(01) 00858939007009 (17) 250101 (10) A1B2C345 (21) Z7J13KO8LPRNS890

The Intersection of Theory and Action:

A Framework for Traceability & Rwanda's Implementation Journey

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

USAID FROM THE AMERICAN PEOPLE

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

USAID FROM THE AMERICAN PEOPLE | CDC Centers for Disease Control and Prevention | U.S. President's Malaria Initiative

GS1

About Us

Munyangaju Jose Edouard
Drug and Food Inspection & Compliance Division Manager
Rwanda Food and Drugs Authority
emunyangaju@rwandafda.gov.rw

Kaitlyn Roche
Manager for Global Standards & Traceability
USAID GHSC-PSM
kroche@ghsc-psm.org

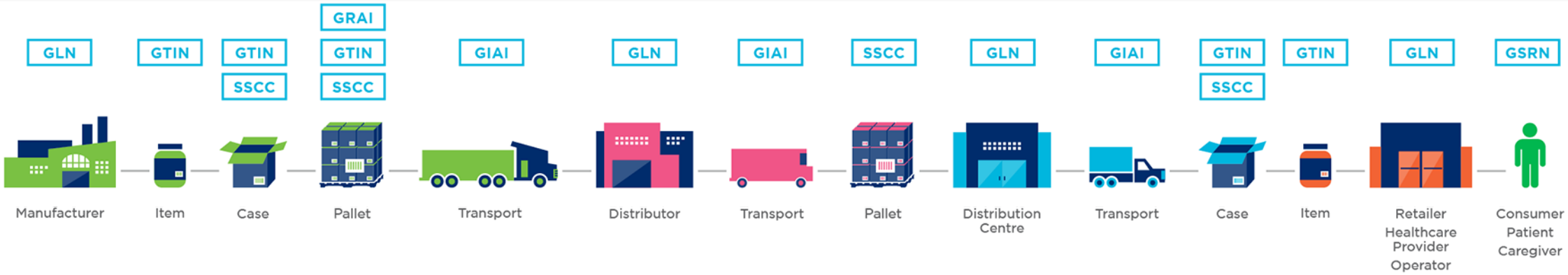
Why do we care about global standards?

- 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 given sector by having one reference code to associate items or products across different stakeholder groups.

GS1 standards enable traceability in the healthcare supply chain

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

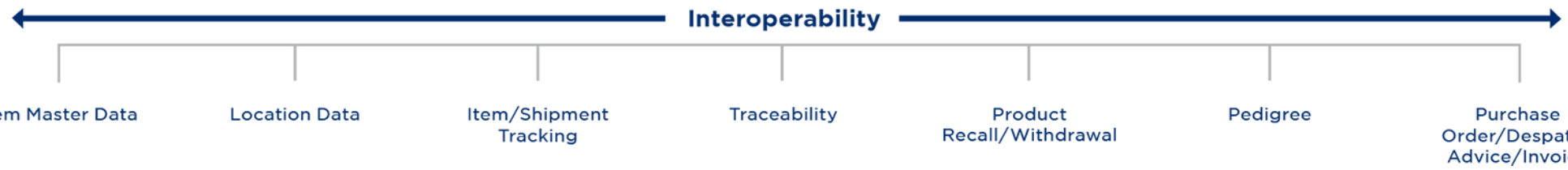


Capture: GS1 Standards for Barcodes & EPC/RFID

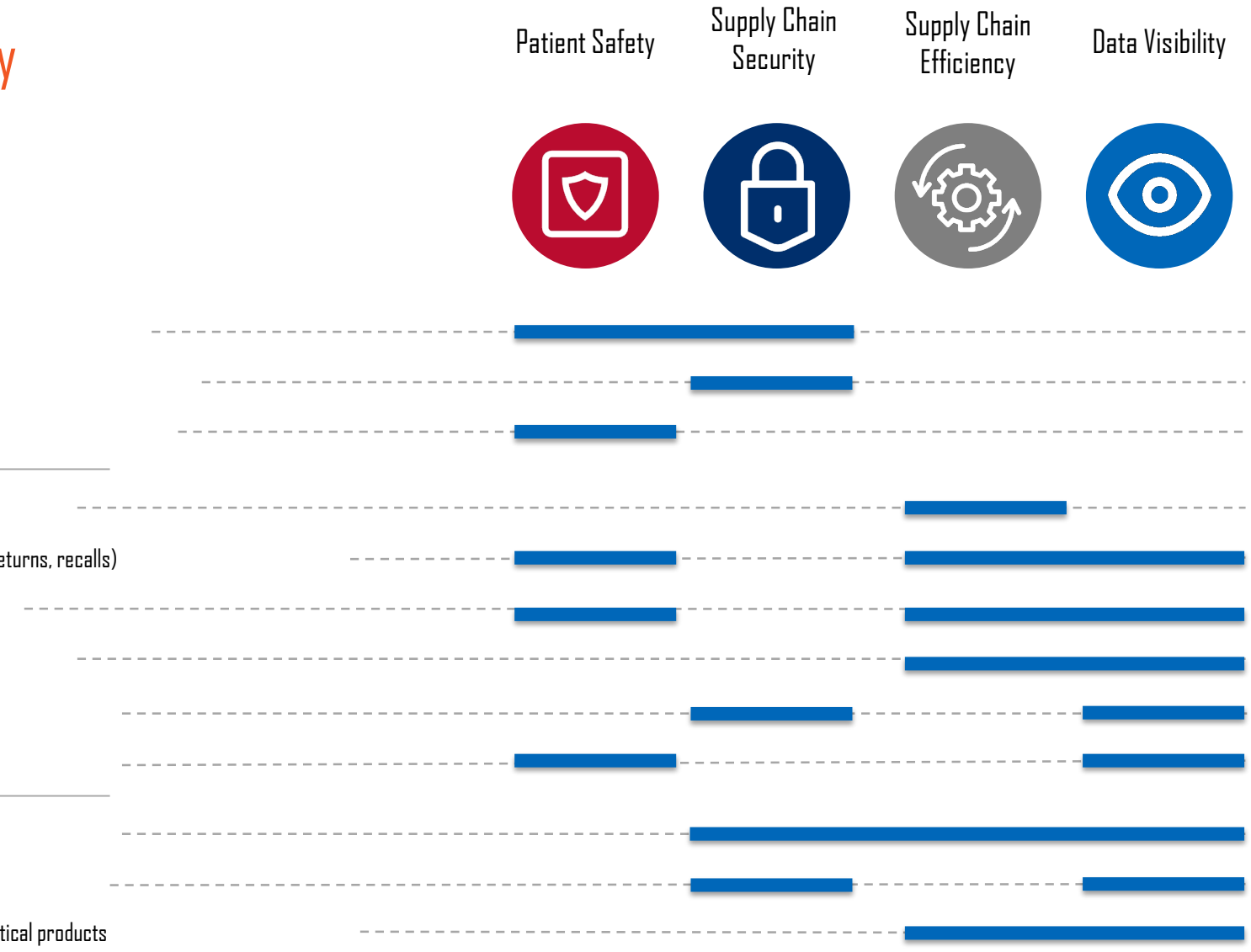
GS1 Barcodes **GS1 EPC/RFID**

Share: GS1 Standards for Data Exchange

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



Global standards enable traceability of health commodities across the supply chain

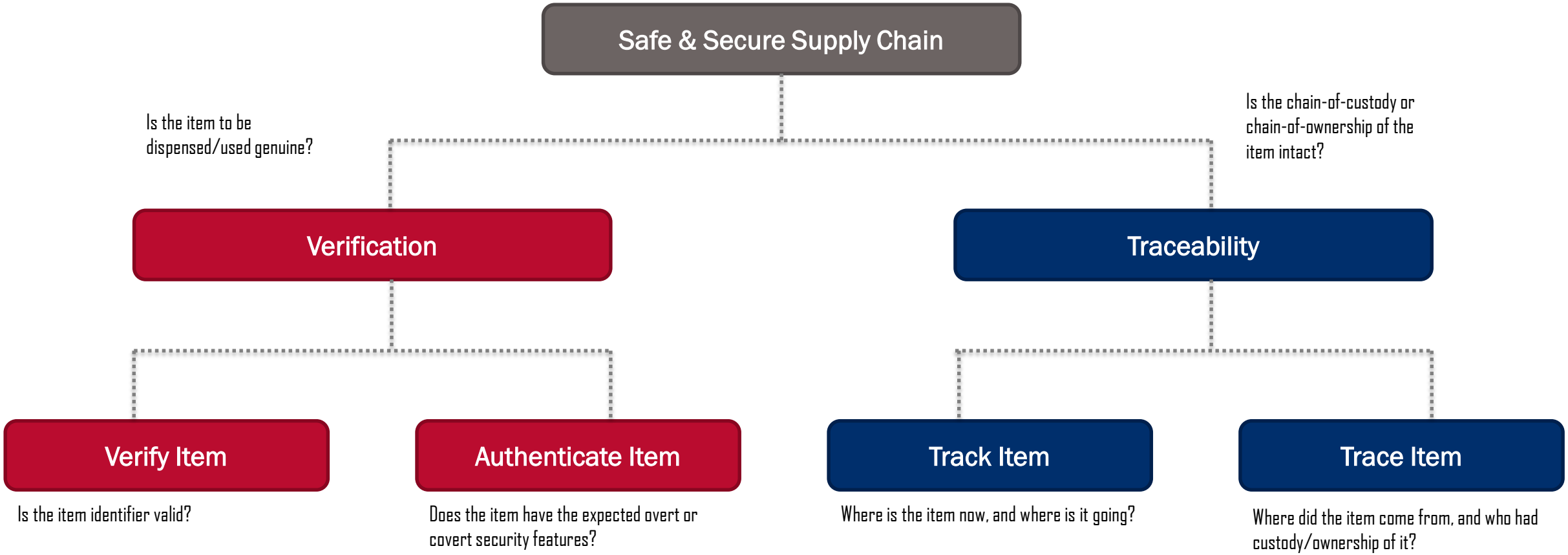


Content Source: GSI Global Office

+Serialization enables identification with increased precision

Feature	Global Trade Item Number (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

There are different approaches to achieving these objectives



Content Source: GSI Global Office

Why we developed this framework

- Intended to compliment the GS1 Regulatory Roadmap by providing guidance beyond regulatory and into supply chain
- Targeted for the unique needs of the countries we support:
  - Limited awareness and use of global standards today
  - High risk of sub-standard or falsified (SF) medicines
  - Limited resources and competing priorities for health sector resources
  - Government-owned public-sector supply chains
  - Emerging local manufacturing environment
- Aim to provide step-by-step guidance to support specific investment in workplans and country strategies

USAID GHSC-PSM's Traceability Planning Framework

Awareness and Advocacy

Raise awareness of global standards and traceability and what it takes for implementation.

Vision and Strategy

Develop a declaration of the reason for implementing traceability, establish short-term and long-term objectives and goals, and identify what strategic initiatives need to be undertaken to launch the work.

Architecture

Develop data and system models to enable implementation of the stated vision.

Policy

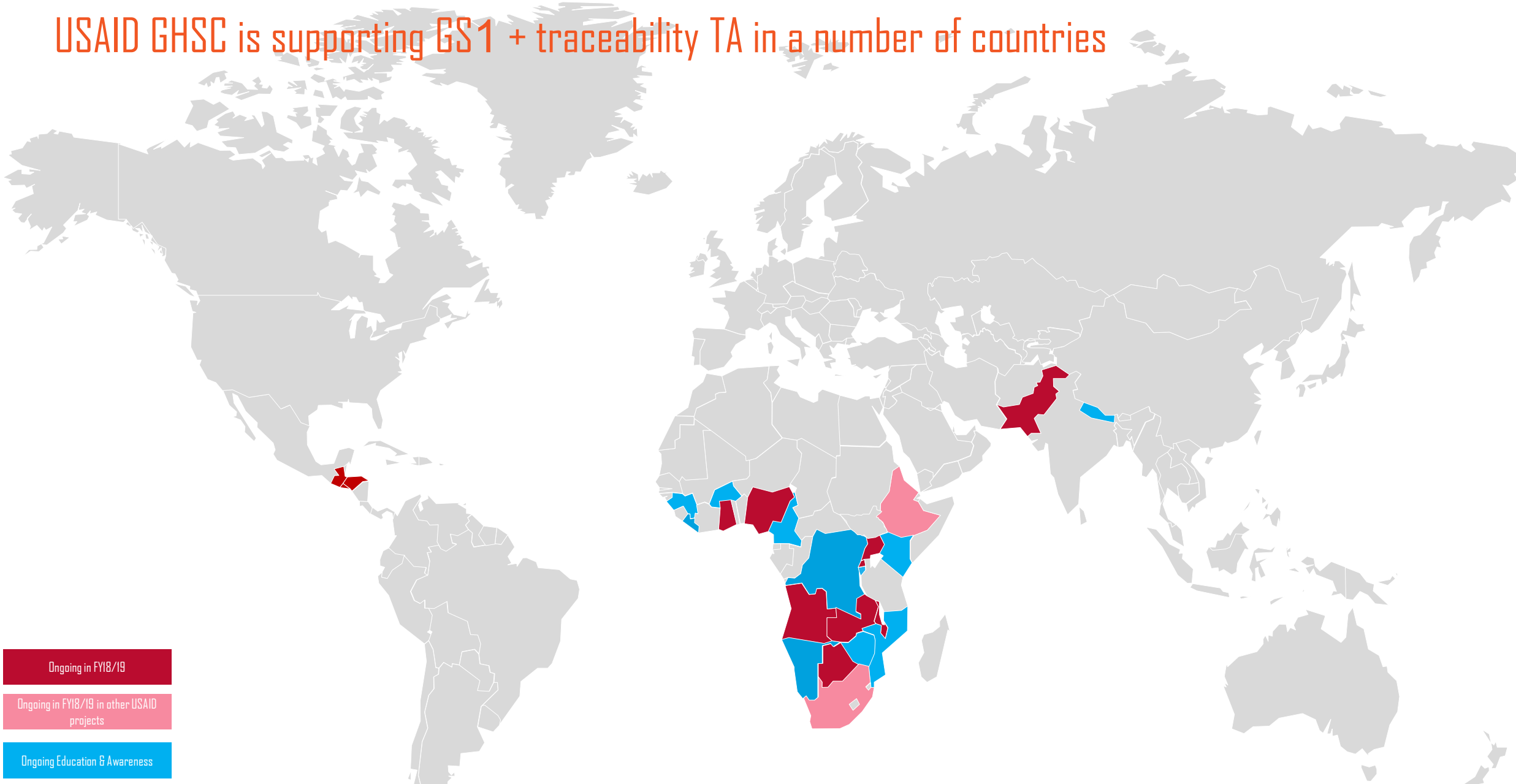
Define and develop policies that enable implementation of the stated vision.

Implementation Plan

Use a management tool that details the critical steps, milestones, and resources required to execute on the strategy.

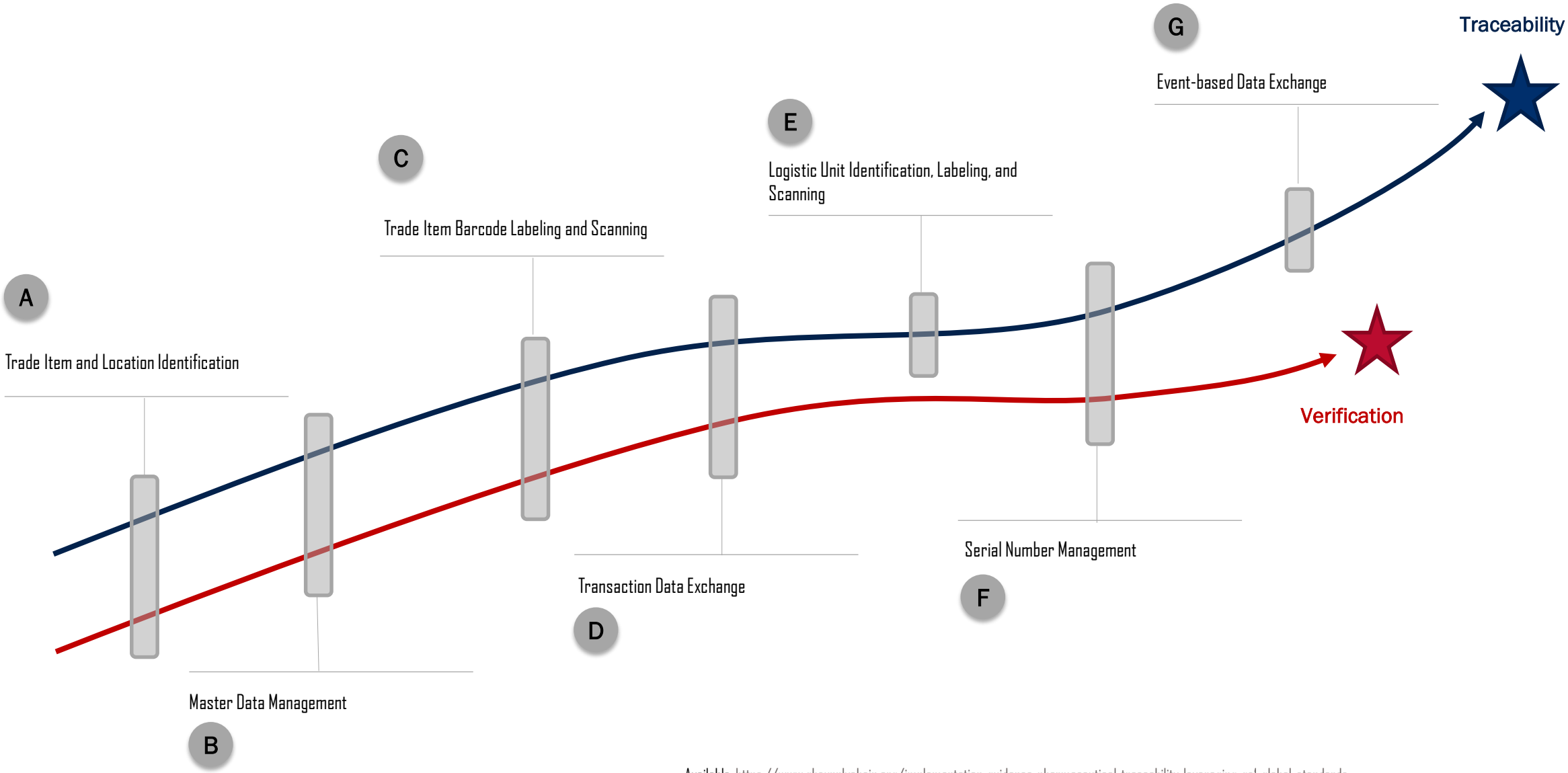
Available: https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gsl-global-standards

USAID GHSC is supporting GS1 + traceability TA in a number of countries



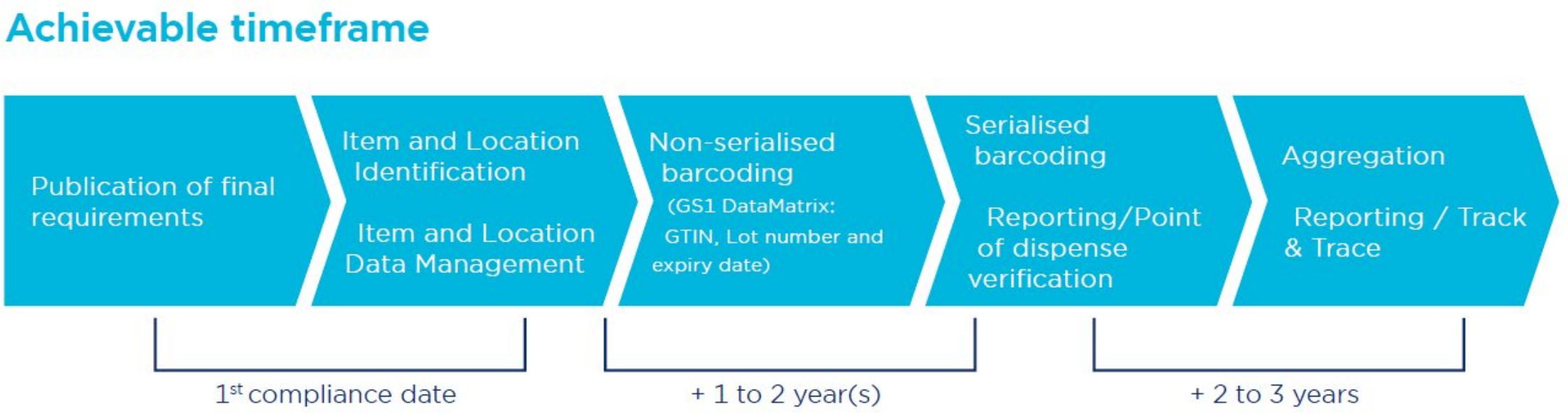
Illustrative example only
Each country will develop an implementation plan based on their vision and strategy

Illustrative Implementation Roadmap



Available: https://www.ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gsl-global-standards

Achievable timeframe



What does it take? A holistic approach that includes…

Governance & Advocacy

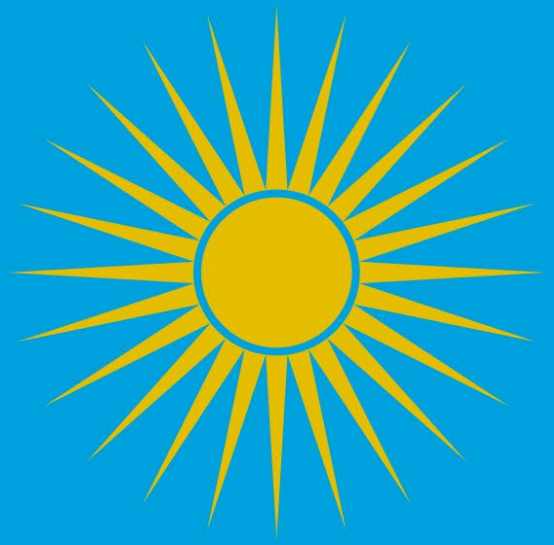
Regulatory & Policy

Supply Chain Operations

Systems & Technology

Service Delivery

Rwanda's Implementation Journey



Our starting point

RWANDA FDA
Rwanda Food and Drugs Authority

Mandate from National Pharmaceutical Sector Strategic Plan (NPSSP) 2018 – 2024

- Build and enforce a QA system to ensure safety, effectiveness and efficacy of health commodities and technologies from manufacturers to consumers
- Strengthen the national health commodities and technologies supply system in order to ensure regular supply of essential health commodities and technologies at all times in sufficient quantities to all health facilities

Gap

To improve monitoring of product quality throughout the value chain, it is critical to improve data accuracy, data capture and efficiency in supply chain operations

Intervention

MOH-led initiative to implement global standards for product identification and data capture

Progress to date

RWANDA FDA
Rwanda Food and Drugs Authority

The "Why"

The "What"

The "How"

Awareness and Advocacy

Raise awareness of global standards and traceability and what it takes for implementation.

Vision and Strategy

Develop a declaration of the reason for implementing traceability, establish short-term and long-term objectives and goals, and identify what strategic initiatives need to be undertaken to launch the work.

Architecture

Develop data and system models to enable implementation of the stated vision.

Policy

Define and develop policies that enable implementation of the stated vision.

Implementation Plan

Use a management tool that details the critical steps, milestones, and resources required to execute on the strategy.

Complete

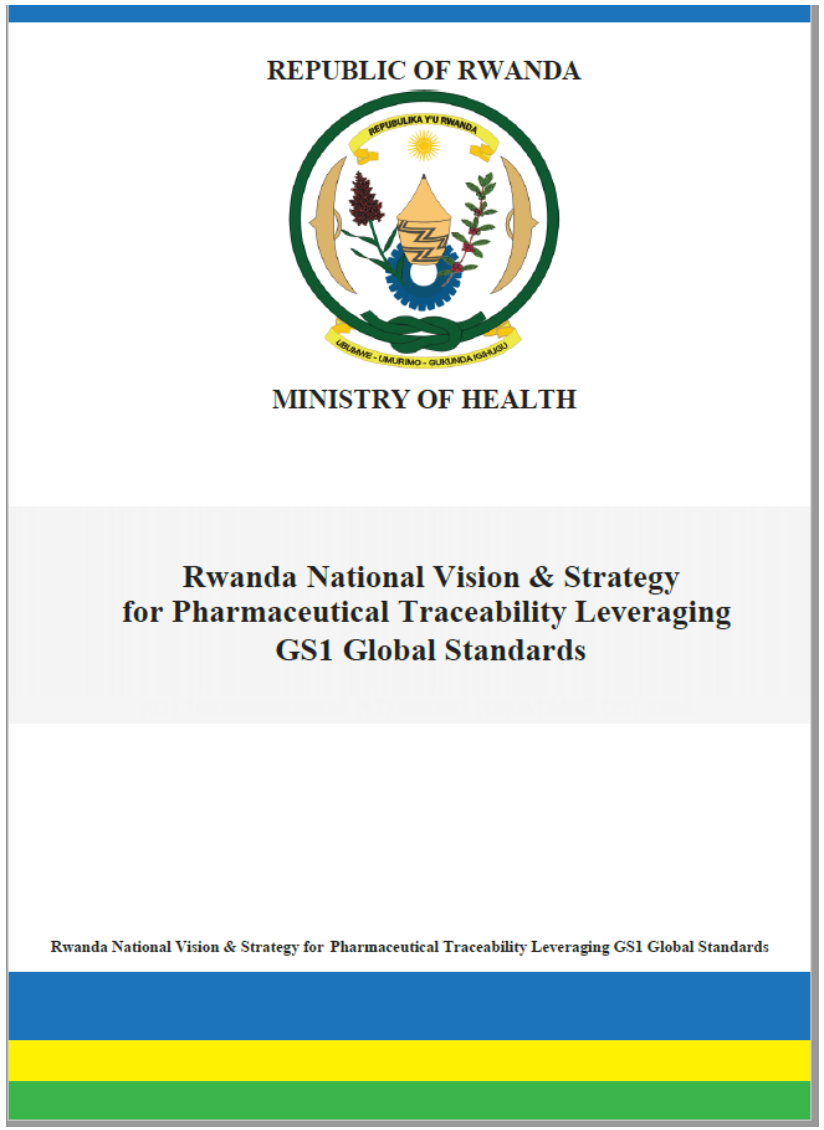
Reviewing

Drafting

Advocacy, awareness & strategy development workshop

- Sponsored by the Minister of Health
- Hosted in June 2018
- Participation from 20 organizations from government, service delivery, private sector, donors, implementing partners, and GS1 Kenya

In May 2019, MOH endorsed the National Vision & Strategy



Through this plan we aim to:

- Decrease the presence of substandard and falsified (SF) medications
- Ensure the quality and desired efficacy of pharmaceuticals
- Promote trust in the pharmaceutical sector and healthcare system
- Provide visibility of product status across the supply chain
- Create supply chain efficiencies from manufacturers to patient receipt
- Increase patient safety

Rapid national healthcare market assessment

RWANDA FDA
Rwanda Food and Drugs Authority

Supply Market

- 50% of market from India – already complaint!
- China – no compliance
- EU – partial compliance
- USA – partial compliance
- Kenya
- 25 importers
- 120 wholesalers

Regulatory & Procurement

- No Existing Requirements for product identification & labelling

Information Systems

- PRIMS (DRIS)
- One Network (eLMIS)
- SageL500 (WMS)
- Ishyiga (Ordering / Revenue)

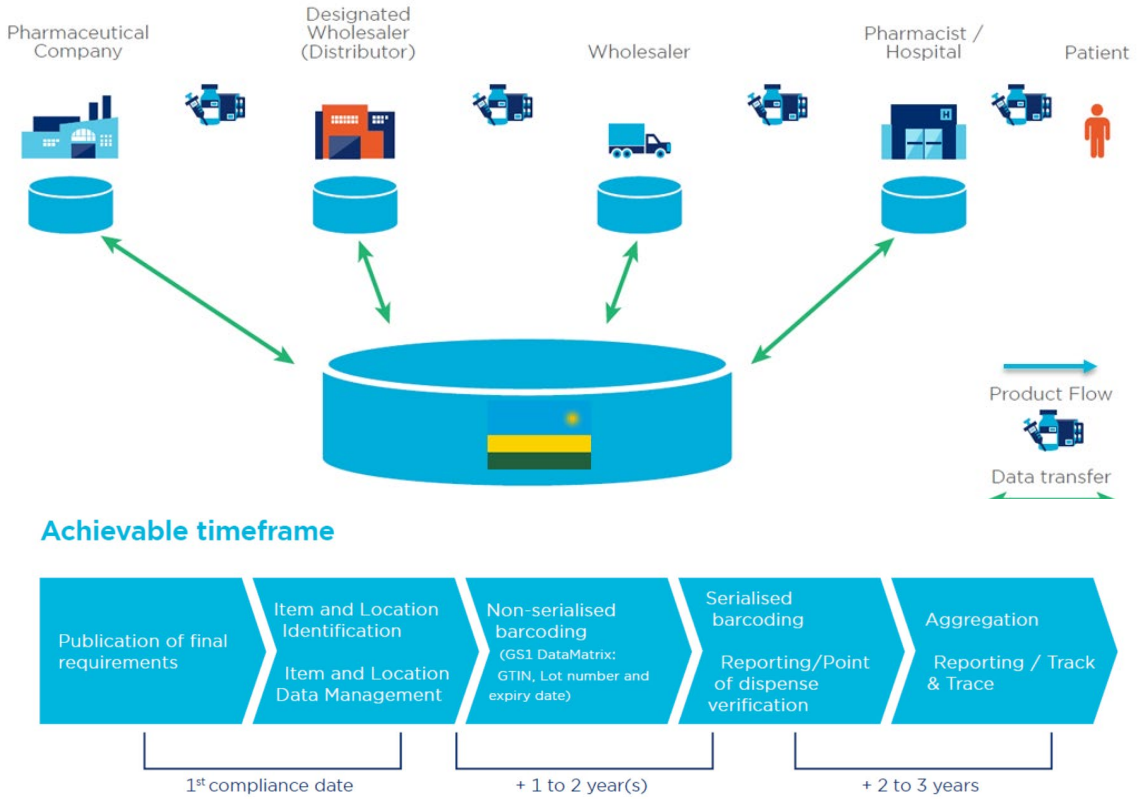
Service Delivery

- 1 Central Medical Store
- 48 hospitals
- 30 district pharmacies
- 542 health centres

Traceability model selection & motivation

RWANDA FDA
Rwanda Food and Drugs Authority

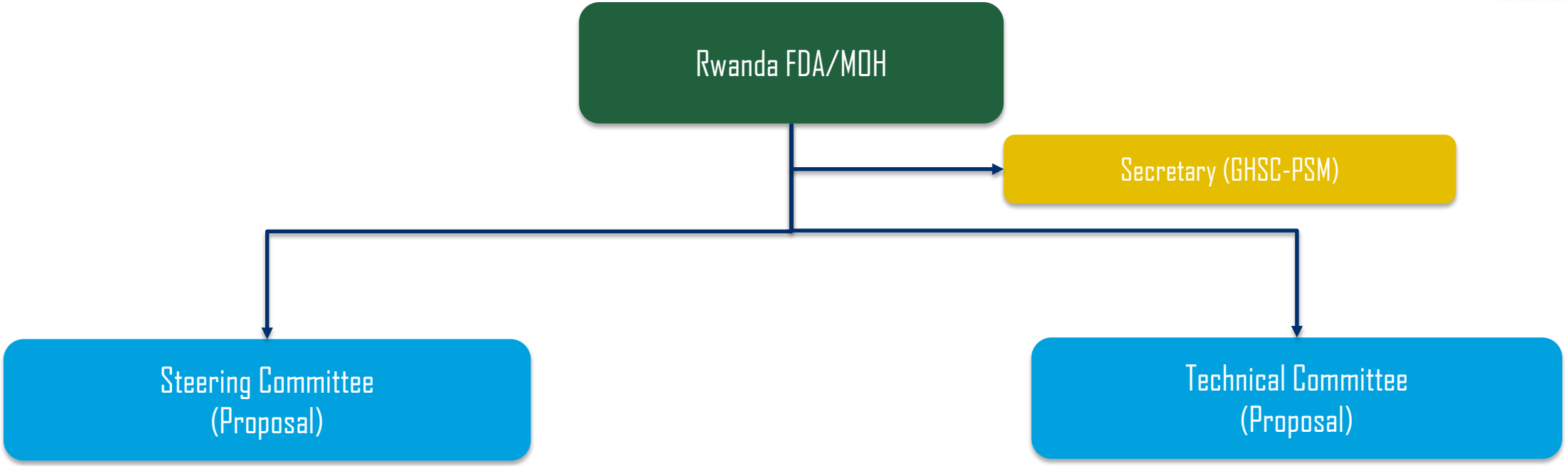
Track and Trace (Centralized)



- Minimizes falsified or stolen medicines in the legitimate supply chain
- Provides visibility into custody / ownership throughout the supply chain
- Minimized reimbursement fraud
- Provides visibility into product status (e.g. expired, recalled)
- Enables efficient inventory management at central level & at the point of dispense

Next step: Develop our implementation plan

Currently establishing a governing body



- Rwanda FDA
- MOH Representatives
- Distributors Association
- Pharmacies Association
- Private Sector Federation
- Donor Agencies Representatives

- Rwanda Public Procurement Authority
- Rwanda Information Systems Authority
- Rwanda Bureau of Standards
- Rwanda Biomedical Centre

Next steps

RWANDA FDA
Rwanda Food and Drugs Authority

- Formalize the governance structure for traceability implementation
- Draft legal frameworks and solicit stakeholder input
- Developing a national product catalog for all public health commodities
- Complete health information systems architecture assessment
  - Which systems and technologies in place support track and trace? What are the gaps?
- Develop 3-5 year costed implementation plan

Murakoze Cyane

Munyangaju Jose Edouard
Drug & Food Inspection & Compliance Division Manager
Rwanda Food and Drugs Authority
emunyangaju@rwandafda.gov.rw

Kaitlyn Roche
Manager for Global Standards & Traceability
USAID GHSC-PSM
kroche@ghsc-psm.org