Dec 2020	Voluntary but preferred	
USAID GHSC-PSM	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022

GHSC-PSM global approach

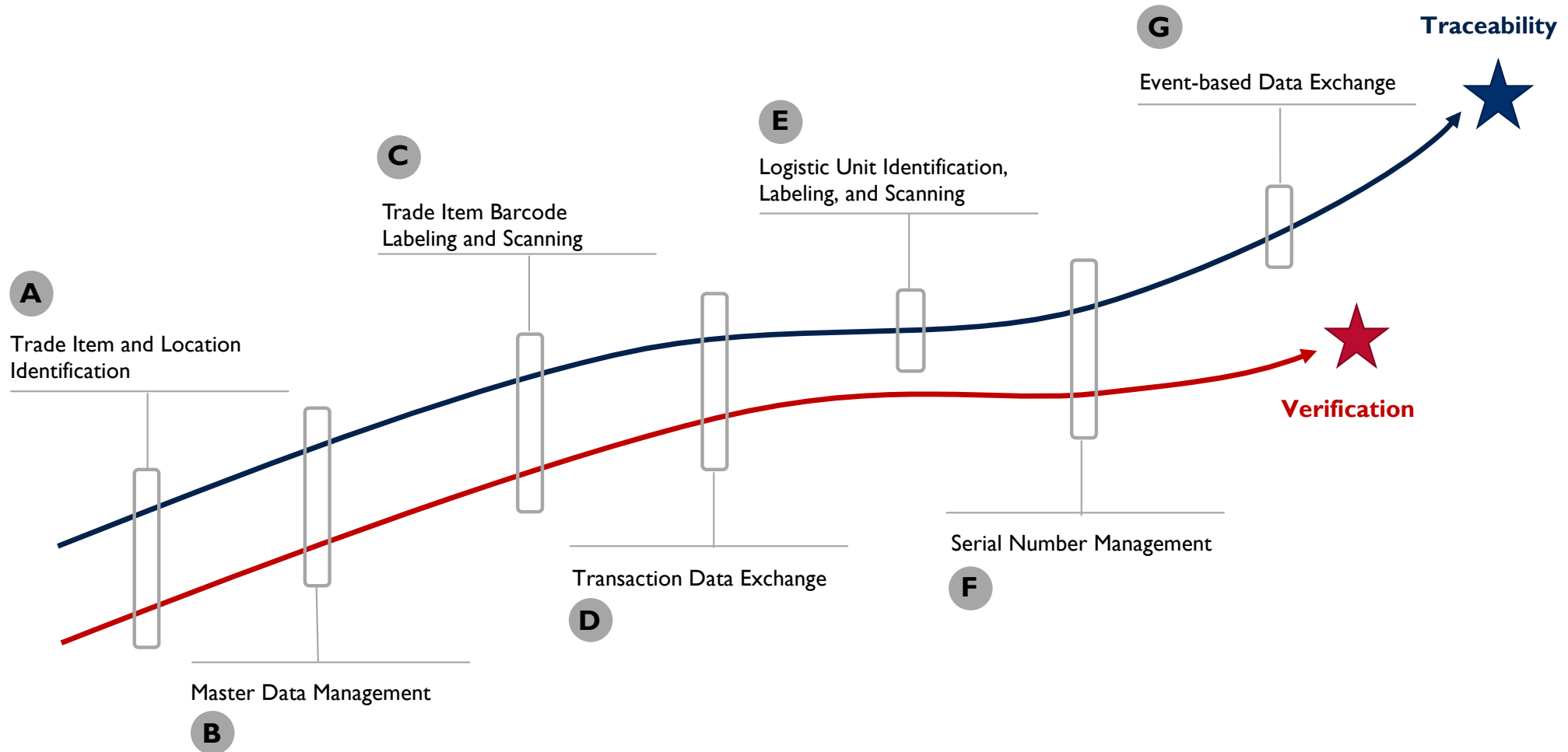


There are different approaches to achieving these objectives



Content Source: GSI Global Office

Illustrative implementation roadmap



Accompanied by capabilities matrix for each road marker

Road Marker A: Trade Item & Location Identification

Function	Foundational Capability	Verification Capability	Traceability Capability
	*Internal use of unique identifiers (stock-keeping units, or SKUs) at the tertiary and secondary trade	*GTIN is the primary identifier at the trade item secondary pack level.	*GTIN is the primary identifier at the trade item tertiary and secondary pack levels.

Road Marker B: Master Data Management

Function	Foundational Capability	Verification Capability	Traceability Capability
	*A product master data file with a minimum set of key attributes from data that are available from trading partners or that can be	*GTIN is the primary identifier at the trade item secondary pack level.	*A minimum set of trade item master data needed for traceability and associated with a GTIN is maintained.

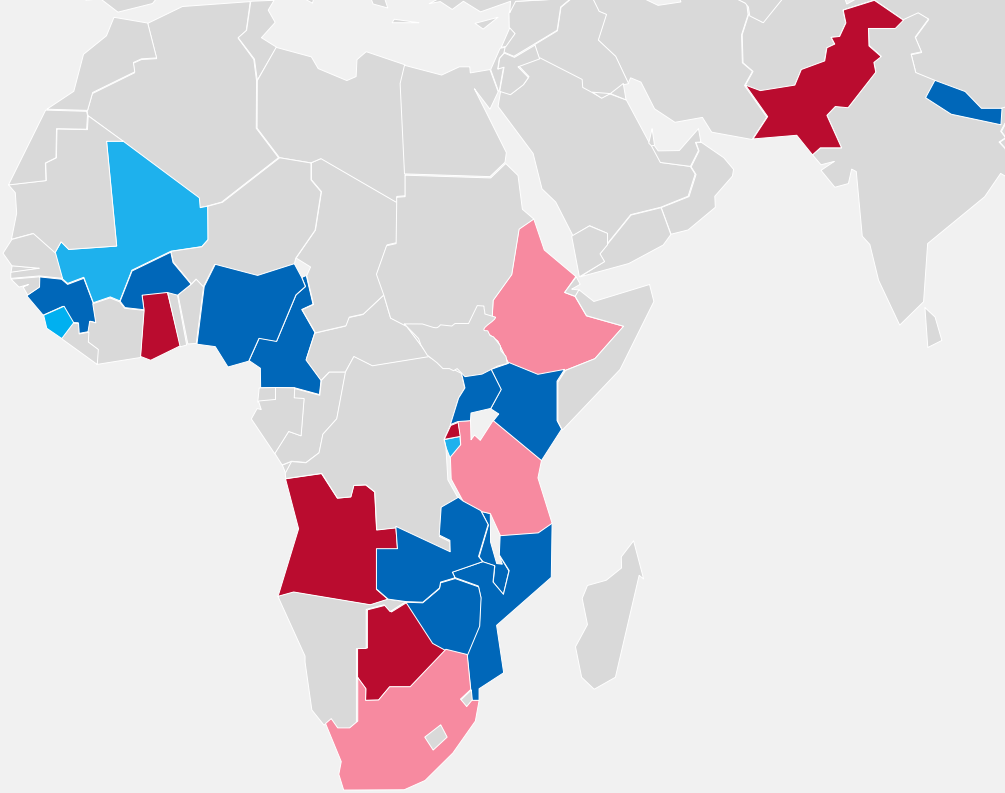
Road Marker C: Trade Item Barcode Labeling and Scanning

Function	Foundational Capability	Verification Capability	Traceability Capability
		*GSI 2D DataMatrix with GTIN, batch/lot, expiration date, and serial number is printed on	*GSI 128-Linear Barcode or 2D DataMatrix with GTIN, batch/lot, expiration date, and serial number is printed on the trade item tertiary pack level.

Road Marker D: Transaction Data Exchange

Function	Foundational Capability	Verification Capability	Traceability Capability
OVERVIEW	*Ability to receive and manage transactional data (e.g., item number, location number, batch/lot, expiry, quantity, price) for each order from PO, ASN, CI, and internal order (IO).	*Automate issuance of POs to manufacturers/suppliers based on GTIN. *Automate receipt of transactional documents for inbound shipments, including GTIN, GLN, batch/lot, expiry, quantity, and price through electronic data interchange (EDI).	*Automate issuance of POs to manufacturers/suppliers based on GTIN. *Automate receipt of transactional documents for inbound shipments, including GTIN, GLN, batch/lot, expiry, quantity, and price through EDI. *Progress toward increasing automation in transaction data exchange to lower levels of the supply chain over time.
Governance		*A mechanism is established to monitor and enforce compliance to stated transaction data exchange and reporting policies.	
Supply Chain Operations	*Use transaction data to enable processes such as receiving, quarantine, put-away, inventory management, order management, replenishment, picking, packing, staging, inventory management and shipping.		

USAID / GHSC-PSM technical assistance footprint



*2019 still tentative

Traceability supports a number of supply chain objectives



	Patient Safety	Supply Chain Security	Supply Chain Efficiency	Data Visibility
ADDRESS	SF or stolen product detected in the legitimate supply chain	Yes	Yes	Yes
	Theft or diversion of products from the legitimate supply chain	Yes	Yes	Yes
	SF or stolen product that is obtained by the patient/end user	Yes	Yes	Yes
IMPROVE	Accuracy and efficiency of procurement operations	Yes	Yes	Yes
	Efficiency of “reverse” logistics processes (e.g., those used for returns, recalls)	Yes	Yes	Yes
	Visibility of product “status” (e.g., expiry, recalls)	Yes	Yes	Yes
	Efficiency of inventory management and distribution	Yes	Yes	Yes
	Efficiency of payment and payment monitoring processes	Yes	Yes	Yes
	Pharmacovigilance and control of treatment outcomes	Yes	Yes	Yes
ENABLE	Visibility into where the product is within the supply chain	Yes	Yes	Yes
	Visibility to decrease or eliminate reimbursement fraud	Yes	Yes	Yes
	Harmonized trade/customs clearance procedures for pharmaceutical products	Yes	Yes	Yes

Content Source: GSI Global Office



Additional Resources

USAID GHSC-PSM Global Standards Homepage:

<https://www.ghsupplychain.org/globalstandards>

International Procurement Agencies Global Standards Technical Implementation Guide for Global Health Commodities:

<https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21>

Implementation Guidance for Pharmaceutical Traceability Leveraging GSI Global Standards:

<https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gsi-global-standards>

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

<https://www.ghsupplychain.org/global-standards-low-and-lower-middle-income-settings>

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The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No.AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

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