Implementation Guidance for Pharmaceutical Traceability Leveraging GS1 Global Standards

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

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USAID FROM THE AMERICAN PEOPLE

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

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CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

U.S. President's Malaria Initiative

About this document

Executive summary

The intent of this document is to provide guidance to country programs for systematically organizing the work of operationalizing and executing a vision and strategy for pharmaceutical traceability. It is not intended to be prescriptive, but to serve as guidance for developing a vision, strategy, and implementation roadmap specific to the country environment—one that considers the key operational components required for successful implementation.

Document structure

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.

Background

What are global standards?

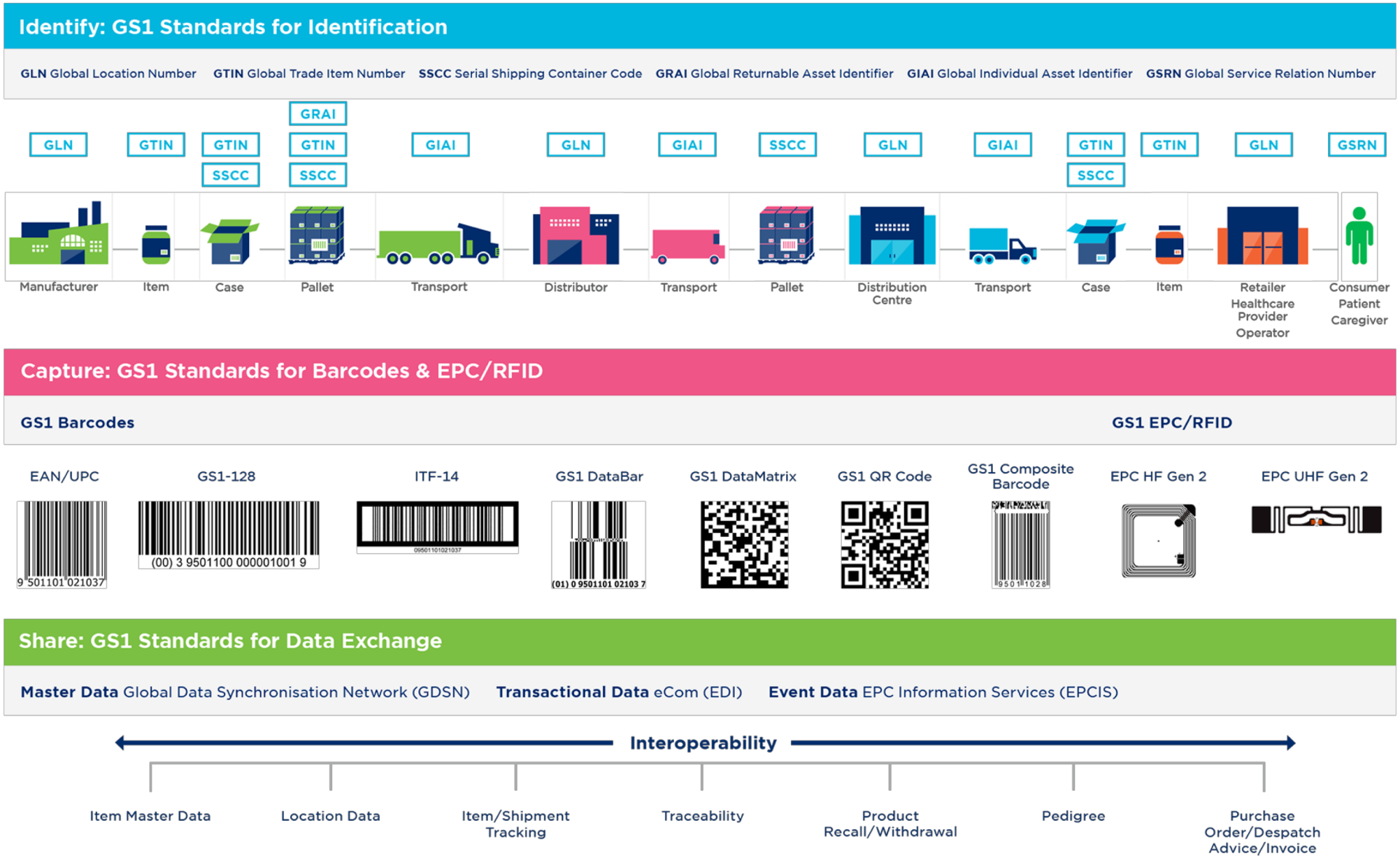
Published documents that:

- Establish specifications and procedures designed to ensure the reliability of the materials, products, methods, and/or services people use every day (IEEE)
- Address a range of issues, including but not limited to a common nomenclature and protocols across various entities in support of interoperability

The benefits of global standards

- National identification and classification structures may exist for pharmaceuticals and related health commodities, but global standards provide a common language to efficiently interact with external trading partners (e.g. , manufacturers, distributors, procurement agents, donors, export clients).
- Within a country, global standards enable interoperability across disparate systems, e.g., drug regulatory information system (DRIS), logistics management information systems (LMIS), in a given sector by having a single reference code to associate items or products across different stakeholder groups.
- Rules and specifications are needed to enable data exchange among different supply chain stakeholders.
- Global standards—a common language for identification, data capture, and data exchange—are the basis for global trade, verification, and traceability.

GS1 is a system of global standards for the health supply chain



GS1 standards enable traceability of items in the supply chain

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

Content Source: GS1 Global Office

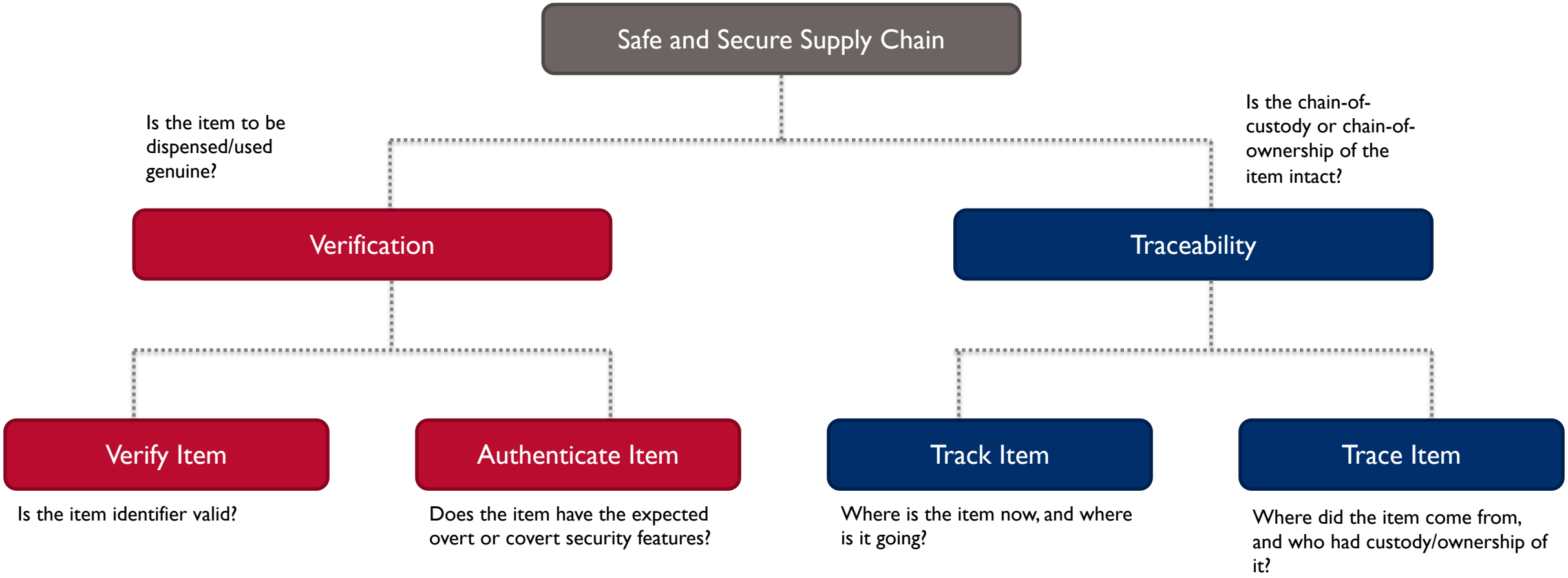
Traceability supports a number of supply chain objectives

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

Content Source: GS1 Global Office

For more information on the concepts of traceability and end-to-end data visibility, please see Appendix A..

There are different approaches to achieving these objectives



Content Source: GS1 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!**

An overview of traceability approaches

Traceability requires trading partners throughout the entire supply chain to exchange data for defined events and to answer the questions **what**, **when**, **where**, and **why** about trade items as they move through the supply chain. The common models for traceability are defined by the criteria that determine which entities are required to report traceability data, either those in the chain-of-ownership or those in the chain-of-custody.

Chain-of-Ownership

Reporting by all entities that currently have or have had **legal title** to the item

Chain-of-Custody

Reporting by all entities that currently have or have had **physical possession** of the item

Additional Resources

WHO Existing Technologies and "Track and Trace" Models In Use and To Be Developed By Member States

Understanding verification

Product verification refers to checking at **any single point** in the supply chain that the unique identifier 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.

An overview of verification approaches

Verification requires, at a minimum, that trading partners at the end of the trade item supply chain check the validity of a trade item's unique identifier and update its status (e.g., decommissioned). The common models for verification are defined by the point at which the verification occurs, generally either at the point-of-use or at the point-of-dispense.

Point-of-Dispense

Before dispense in health centers, pharmacies, or health posts, the unique identifier on a product's packaging is validated by comparing it with information provided by the product manufacturer

Point-of-Use

Before use of a product by a patient or consumer, the unique identifier on a product's packaging is validated by comparing it with information provided by the product manufacturer

Additional Resources

WHO Available Authentication Technologies for the Prevention and Detection of SSFFC Medical Products

The "Why"

This section is intended to provide guidance about approaches to building awareness of global standards and traceability within a country. The goal is to enable a common baseline of knowledge among key stakeholders who will be involved in developing a vision and strategy.

Awareness and Advocacy

Understanding what a global system of standards is and how it enables traceability is critical in developing a vision and strategy and designing a traceability architecture, supporting policies, and implementation plan that are realistic and achievable. Through awareness and advocacy initiatives, champions should be identified in different stakeholder groups to serve as advocates for traceability and global standards in their various functions.

For a sample stakeholder map, please see Appendix B.

Awareness

Expected Benefits

- All key stakeholders have a baseline of knowledge of global standards and traceability that informs their perspective for the vision, strategy, and implementation plan
- Champions and technical leads support advocacy across stakeholder groups

Sample Activities

- Host trainings and workshops, where possible, in partnership with your local GS1 Member Organization
- Attend global conferences, webinars, and workshops to keep abreast of new developments, lessons learned, and emerging good practices

Potential Outputs

- Key stakeholders, including sponsors and champions, are identified and have baseline knowledge of global standards
- In-country working group or Steering Committee is established
- Local training materials are developed to disseminate among target audiences

Additional Resources

Find a GS1 Member Organizations, GS1 Healthcare Events

The "What"

This section is intended to provide guidance about how to approach developing the vision and strategy for your country and to provide resources to define two critical prerequisites: (1) data models and subsequent systems architectures and (2) enabling policies to ensure the vision and strategy are executed by in-country stakeholders and internal and external trading partners.

Vision and Strategy

A **vision** identifies the problem statement and describes what a country wants to achieve through traceability implementation, including its short-term and long-term goals and objectives. A **strategy** describes, at a high level, what the current gaps are and what needs to be done to achieve the vision. It is important to consider scope as you develop your vision:

- ✓ Regional (multicountry) or national?
- ✓ Public sector, private sector, or both?
- ✓ Imported drugs, locally produced drugs, or both?
- ✓ Prescribed medicines, over-the-counter medicines, or both?
- ✓ Batch/lot or serial number?

Vision & Strategy

Expected Benefits

- All key stakeholders are aligned on the objectives of implementing global standards for traceability
- Vision can be shared with internal and external stakeholder groups to build awareness and consensus
- Stakeholders have a clear understanding of what needs to be done to achieve the vision

Sample Activities

- Host a workshop with representatives from key stakeholder groups to cocreate a national vision and strategy, incorporating the perspective of all relevant stakeholder groups

Potential Outputs

- A strategy document that includes a declaration of the reason for implementing traceability, including short-term and long-term objectives and goals
- A high-level roadmap and guiding principles for achieving the stated aims of implementing traceability
- A prioritization matrix that maps objectives against impact and feasibility

Architecture

The overall systems architecture requirements and supporting data models need to be developed and implemented. The architecture design will largely depend on the traceability model chosen and the vision for implementation. The architecture should leverage existing country systems where available but, depending on the traceability model, may require investments in additional platforms or capabilities to manage data exchange across trading partners down to the item level.

For sample architecture models, please see Appendix C.

Architecture

Expected Benefits

- The traceability model and the systems architecture required to support implementation are established to inform trading partner roles and policy requirements for data exchange
- The traceability model should also take into account data storage, security, ownership, and access requirements

Sample Activities

- Conduct a systems landscape assessment to map the current information technology (IT) landscape and determine opportunities to leverage existing systems or integrate new technologies
- Host a workshop to develop the traceability approach and IT system choreography model accounting for the roles and capabilities of various trading partners

Potential Outputs

- Current-state and future-state system architecture models
- Specifications and requirements for systems or new technology requirements
- Traceability data source and flow diagrams

Additional Resources

APEC Supply Chain Security Tool Kit, GS1 Healthcare Supply Chain Traceability Models

Policy

A policy is an overall plan, principle, or guideline that will define item identification and labeling requirements, data-sharing protocols, and the specific roles of various trading partners in implementing the verification or traceability requirement. A policy can be implemented through one or more mechanisms, including legislation, a procurement requirement, or a formal guidance issued to trading partners in a published document.

Policy

Expected Benefits

- A policy will provide supply chain stakeholders–both internal and external trading partners–with clear direction and accountability measures on what actions they need to take for the country to implement verification or traceability

Sample Activities

- Hold stakeholder forums to share the vision and strategy and request input into policy requirements
- Assess the market of current-state trading partner capabilities in identification, data capture, and data sharing
- Conduct a landscape analysis or study tour of existing global implementations to inform policy development

Potential Outputs

- Notification of intention to implement policy for feedback by trading partners
- Pilot studies to test assumptions and implementation challenges to inform policy development
- Published policies stating trading partner roles, responsibilities, and requirements
- Governance mechanism through which policies will be enforced

Additional Resources

GS1 Regulatory Roadmap: Traceability of Medicinal Products, RxGPS Alliance Implementation Roadmap & Model Regulation
GHSC-PSM Considerations for Traceability Policy Design Inclusive of Local Manufacturers

The "How"

This section is intended to provide guidance on how to approach foundational capabilities for traceability from a strategic perspective through assessing where a program is today compared to where it needs to be in the future. It will support identification of near-, mid-, and long-term activities to achieve traceability objectives. The framework is not prescriptive and should be used as a guidance document to support development of a country-specific implementation roadmap.

Implementation Plan

An implementation plan is a management tool that details the critical steps, milestones, and resources required by various trading partners to execute on the traceability strategy. The implementation plan will be developed and managed by the championing body of the traceability initiative (e.g., health ministry, regulatory body, or cross-sector steering committee). To be achievable, the plan must consider reasonable timelines and resources required by various sector stakeholders and trading partners to meet implementation requirements.

Implementation Plan

Expected Benefits

- All key stakeholders understand the activities, costs, and resource requirements to implement the verification and/or traceability vision and how these capabilities will be implemented over a defined period of time

Sample Activities

- Host a workshop or conduct stakeholder interviews to determine requirements, timelines, and cost estimates to implement the architecture and policy requirements across stakeholder groups, including governance, supply chain operations, systems and technology, and service delivery

Potential Outputs

- A costed implementation plan that details the near-, medium- and long-term capabilities that will be phased in over time and the resources required to enable this implementation

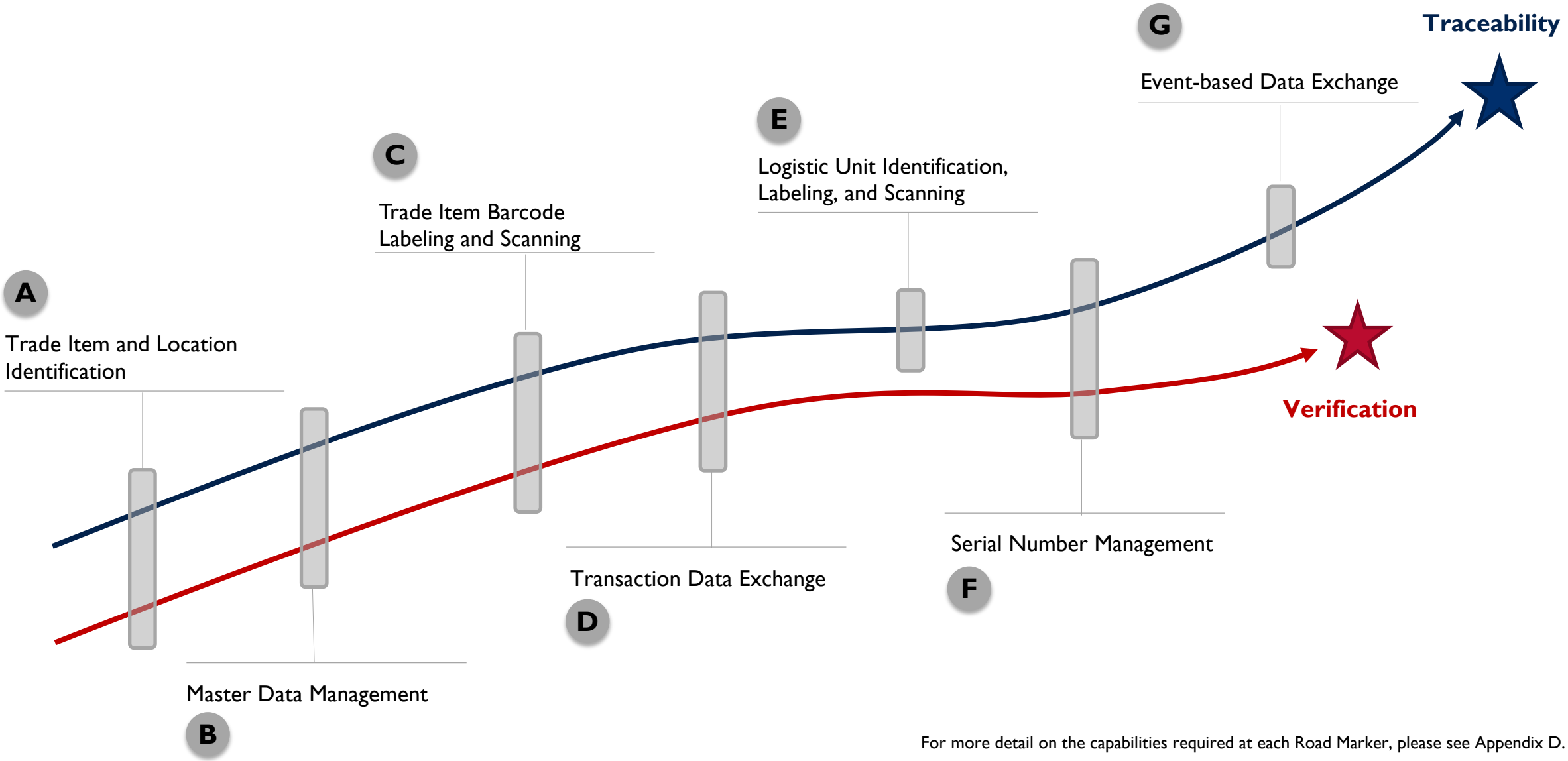
Additional Resources

The RxGPS Toolkit: Implementation Roadmap & Model Regulation

Illustrative example only

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

Illustrative Implementation Roadmap



For more detail on the capabilities required at each Road Marker, please see Appendix D.

Awareness & Advocacy

Establishes a baseline understanding of traceability and global standards, including defining the problem statement and opportunities and challenges for implementation, among key country stakeholders to inform the vision and strategy developed for country implementation.

Vision & Strategy

Outlines a high-level vision for what the country expects to achieve through traceability and the documentation and messaging needed to clearly define the strategic, overarching purpose of the initiative and how it will be implemented in collaboration with key stakeholders. Underscores the importance of mutually agreed upon priorities, clarity of purpose, and well-defined scope.

Architecture

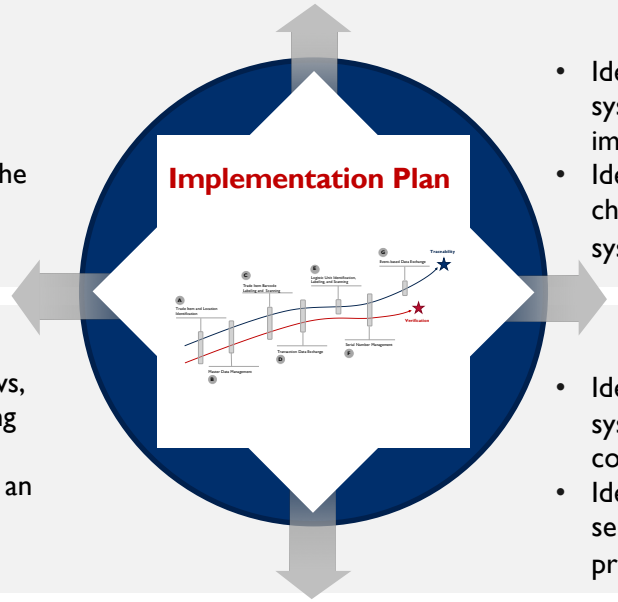
Identifies the overall system architecture requirements and supporting data models that need to be developed and implemented to enable traceability.

Policy

Identifies the set of principles or guidelines needed to implement the strategy. A policy can be disseminated and enforced as a legislation or regulation, procurement requirement, or formal guidance to trading partners in scope for the implementation.

Governance

- Creates a framework that includes decision authority, reporting lines, communication, and engagement among the various stakeholders responsible for traceability implementation.
- Determines the division of responsibilities and scope boundaries for the government vis-à-vis their trading partners.
- Ensures enforcement of policies and implementation requirements.



Supply Chain Operations

- Identifies and provides guidance on procedural norms for processes and systems use across the supply chain operations including procurement, importation, warehousing, inventory management, and distribution.
- Identifies key areas and requirements for capacity building within the supply chain workforce to enable implementation of established processes and systems at strategic points in the supply chain.

Systems & Technology

- Identifies supply chain systems and technology requirements, data flows, and architectures to support traceability implementation across trading partners.
- Enables capture and exchange of the appropriate data associated with an item for each physical movement of goods through the supply chain.
- Defines norms and good practices for their use.

Service Delivery

- Identifies and provides guidance on procedural norms for processes and systems use in service delivery functions across hospitals, clinics, and community health posts.
- Identifies key areas and requirements for capacity building within the service delivery workforce to enable implementation of established processes and systems.

Performance Management

Defines the key metrics and measurement processes to determine the performance and ability of the implementation plan to deliver stated objectives.

Pilot

Identifies the pilot activities that should be conducted at each step of implementation to identify any roadblocks and inform viability and strategy to scale.

Scale

Identifies the steps to scale, including key required documentation to codify established policies, processes, and structures for governance and ownership.

Road Marker A: Trade Item and Location Identification

What Is It?
A trade item is any product or service that is priced, ordered, or invoiced at any point in the supply chain. Unique identification of trade items and locations/legal entities is a foundational requirement for verification and traceability as a means to access master, transaction, and event information about items and locations in the supply chain and to share this information with internal and external trading partners. Use of GS1 Identification Keys, including the GTIN for items and the Global Location Number (GLN) for location legal entities, is recommended because they are globally unique and widely used in health care and retail. The use of global identification keys like the GTIN and GLN by all trading partners facilitates the exchange of information, increasing supply chain data visibility for all trading partners.

Expected Benefits
- Ensures that products have a globally unique identification number assigned to them across the entire product hierarchy, from pallet down to the lowest transaction unit
- Provides item/product clarity to all parties involved with shipping, receiving, invoicing, and payment and eliminates external product number cross-references
- Helps in identifying the physical item or location and reference data associated with that item or location in an information system
- Serves as the foundation for procurement accuracy, Good Distribution Practices (GDP), inventory management, verification, and traceability

Good Practices
- Establish a classification and identification strategy in accordance with global standards.
- Develop requirements for item identification that follow global standards and best practices.
- Develop an entity/location hierarchy.

Potential Pitfalls
- Attempting to create a national coding structure. Existing global standards have been shown to reduce overall cost for all trading partners and governments. National coding structures cannot leverage existing systems that incorporate global standard use.

Additional Resources
- GS1 Healthcare GTIN Allocation Rules
- GS1 GLN Allocation Rules Standard

Road Marker B: Master Data Management

What Is It?
Master data management (MDM) is, at its most basic, the process of linking identification data and reference data across multiple systems into a single, consistent point of reference. That single point of reference could be an item (GTIN) or location (GLN) identification number. MDM includes 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.[1]

Expected Benefits
An organization with strong MDM has a reliable asset that serves as a "single source of truth" to enable strategic decision making. These data are foundational for all items and locations to be used across supply chain business functions, from registration and importation to service delivery.

Good Practices
- Use a clear set of standard identifiers across products and locations.
- Leverage global identifiers to link data provided by trading partners to internal reference data.
- Leverage one or more global classification standards to establish linkages between items and products.
- Develop a strategy to manage legacy data through any transition to new practices and data structures.
- Establish a governance structure that defines roles and responsibilities, processes and rules for data access and management, data validation protocols, and metrics to manage data and ensure data quality.

Potential Pitfalls
- Treating MDM like an information technology project rather than a business strategy that is optimized with appropriate use of enabling technologies.
- Considering MDM as a point-in-time exercise rather than a discipline that is implemented and matures over time.

Additional Resources
- Introduction to Master Data Management
- Product Classification in Healthcare
- GS1 Global Data Synchronization Network™

1 Health Catalyst

Road Marker C: Trade Item Barcode Labeling & Scanning

What Is It?
Barcodes are symbols that can be scanned electronically using laser or camera-based technologies to automatically capture data encoded in the barcode and input it into relevant supply chain information systems, e.g., enterprise resource planning, warehouse management system (WMS), and LMIS. Barcodes play a key role in supply chains, enabling parties like retailers, manufacturers, transport providers, and hospitals to automatically identify and track products as they move through the supply chain.[1] Trade item packages should be labeled with a barcode with a minimal set of key data elements like the GTIN, batch/lot, and expiry date to ensure that these data can be captured and referenced at every point in the supply chain, through to the point of dispense. By scanning the GTIN, the user can also access other item master data stored within a given database.

Expected Benefits
As the physical item moves through the supply chain–whether across borders or in a warehouse–important reference data about that item can be automatically captured in a standardized format by all trading partners to improve accuracy of item data and efficiency of its input into a relevant database.

Good Practices
- Ensure physical movement of an item is accompanied by a barcode scan that captures GTIN, activity code, location, and value.
- Align barcode data carrier specifications and quality parameters with global standards (e.g., GS1-128 and GS1 DataMatrix).
- Identify the entity that is responsible for barcode quality and testing.
- Ensure barcode scanners can scan 1D and 2D barcodes in various environments.

Potential Pitfalls
- Developing proprietary barcode labeling is redundant and creates challenges to interoperability and future standards implementation.
- Including more data in the barcode than what is required to enable traceability increases costs for trading partners in applying and using that information.

Additional Resources
- GS1 AIDC Healthcare Implementation Guideline
- GS1 DataMatrix: A tool to improve patient safety through visibility in the supply chain
- Position paper on the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers and the Global GS1 Healthcare preference for the use of GS1 DataMatrix
- Position statement on camera-based scanners; Enabling Smartphones to read GS1 Data Matrix

[1] GS1 Global Office

Road Marker D: Transaction Data Exchange

What Is It?
Transaction data are any data derived from transactions, such as a requisition order (RO), purchase order (PO), advance ship notice (ASN), stock count, distribution order (DO), or invoice. Leveraging standards for transaction data exchange is important to enable automation of common business transactions commonly occurring across the supply chain in support of data accuracy and process efficiency. Fundamental to successful transactional data exchange is accurate master data and strong MDM practices, as master data constitutes approximately 80 percent of data elements in supply chain transactions. GS1 electronic data interchange standards are the global standard for transaction data exchange and include three sets of complimentary standards, including GS1 XML ,which is most commonly adapted to exchange transaction data using internet-based technologies.

Expected Benefits
Through automating transaction data exchange, trading partners can improve data accuracy, speed up business cycles, create business efficiencies through the reduction in low-value tasks like manual data entry, and enable near-real-time visibility into transaction status.

Good Practices
- Leverage a global standard for transaction data exchange minimizes the cost for trading partners to interact with different businesses.
- Start with supply chain systems that already have the capability to send or receive automated transaction data (e.g., national or central systems) and build out capabilities to subsequently lower levels of the supply chain over time.

Potential Pitfalls
- Scaling too quickly before protocols have been defined and tested with multiple types of trading partners and systems.

Additional Resources
- GS1 Electronic Data Interchange
- Healthcare EDI Implementation Toolkit

Road Marker E: Logistic Unit Identification and Barcode Labeling

What Is It?
A logistic unit is an item of any composition established for transport and/or storage that needs to be managed throughout the supply chain, for example, a case, pallet, parcel, or tote. The serial shipping container code (SSCC) is a unique serialized number assigned by and labeled on the package by the creator of the logistic unit. SSCCs are matched with the electronic business messages that refer to them, such as packing slips and advanced ship notices (ASNs), to track them individually to support order and delivery tracking, automated goods receiving, and as a reference number to provide detailed information on the contents of a given unit. The SSCC can be captured when a unit is dispatched, arrives at its destination, and at any other intermediary point during its useful life. The SSCC also serves as a critical identifier for aggregating serial numbers when implementing track and trace.

Expected Benefits
Logistic unit identification and labeling are critical to enabling automation in the supply chain process through ensuring that every item is uniquely identified on the physical package and in subsequent reference documents. This supports efficiencies in shipping, receiving, and handling logistic units and their contents.

Good Practices
- The SSCC is assigned by the creator of the logistic unit. If the logistic unit is broken down and repacked, a new SSCC will have to be assigned to the new logistic unit(s).

Potential Pitfalls
- Underestimating the role of all logistics providers in being able to generate and manage SSCCs for all logistic units.

Additional Resources
- An Introduction to the Serial Shipping Container Code (SSCC)
- GS1 Logistics Label Guideline
- GS1 General Specifications

Road Marker F: Serial Number Management

What Is It?
Both batch/lot and serial numbers can be used for track and trace at different levels of granularity. Batch/lot numbers correspond to a certain number of items assigned to a common group of items that were manufactured at the same time. Batch/lot and items have a one-to-many relationship, as many items can have the same batch/lot number. Serial numbers correspond to a unique instance of a given item; the serial number and its item have a one-to-one relationship, allowing an entity to track and trace the item from manufacture to dispense. The combination of a GTIN + serial number creates a globally unique identifier for every instance of an item. With serialization comes a significant increase in the amount of data that needs to be exchanged and managed through the supply chain. Evaluating these different models based on the vision and goals for a specific implementation and ensuring sufficient capability to manage and exchange this information are paramount for a successful outcome.

Expected Benefits
Serialization allows for the highest degree of precision in identifying a unique instance of an item in the supply chain. Serialization is a critical component for the most granular form of track and trace and offers a mechanism for a high degree of accountability in distributing each item, as it changes custody or ownership in the supply chain.

Good Practices
- Protect the integrity of the serial number by ensuring data security, including restricted access to the serial numbers assigned by the manufacturer and shared with the implementing organization.
- Archive serial numbers for continued reference. They play a critical role in a range of health regulatory functions, including product recalls and pharmacovigilance, and access must be ensured during and after the product's lifecycle.

Potential Pitfalls
- Clarifying intent of use. Serialization of items is a significant investment of manufacturers and does not provide a benefit to the supply chain unless the serial number data are used for track and trace or verification. It is recommended that an implementer not mandate serialization until the intent of use of that serial number data and the mechanisms for data exchange are clear.
- Varying complexity of serial number data management. Data models can range from being relatively rudimentary for verification to highly complex, including managing aggregation of serial number data, for track-and-trace initiatives. Ensure stakeholders understand the complexity of the solution proposed and resources required to secure adequate infrastructure at the central level and for in-scope trading partners.

Additional Resources
- RxGPS Alliance Serialization Primer
- RxGPS Alliance Position Statement: Benefits and Complexity of Common Serialization Models

Road Marker G: Event Data Exchange

What Is It?
Track and trace requires that different trading partners share information about the physical movement and status of products as they move through the supply chain–from partner to partner, and ultimately to the end user. Event data answer the questions "what, where, when, and why?" to meet reporting demands from a range of public health stakeholders, from regulatory authorities to consumers. The GS1 Electronic Product Code Information Services (EPCIS) standard, in conjunction with the GS1 Core Business Vocabulary (CBV), is the global standard for event data exchange to enable disparate applications to create and share visibility event data, within and across enterprises, according to common definitions of data values.[1]

Expected Benefits
Event data exchange enables a complete ledger of item status, custody/ownership, and location over the lifecycle of the item, from manufacturer to dispense. The benefit of using the EPCIS standard to implement event data exchange is that it leverages with the GS1 global standards already being implemented worldwide and is versatile to meet the needs of a wide range of trading partners.

Good Practices
- Pilot event data exchange with various trading partners to validate requirements before scaling implementation efforts.

Potential Pitfalls
- Overestimating the capabilities of trading partners to scan and report for all events in scope.

Additional Resources
- GS1 EPCIS and CBV
- EPCIS and CBV Implementation Guideline
- Healthcare Supply Chain Integrity Enabled by EPCIS

[1] GS1 Global Office

For more information, please contact:

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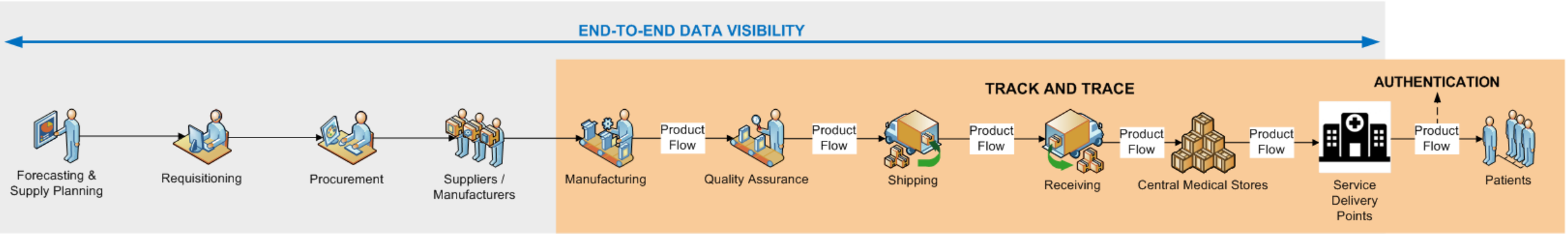
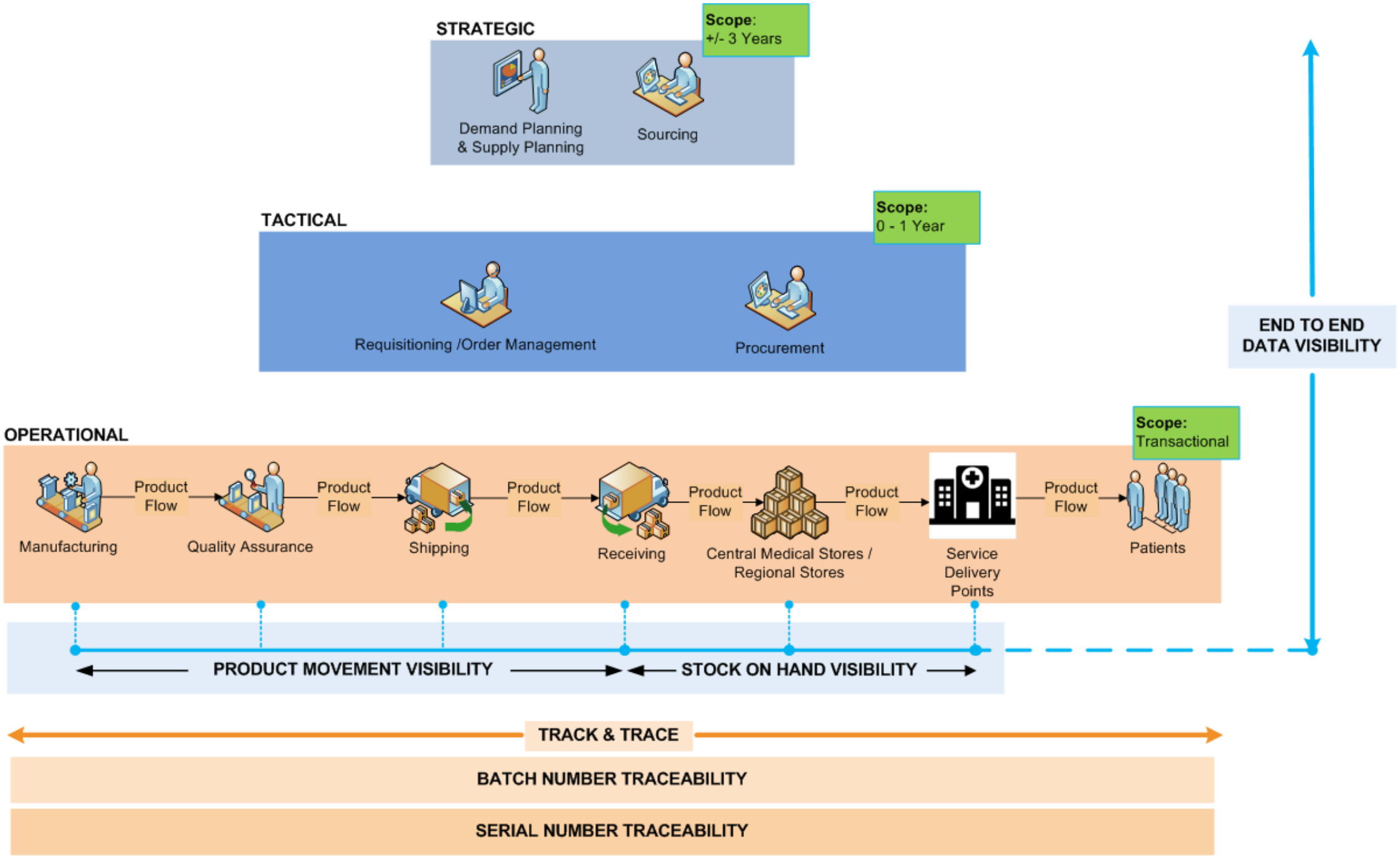
The USAID Global Health Supply Chain-Procurement and Supply Management project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, and population and reproductive health commodities.

Appendix A. Traceability and end-to-end data visibility

Differentiating traceability and end-to-end data visibility



	End-to-End Data Visibility	Traceability
Objective	• Ensure data visibility from planning until delivery of products/commodities to enhance decision making • Monitor execution to guide every task and manage supply chain exceptions	• Tracking movement of products across the supply chain to improve supply chain efficiency • Tracing where products came from and where they went to to facilitate product recalls • Verifying products to remove SF medicines and improve patient safety
Scope	• Strategic, tactical, and operational • Processes and data related to supply chain planning and order management as well as physical product movement	• Operational and transactional • Processes and data related to physical product movements
Level of Detail	• Data aggregated at the product level	• Data at GTIN, batch/lot, and serial number levels of granularity
Benefits	• Manage supply chain exceptions, such as delays, stockouts, and demand fluctuations • Facilitate better decision making around supply planning • Provide better coordination across supply chain enabling efficient resource allocation	• Ability to locate products accurately through different supply chain stages • Improved patient safety • Elimination of counterfeit products • Ability to recall products effectively


STRATEGIC
Scope:
+/- 3 Years
Demand Planning
& Supply Planning
Sourcing
TACTICAL
Scope:
0 - 1 Year
Requisitioning /Order Management
Procurement
END TO END
DATA VISIBILITY
OPERATIONAL
Scope:
Transactional
Manufacturing
Product Flow
Quality Assurance
Product Flow
Shipping
Product Flow
Receiving
Product Flow
Central Medical Stores /
Regional Stores
Product Flow
Service
Delivery
Points
Product Flow
Patients
PRODUCT MOVEMENT VISIBILITY
STOCK ON HAND VISIBILITY
TRACK & TRACE
BATCH NUMBER TRACEABILITY
SERIAL NUMBER TRACEABILITY

Appendix B. Stakeholder engagement

The importance of stakeholder engagement

A successful traceability initiative requires an integrated approach incorporating all major stakeholder groups that will have a role in implementation. Because traceability requires investment in people, process, and technology across a number of health sector functions—including manufacturing, regulatory, procurement, importation, warehousing, distribution, and service delivery—those perspectives must be considered from the onset to ensure they are appropriately represented in designing the vision, strategy, architecture, policy, and implementation plan.

INTERNATIONAL

Manufacturers

Importers/Distributers/Wholesalers

GS1 Member Organizations

Regional Harmonization Initiatives

NATIONAL

Ministries of Health

Regulatory Authorities

Customs and Revenue Authorities

Law Enforcement/Inspector General

National Standards Bureaus

Central Medical Stores

Private Sector Federations

DEVELOPMENT PARTNERS

Donors

Procurement Agents

Financing Institutions

Public Health Implementing Partners

SUBNATIONAL

Regional/District Medical Stores

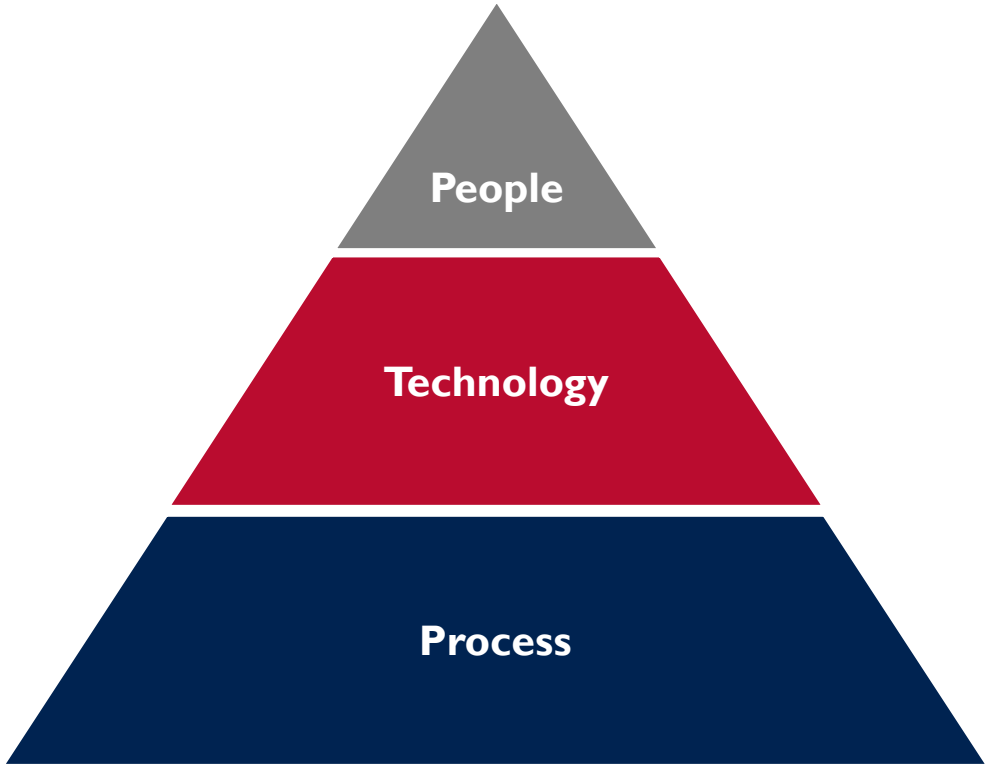
Service Delivery Points (e.g. , Hospitals, Clinics)

Health Workers

Patients

Appendix C. Example architecture models

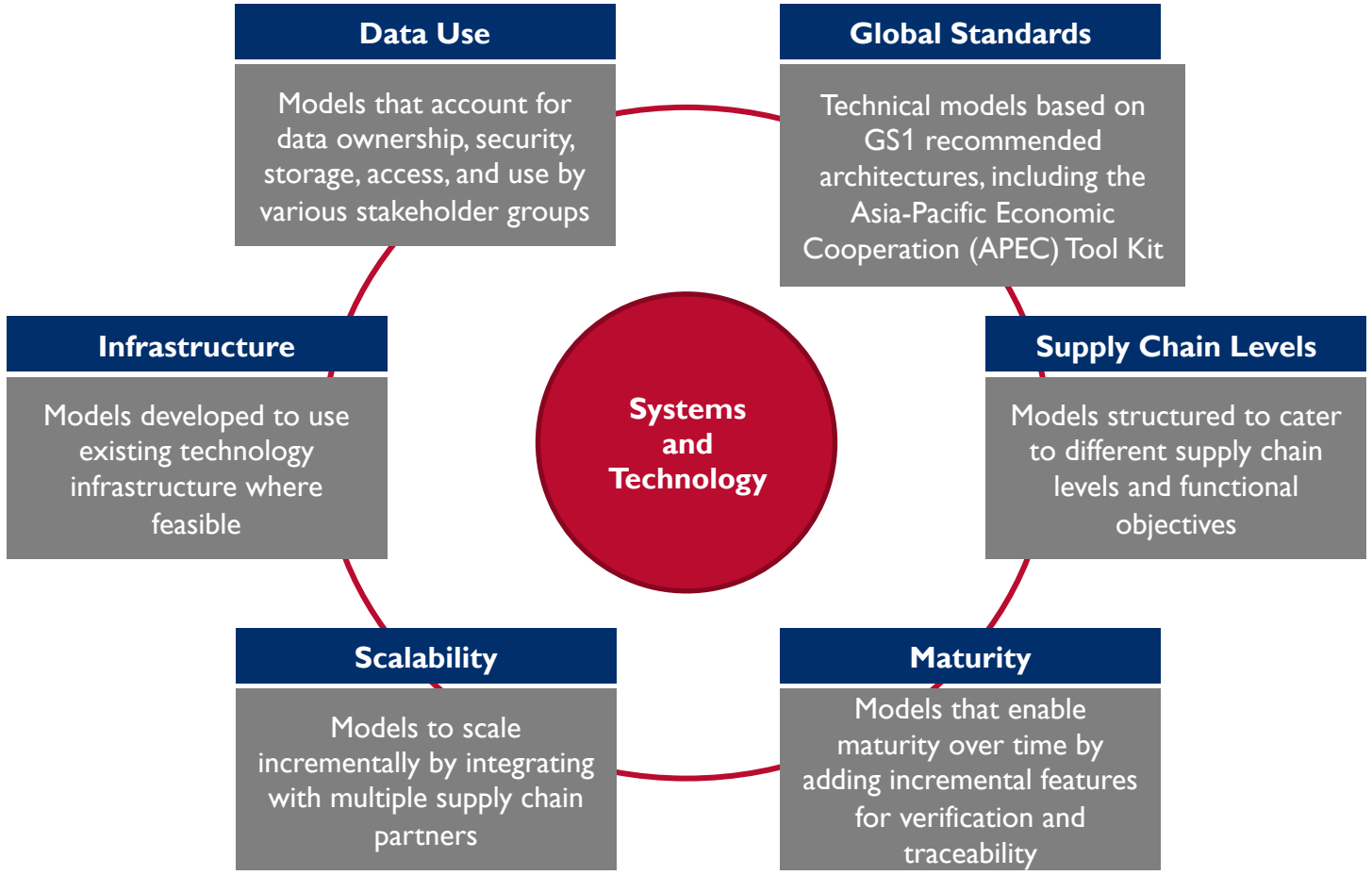
What is Technology Architecture?



Along with people and process, technology is a foundational element of any traceability solution. The architecture organizes how you plan to implement systems, their associated technologies, and data flows.

The following slides detail the considerations needed to outline an efficient, effective, scalable architecture that is based on industry standards.

Considerations in Architecture Design



Additional Resources

APEC Supply Chain Security Tool Kit

GS1 Healthcare Supply Chain Traceability Models

Leveraging the Existing Technology Landscape

It is recommended that countries that implement verification and/or traceability seek to leverage their existing systems and technology investments wherever possible to support the implementation of their initiatives and invest only in new modules, integration layers, or capabilities as needed to close gaps between what exists and what is required to achieve stated objectives.

Verification

Current enterprise resource planning (ERP), DRIS, LMIS, or WMS can be leveraged, if the capabilities exist to:

- Manage item master data
- Capture and retain inbound event data, including batch/lot and/or serial numbers, as commodities enter the country
- Have downstream trading partners validate batch/serial numbers against the retained event data

Traceability

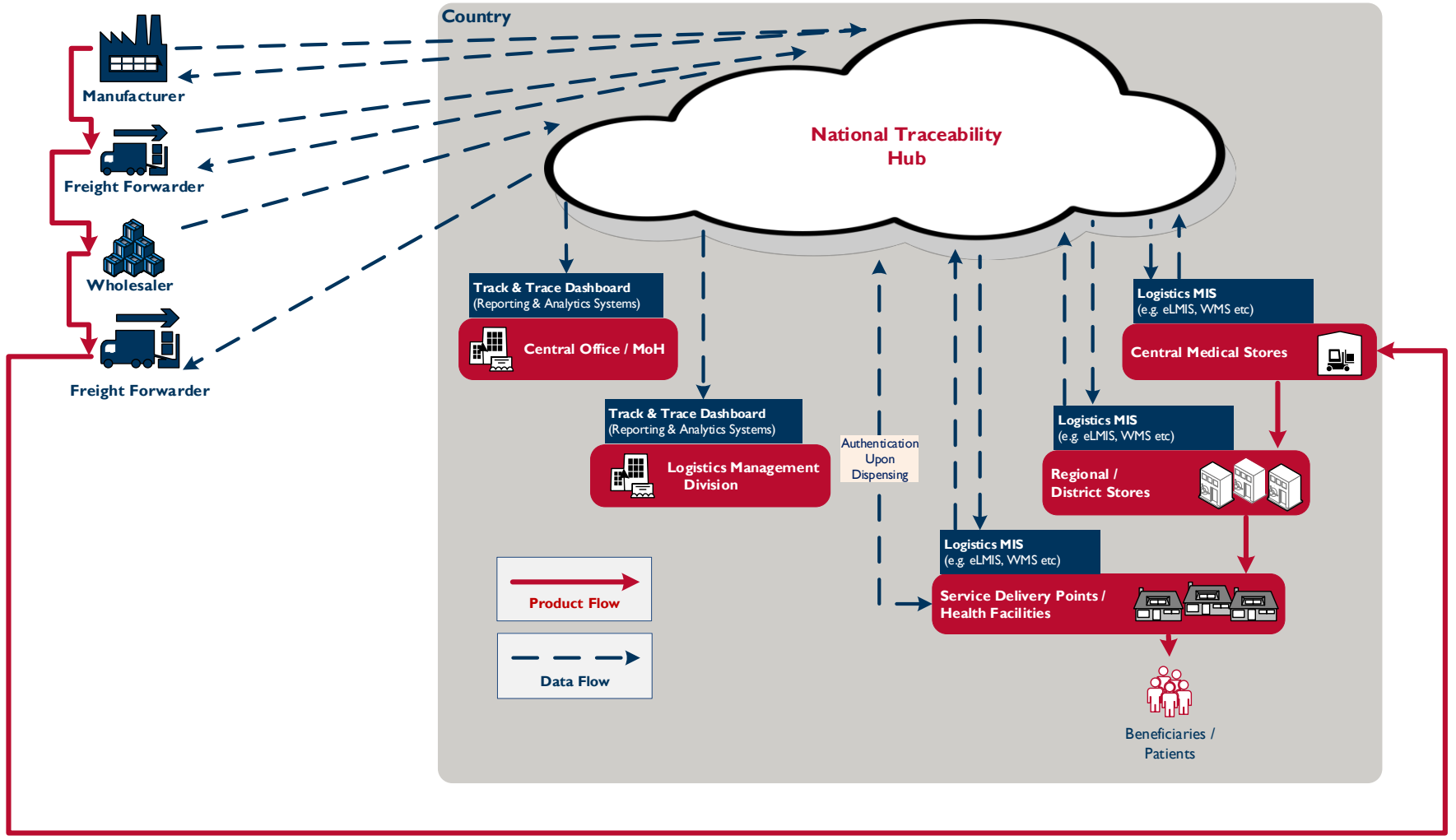
Current ERP, DRIS, LMIS, or WMS can be leveraged, if the capabilities exist to:

- Manage item and facility master data
- Capture and retain inbound event data, including batch/lot and/or serial numbers, as commodities enter the country
- Capture and retain event data, including batch/lot and/or serial numbers, as reported by trading partners as product custody or ownership changes through the supply chain

Illustrative example only

Each country will develop a traceability model based on their vision and strategy

Centralized Model (National)



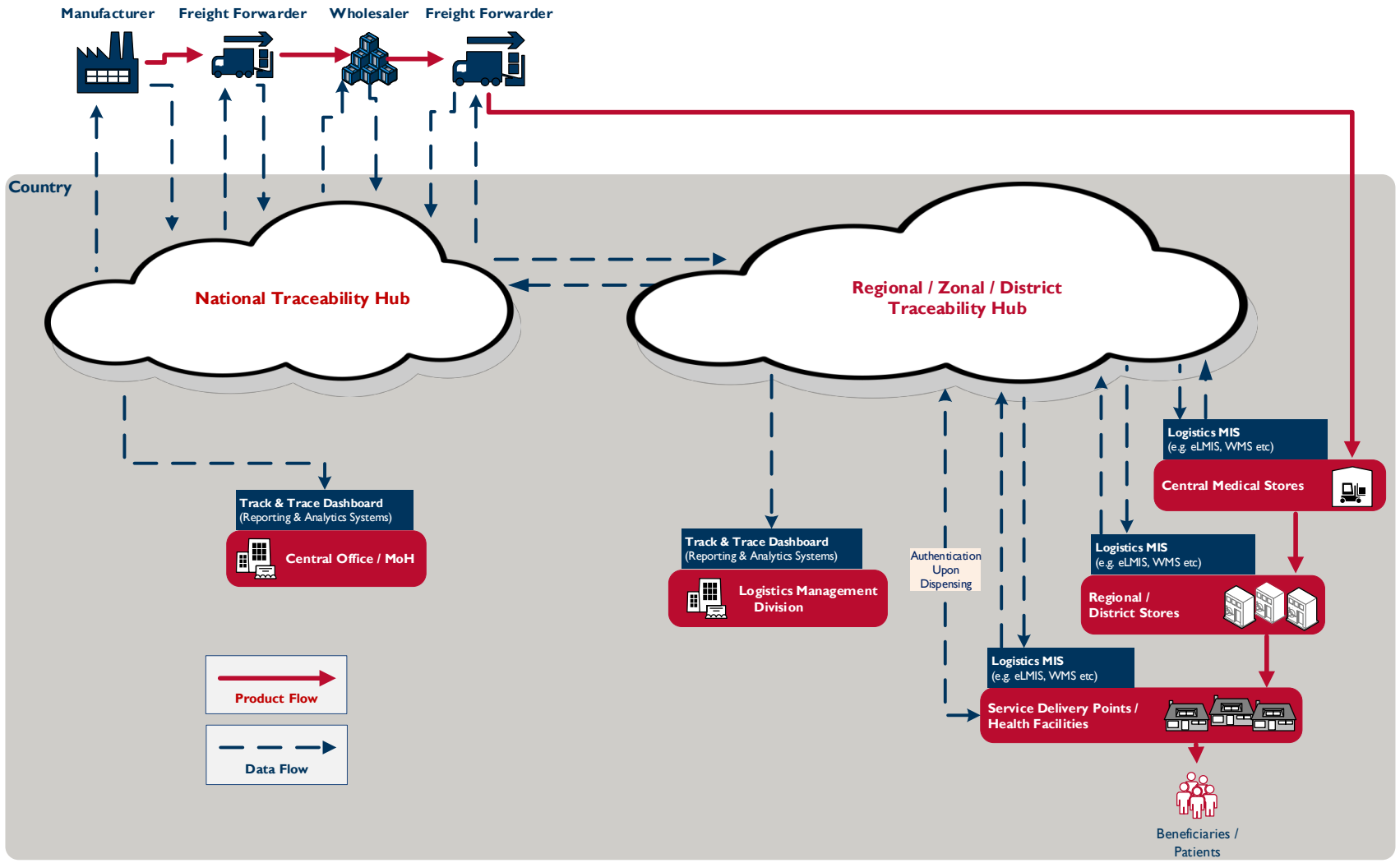
Central Hub Highlights:

- One centralized data repository (hub) at the country level managed by a ministry, regulatory authority, or logistics management unit
- Trading partners to share event data with the central hub
- Requires data integration with trading partners for data exchange

Illustrative example only

Each country will develop a traceability model based on their vision and strategy

Semi-Centralized Model (National)



National Hub Characteristics

- National data hub managed by ministry, regulatory authority, or logistics management unit
- External trading partners to share event data with the central hub
- Requires data integration with trading partners for data exchange

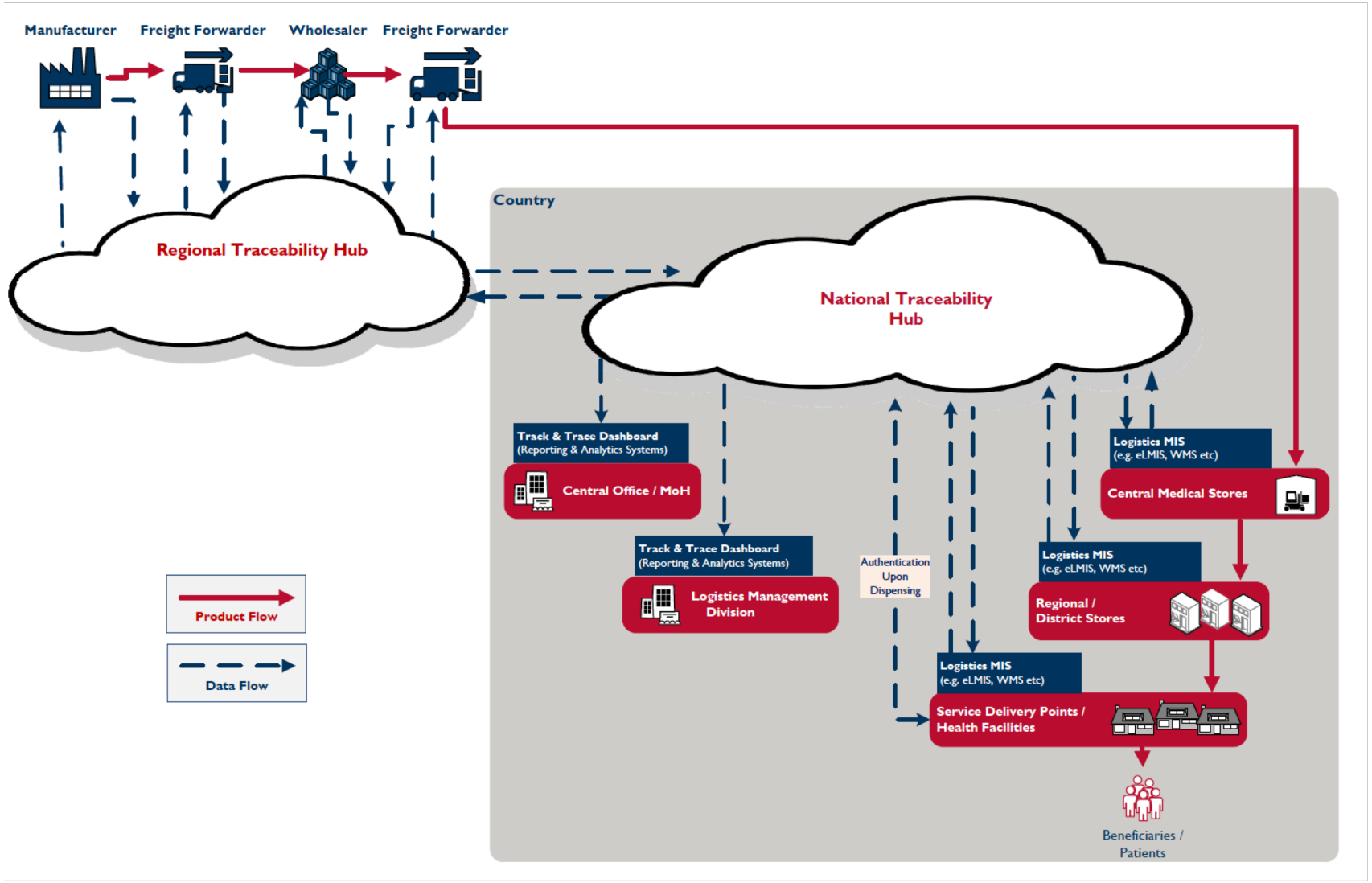
Subnational Hub Characteristics

- Regional-, zonal- or district-level hub to manage subnational event data reporting
- Requires data integration with internal trading partners for data exchange

Illustrative example only

Each country will develop a traceability model based on their vision and strategy

Semi-centralized Model (Regional)



Regional Hub Characteristics

- Regional hubs managed by a representative group of regional governments
- External trading partners to share event data with the central hub
- Requires minimal data integrations with external trading partners for data exchange (e.g., report to only one regional hub)

National Hub Characteristics

- National or subnational hubs to manage internal event data reporting
- Requires data integration with internal trading partners for data exchange

Key Considerations for Traceability Models

	Centralized	Semi-Centralized
Architecture	• One repository for a country or region • All event data are reported into one repository	• More than one repository by country, region, etc. • Event data are reported into multiple repositories
Data Security	• The more centralized the data, the greater the security risk • Security will be managed by a central authority	• Security risk is distributed, but secure solutions need to be managed at multiple points in the supply chain
Data Sharing and Access	• Centralized management of data rights, access, and use • Data accessed from one central repository by all users	• Data reported to and accessed from multiple repositories • Need to clearly defined data ownership and exchange protocols
Governance	• Less complex with a single repository that can be managed by a central authority (e.g. Ministry of Health, National Drug Regulatory Authority, or similar)	• More complex with multiple repositories governed by different entities within a country or across countries
Ease of Implementation	• Responsibility for implementation and enforcement resides with a single entity • Can take a phased approach with incrementally more reporting incorporated over time	• Responsibility of implementation and enforcement resides with multiple entities within or across countries • Can take a phased approach with additional hubs onboarding over time
Interoperability	• Integrating master, transaction, and event data from different supply chain partners requires use of data standards to support a high level of interoperability	• Enabling traceability across multiple repositories requires use of data standards for master, transaction, and event data to support a high level of interoperability
Benefits	• Strong centralized coordination and control • High levels of visibility across the entire supply chain	• Can expand scope of traceability across regions as they mature • Address challenges related to regional trade and open borders • External trading partners can integrate to a single system while internal trading partners can report to regional systems
Limitations	• Data visibility will be restricted to items legally imported into the country (rather than legally imported into the region but not being distributed in country)	• Visibility limited to subnational or subregional repositories • Need to manage risk of items being reported across multiple repositories through the distribution lifecycle

Appendix D: Capabilities requirements matrix

Road Marker A: Trade Item and Location Identification

Road Marker A: Trade Item & Location Identification

Function	Foundational Capability	Verification Capability	Traceability Capability
OVERVIEW	*Internal use of unique identifiers (stock-keeping units, or SKUs) at the tertiary and secondary trade item levels, with the option to use GTIN as an additional identifier. *Internal use of unique identifiers for locations/entities, including vendors, supply chain partners, and facilities, with the option of using GLN as an additional identifier.	*GTIN is the primary identifier at the trade item secondary pack level. *GLN is the primary identifier for the manufacturer or responsible entity. *For point-of-dispense verification, each point of dispense is assigned a unique identifier (with preference for GLN).	*GTIN is the primary identifier at the trade item tertiary and secondary pack levels. *GLN is the primary identifier for all locations/entities, including vendors, supply chain partners, and facilities.
Governance	*An organization or entity is responsible for managing item and location identification.	*A mechanism is in place to: - Monitor and enforce compliance with stated policies - Collect and validate uniqueness and completeness of trade item and location identifiers - Enforce policy and process, conduct basic data quality checks, and avoid duplication	
Supply Chain Operations	*Warehousing, inventory management, order management, and distribution processes use SKUs for the transaction unit of measure. *Stocking unit of measures are in place to manage products and trade items at the secondary and tertiary pack levels.		*Warehousing, inventory management, order management, and distribution processes use GTINs to manage trade items at the secondary and tertiary pack level. *Business rules are established to determine on which packaging hierarchy level supply chain partners will transact.

Road Marker A: Trade Item and Location Identification (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	* Supply chain systems can: - Generate and maintain SKUs at the transaction unit of measure, accounting for unit conversion between the transactional SKU and its multiple trade item packaging and product hierarchies used for stocking and other logistics purposes - Capture data on SKUs during warehousing, inventory management, order management, and distribution functions to reconcile transactions - Generate and maintain unique identifiers for locations, including vendors, warehouses, facilities, etc. - Use location identifiers in transactions, such as to identify where commodities are shipping from, where they are being shipped to, and where they will be stored	*Regulatory information system can maintain GTIN and GLN in association with item marketing authorization. * Supply chain systems can: - Capture and share GTINs for the trade item secondary pack level to/from service delivery points (SDPs) - Capture and share unique location identifiers, including GLN, for vendors and facilities to/from SDPs	*Regulatory information system can maintain GTIN and GLN in association with item marketing authorization * Supply chain systems can: - Capture and share GTINs for the trade item secondary and tertiary pack levels - Use GTINs during warehousing, distribution, and inventory management functions to reconcile transactions - Capture and share GLNs for vendors, warehouses, and facilities *WMS, ERP, and/or electronic logistics management information systems (eLMIS) can use GLNs in transactions, such as to identify where commodities are shipping from, where they are being shipped to, and where they will be stored.
Service Delivery	*Mechanisms are in place to identify trade items. *Processes are in place to record orders, receipts, stock, and dispense.	* GTIN can be used to identify a trade item at point of dispense. *GLN or another unique identifier can be used to identify a point of dispense.	*GTIN can be used to identify a trade item at point of dispense. *GLN can be used to identify a point of dispense.

Road Marker B: Master Data Management

Road Marker B: Master Data Management			
Function	**Foundational Capability**	**Verification Capability**	**Traceability Capability**
OVERVIEW	*A product master data file with a minimum set of key attributes from data that are available from trading partners or that can be collected in country. *Location master data files for supplier/manufacturer and recipient/facility with a minimum set of key attributes from data that are available from trading partners or can be collected in country.	*GTIN is the primary identifier at the trade item secondary pack level. *GLN is the primary identifier for the manufacturer or responsible entity. *For point-of-dispense verification, each point of dispense is assigned a unique identifier.	*A minimum set of trade item master data needed for traceability and associated with a GTIN is maintained for the tertiary and secondary trade item level. *A minimum set of location or legal entity master data needed for traceability and associated with a GLN is maintained for all trading partners in the supply chain.
Governance	*A data governance framework that captures roles, responsibilities, metrics, and basic rules for trade item and location identification, nomenclature, and classification. *Processes are in place to manage new item introduction, including master data sourcing, quality check, and publishing.	*A data steward is identified as the responsible party for maintaining the master data file. *Master data sharing requirements are defined for all trading partners. *GTIN and GLN data are linked to the marketing authorization process and data management. *Data quality metrics are established, tracked, and reviewed routinely.	
Supply Chain Operations	*Master data serve as the primary reference data for all supply chain transactions. *Supply chain functions can manage both products (e.g., on in-bound requisitions) and items (e.g., on order fulfillment).	*GTIN is used as primary identifier for ordering items from vendors to improve procurement accuracy.	

Road Marker B: Master Data Management (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	* Supply chain systems can: - Create and maintain single- and multi-value master data attribute for trade items. - Manage multiple hierarchies, including parent/child relationships between products and items; packaging hierarchies; and relevant product classification structures. - Create and maintain master data attributes for locations and legal entities. - Manage multiple hierarchies, including manufacturer/supplier relationships.	*Trade item and location master can be accessed through application or eHealth system at point-of-dispense.	*Master data collection is automated through synchronization (e.g., Global Data Synchronization Network). *Master data are accessible across eHealth systems in the country through a product data registry, repository, or hub. *The same item master data are referred across all transactions and across all supply chain systems so that batches and serial numbers associated with those transactions can be linked and traced with the associated products/items. *The same location master data are referred across all transactions and across all supply chain systems so that batches and serial numbers associated with those transactions can be traced across the supply chain as they move.
Service Delivery	*SDPs have access to master data to identify trade items and locations to support processes for recording orders, receipts, stock, and dispense.	*SDPs can access trade item and location master data that are required for verification and traceability of health commodities.	

Road Marker C: Trade Item Barcode Labeling and Scanning

Road Marker C: Trade Item Barcode Labeling and Scanning

Function	Foundational Capability	Verification Capability	Traceability Capability
OVERVIEW		*GS1 2D DataMatrix with GTIN, batch/lot, expiration date, and serial number is printed on the trade item secondary pack level. *2D barcode scanning is enabled at the point-of-dispense or point-of-use.	*GS1 128-Linear Barcode or 2D DataMatrix with GTIN, batch/lot, expiration date, and serial number is printed on the trade item tertiary pack level. *GS1 2D DataMatrix with GTIN, batch/lot, expiration date, and serial number is printed on the trade item secondary pack level. *1D and 2D barcode scanning are enabled at each point in the supply chain.
Governance		*A mechanism is established to monitor and enforce compliance to stated data capture and reporting policies.	
Supply Chain Operations	*SOPs are in place for managing data capture about trade items in warehousing, inventory management, order management, and distribution processes.		*All warehousing, inventory management, and distribution processes are enabled through barcode scanning. *Locations are labeled within warehouses. *All product movement is associated with a barcode scan that captures GTIN, activity code, location, and value. *GTINs are registered, assigned, and labeled for any new trade items created in the supply chain (e.g.. kits, bundles). *Supply chain workforce is trained in data capture through barcode scanning for processes in scope for their position. *Mechanisms are in place to monitor adherence to standard operating procedures (SOPs).

Road Marker C: Trade Item Barcode Labeling and Scanning (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	*Supply chain systems can read, generate, and print 1D and 2D barcodes.	*Supply chain systems can capture data scanned from 2D barcodes at the trade item secondary pack level.	*Systems capable of capturing data scanned from 1D and 2D barcodes by all trading partners in scope at the trade item tertiary and secondary pack levels. *Captured data are cross-referenced to other transactional data, such as POs, packing slips, CIs, ASNs, and proof of deliveries (PoDs) to facilitate transaction processing. *Supply chain systems have controls in place to require validation through a scan to support any change in item movement, status, or custody.
Service Delivery	*SDPs can scan barcodes or record human readable interpretation from packages to identify trade items to support processes to record orders, receipts, stock, and dispense.	*SDPs have technology and processes in place to capture data at the trade item secondary pack level. *The health-care workforce is trained in data capture through barcode scanning for dispense-related processes in scope for their position. *Mechanisms are in place to monitor adherence to SOPs.	*All receipt, inventory management, and dispense processes are enabled through barcode scanning. *The health-care workforce is trained in data capture through barcode scanning for processes in scope for their position. *Mechanisms are in place to monitor adherence to SOPs.

Road Marker D: Transaction Data Exchange

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.		

Road Marker D: Transaction Data Exchange (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	*Supply chain systems record transactional documents such as POs, IOs, ASNs, CIs, air waybills (AWBs), and PODs *If an end-to-end system is not available, leverage a rudimentary system that can facilitate capturing and storing such data and providing access to such data when required, e.g., a reporting database. *Supply chain systems have automated data exchange through SFTP, integration bus, EDI/XML, or application program interface (API).	*Supply chain systems electronically receive transaction data on inbound shipments from vendors.	*Supply chain systems send and receive transactional data electronically to and from supply chain participants such as vendors, warehouses and facilities. *Supply chain systems are able to capture change in valuation of item as it changes custody or ownership as a record in the case of return, diversion, theft, or loss. *Transaction data exchange should be near-real-time if not real time (e.g., within at least a day of transacting).

Road Marker E: Logistic Unit Identification, Labeling, and Scanning

Road Marker E: Logistic Unit Identification, Labeling, and Scanning			
Function	**Foundational Capability**	**Verification Capability**	**Traceability Capability**
OVERVIEW	*Standard shipping label is used consistently across logistic units. *A serial shipping container code (SSCC) may be used as a license plate/tracking number.		*SSCCs are applied to all logistic units by the creator of that logistic unit and referenced on all relevant transactional documentation.
Governance	*No requirement.		*A mechanism is established to monitor and enforce compliance to stated logistics unit labeling policies.
Regulatory/Procurement	*A policy or guidance document is in place that states the requirement for product and location/entity identification. *A policy is in place that states the labeling requirement for data capture at one or more trade-item levels.		

Road Marker E: Logistic Unit Identification, Labeling, and Scanning (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Supply Chain Operations	*Use SSCC as tracking number to enable processes such as logistic unit receiving and shipping.		*Use SSCC number to enable processes such as logistic unit receiving, packing, and shipping against transactional documentation.
Systems & Technology	*Supply chain systems can capture unique identification for logistic units for all related processes.		*An SSCC can be captured from a barcode and managed in the system. *SSCC numbers can be generated by the system and printed on a GS1-128 linear barcode.

Road Marker F: Serial Number Management

Road Marker F: Serial Number Management			
Function	**Foundational Capability**	**Verification Capability**	**Traceability Capability**
OVERVIEW	*Trade items are identified in systems and processes uniquely by batch/lot and expiration date.	*Unique serial number is added to the data set encoded at the trade item secondary pack level. *GTIN + unique serial number is maintained in a database (centralized) or series of databases (semicentralized or decentralized) and can be accessed by dispenser or end-user through a user interface.	*Unique serial number is added to the data set encoded at the trade item secondary and tertiary pack levels. *GTIN + unique serial number is maintained in a database (centralized) or series of databases (semicentralized or decentralized) and can be referenced by supply chain trading partners.
Governance		*A mechanism is established to monitor and enforce compliance to stated serialization identification, labeling, and data exchange policies. *Rules are established for serial number data storage, security, access, and use. *Policies and processes are developed to verification at the point-of-use or point-of-dispense, including policies and processes for dispensers when an item is found to be unverifiable.	*A mechanism is established to monitor and enforce compliance to stated serialization identification, labeling, and data exchange policies. *Rules are established for serial number data storage, security, access, and use. *Policies and processes are developed to govern management of serial numbers by item custodians or owners through the supply chain through to point-of-dispense or point-of-use.
Supply Chain Operations	*Inventory of trade items is managed based on batch/lot and expiration date.		*Supply chain processes are adjusted to manage items at the unique serialized item level (e.g., receiving, inventory management, picking, packing, shipping). *SSCC number is used to manage aggregation and disaggregation of serial numbers in supply chain processes.

Road Marker F: Serial Number Management (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	*Supply chain systems have the capability to manage trade items based on batch/lot and expiration date. *Supply chain systems capability is developed to securely capture and maintain or route serialization data.	*System can validate, or route validation, serial number queries against a reference database to validate the origin of the trade item. *Technology applications are developed for use at point-of-dispense or point-of-use to scan barcodes. *User interfaces are developed to link the system to the technology applications to notify dispensers or users of verifiable or nonverifiable outcomes.	*Serial numbers are linked to GTINs, batch/lot, and expiration date. This linkage is retained even if serial numbers are aggregated or disaggregated to/from their associated batches. *Serial numbers are captured and exchanged across supply chain systems as items flow through transactions. *Serial numbers and their associated GTINs, batch/lot, and expiry are managed and maintained through a secure database and archived upon decommission. *Systems can enable aggregation and disaggregation of serial numbers as logistics units and trade item packs are dismantled and/or repackaged through the supply chain. Exchange of transactional data should provide the linkage between GTINs, serial numbers, and their associated batch/lot numbers to facilitate this process. This linkage and information should continue to be maintained across the supply chain and all systems as commodities move through and get redistributed, repackaged, etc.
Service Delivery	*SDPs manage items based on batch/lot and expiration date.	*For point-of-dispense, SDPs must have access to the technology and capability required to scan an item barcode to verify the serial number before dispense to patient. *Health workers must be trained on required policies and processes should they scan a barcode that is found to be unverifiable.	*SDPs must have access to the technology and capability required to scan an item barcode to record the serial number upon receipt and/or before dispense to patient.

Road Marker G: Event Data Capture and Exchange

Road Marker G: Event Data Capture & Exchange			
Function	**Foundational Capability**	**Verification Capability**	**Traceability Capability**
OVERVIEW	*Ability to receive and capture foundational data about major events in the supply chain (e.g., shipping, receiving, issuing)		*Data capture is associated with a specific item, location, legal entity, and business process. *Event data are captured and exchanged in adherence with the GS1 Electronic Prodcut Code Information Services (EPCIS) and Core Business Vocabulary traceability standards. *Chain-of-custody or chain-of-ownership events are captured in a standard, structured format.
Governance			*A mechanism is established to monitor and enforce compliance to stated event data capture and exchange requirements by various partners in the supply chain. *Policies and processes are developed to govern management and use of event data.
Supply Chain Operations	*Transactions are recorded in near-real time if not real time (e.g., within at least a day of transacting) *Foundational event data are captured for major supply chain processes		*Events are captured for every physical change of ownership or custody of an item in various supply chain processes. *Mechanisms are in place to monitor adherence to SOPs.

Road Marker G: Event Data Capture and Exchange (cont.)

Function	Foundational Capability	Verification Capability	Traceability Capability
Systems & Technology	*Transaction data exchange is fully automated and should be near-real time if not real time (e.g., within at least a day of transacting) and/or synchronized from a device at an established frequency. *Event data exchange is enabled through SFTP, integration bus, EDI/XML, or API.		*Event data exchange is managed leveraging the GS1 EPCIS standard. *Technology is in place to capture an event and associate it with a specific item and entity through GTIN and GLN, respectively. *Receive, record, and exchange supply chain event data from and to other supply chain partners, such as vendors, warehouses, freight forwarders, and health facilities. *Exchanged event data include information of the products/items, batches, serial numbers, packages, etc. (what), event date/time (when), location details of the event (where), and transaction details (why).
Service Delivery			*Events are captured for every physical change of ownership or custody of an item through to dispense to a patient. *The health-care workforce is trained in event data capture through processes in scope for their positions. *Mechanisms are in place to monitor adherence to SOPs.

Acronyms & Glossary

Acronyms

AI	GS1 Application Identifier
AIDC	automatic identification and data capture
ASN	advance ship notice
AWB	air waybill
CBV	Core Business Vocabulary
CI	commercial invoice
DRIS	drug regulatory information system
EDI	electronic data interchange
eLMIS	electronic logistics management information system
EPCIS	Electronic Product Code Information Services
GDSN	Global Data Synchronization Network
GLN	Global Location Number

Acronyms (cont.)

GTIN	Global Trade Item Number
HRI	human readable interpretation
IO	internal order
MDM	master data management
MIS	management information system
MO	GS1 Member Organization
PO	purchase order
POD	proof of delivery
RO	requisition order
SSCC	serial shipping container code
SDP	service delivery point

Glossary

Term	Definition
automatic identification and data capture*	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 Standards Organization (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 typically responsible for managing 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.
DataMatrix*	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
Global Trade Item Number	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.
GS1-128 linear barcode	A barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128, used exclusively for GS1 system data structures.
GS1 Application Identifier*	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 DataMatrix*	GS1 implementation specification for use of ISO/IEC DataMatrix, a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.

* GS1 AISBL. *GS1 General Specification*. Release 19

Glossary

Term	Definition
GS1 Healthcare	A global, voluntary user group that develops standards to advance global harmonization. GS1 Healthcare consists of manufacturers, wholesalers, distributors, hospitals, and pharmacy retailers and maintains close contacts with regulatory agencies and trade organizations worldwide. It drives the development of GS1 standards and solutions to meet the needs of the global healthcare industry and promotes the effective use and implementation of global standards for the industry.
GS1 Member Organization*	A member of GS1 that is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and have access to play an active role in the global standards management process.
healthcare primary packaging*	The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For nonsterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy, such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
healthcare secondary packaging*	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
human readable interpretation (HRI)*	Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The HRI is a one-to-one illustration of the encoded data. However, start, stop, shift, and function characters, as well as the symbol check character, are not shown in the HRI.
logistic unit*	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.
manufacturer	An entity that makes or produces drugs, pharmaceutical, or medical devices through a process involving raw materials, components, or assemblies, usually on a large scale.
medical device*	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for any medical purpose.
serial number*	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined GTIN and serial number.

* GS1 AISBL. *GS1 General Specification*. Release 19

Glossary

Term	Definition
serial shipping container code*	The GS1 identification key used to identify logistic units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.
solution provider	A vendor that provides technical or service support to a company. It offers companies hardware, software, guidance, resources, and tools in a variety of areas. Examples are barcode services, including labels, printing, designing, and verifying; barcode hardware, including printers, readers, and scanners; and barcode software.
supplier	An entity with which a procurement agency has a contractual relationship for providing one or more trade items. The supplier is involved or plays a role in the buying, selling, or production of the pharmaceutical or medical device and can be a manufacturer, brand owner, wholesaler, or distributer.
tertiary homogenous pack	A tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.
tertiary mixed pack	A tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.
tertiary packaging	The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.
tertiary partial pack	A homogenous pack of products that is not to be considered a trade item because it is less than full.
trade item*	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.

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