USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

PRODUCT MASTER DATA MANAGEMENT REFERENCE GUIDE

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

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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.

GHSC-PSM is implemented by Chemonics International, in collaboration with Arbola Inc., Axios International Inc., IDA Foundation, IBM, IntraHealth International, Kuehne + Nagel Inc., McKinsey & Company, Panagora Group, Population Services International, SGS Nederland B.V., and University Research Co., LLC. To learn more, visit ghsupplychain.org

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Acronyms

ATC	Anatomical Therapeutic Chemical
CMS	central medical store
DDD	defined daily dose
DI&I	data integration and interoperability
DQM	data quality management
FDA	Food and Drug Administration
GDD	Global Data Dictionary
GDSN®	GS1 Global Data Synchronization Network®
GHSC-PSM	Global Health Supply Chain-Procurement and Supply Management
GLN	Global Location Number
GPC	Global Product Classification
GTIN	Global Trade Item Number
INN	International Nonproprietary Names
KPIs	key performance indicators
NFC	New Form Code
OpenHIE	Open Health Information Enterprise
PIM	product information management
RACI	responsible, accountable, consulted, informed
SKU	stock-keeping unit
SOP	standard operating procedure
TOR	terms of reference
UNSPSC	United Nations Standard Product and Services Code
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration

Executive Summary

Product master data underpin all functions of the health care supply chain, from marketing authorization by regulatory authorities to stock management and issuance of commodities at the point of dispensing. The increasing reliance on data for decision making and the need to communicate and manage accurate product information throughout the product lifecycle require supply chain stakeholders to implement more rigorous, disciplined approaches to defining, sourcing and managing product master data. The methodology associated with these functions is referred to as **product master data management (PMDM).**

Figure 1: Product Master Data Key Components

Using a "best of breed" approach, the PMDM Reference Guide identifies six core components as the foundation for definitions, standards, accuracy and authority for pharmaceutical product data management, as illustrated in Figure 1. Targeted at stakeholders working in public health supply chains who are seeking to put in place a structured PMDM discipline, this PMDM Reference Guide addresses people, process and technology requirements in a stepwise approach, with maturity considerations, from strategy and design to a fully integrated PMDM program. The guide is intended to complement existing tools and guidelines[1] that detail good practices and recommendations for implementing GS1 standards and traceability.

[1] See http://ghsupplychain.org/globalstandards for additional tools and guidelines.

Table 1. PMDM Reference Guide Summary

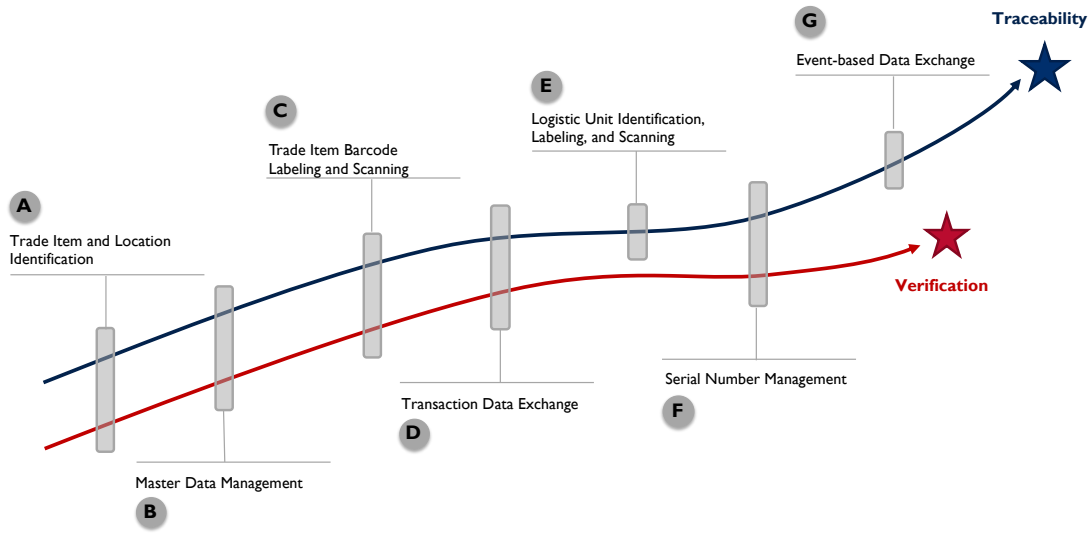
DATA GOVERNANCE	A set of business processes that manages actions, methods, timing and responsibilities for supporting master data within an organization.
Subcomponents	Data Governance Organization; Data Governance Strategy; Data Governance Operations
Tools	Governance Terms of Reference Template; Illustrative Governance Roles and Responsibilities Matrix; Responsible, Accountable, Consulted, Informed (RACI) Matrix Template; Illustrative PMDM Implementation Roadmap; Illustrative Standard Operation Procedure (SOP) for New Product Introductions
DATA ARCHITECTURE	Models, policies, rules and standards that define how data are stored, managed and used in an information system
Subcomponents	Master Data Terminology Strategy; Data Reference Model
Tools	Illustrative Product Master Data Attributes; Sample Logical Produce Master Data Reference Model
DATA QUALITY	A series of documented, periodically reviewed procedures implemented to maintain and support the production of good-quality data
Subcomponents	Data Quality Strategy; Data Quality Audits; Data Validation Rules and Reasonability Checks
Tools	Data Quality Strategy Outline; Illustrative Data Quality Assessment Scorecard; Illustrative Trade Item Physical Inspection Protocol
DATA STORAGE AND OPERATIONS	The technical infrastructure needed to create the foundation for the integration and interoperability of the PMDM
Subcomponents	Data Operations and Configuration Management; Data Lifecycle Management; Data Auditing, Logging and Reporting
DATA SECURITY	A set of business processes governing the assurance of secure, up-to-date and correct data
Subcomponents	Privacy, Access Control and Authentication; Data-Sharing Agreements
DATA INTEGRATION AND INTEROPERABILITY (DI&I)	Requirements and management standards required to stand up technology that will need to be acquired or licensed for managing PMDM information assets
Subcomponents	DI&I Platform Architectural Approach; DI&I Architectural Standards; DI&I Integration & Data Sharing; DI&I Historical Data, Archiving and Retention

Background

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is committed to incorporating lessons learned over the last decade of global health supply chain management and to exploring industry innovations that will lead to a better, more efficient supply chain. Central to achieving these goals is the implementation and use of global supply chain standards for product identification, location identification, and product master data. Adoption of global standards has become a central part of GHSC-PSM to reduce costs, enhance efficiency, and improve the availability of health commodities worldwide. Part of this effort is to provide health systems strengthening technical assistance to USAID-supported national governments in implementing global standards and traceability in their national supply chains.

To this end, GHSC-PSM has developed a suite of tools to support country programs to plan and organize the work of implementing GS1 global standards and traceability. One of these tools is Implementation Guidance for Pharmaceutical Traceability Leveraging GS1 Global Standards,[2] which includes an illustrative implementation roadmap that describes seven capabilities (Road markers A–G) required to implement traceability. The intention of the PMDM Reference Guide is to empower national stakeholders with the information they need to make decisions on how to identify trade items (Road marker A) and implement a rigorous master data management program (Road marker B) as part of a broader implementation agenda. The ability to properly maintain product master data is foundational for higher-level business processes that support end-to-end data visibility and pharmaceutical traceability.

Figure 2. Illustrative Roadmap from Implementation Guidance for Pharmaceutical Traceability Leveraging GS1 Global Standards



[2] Implementation Guidance for Pharmaceutical Traceability Leveraging GS1 Global Standards. (March 2019). Retrieved from http://ghsupplychain.org/implementation-guidance-pharmaceutical-traceability-leveraging-gs1-global-standards.

Problem Statement

In most public health supply chains today, health commodities are identified in nonstandard ways. Proprietary identification numbers are often reassigned at various points in the supply chain from procurement agencies down to the point of dispense. Inconsistencies in how commodities are identified throughout the supply chain—from manufacturer, freight forwarders, medical stores and other points—often result in duplicative, incomplete and inaccurate data. This limits data visibility as a product moves through the supply chain and hinders integration, interoperability and electronic data exchange across varying supply chain information systems. This poses supply chain security risks (counterfeit and substandard products) because commodities are inconsistently identified as they change custody from trading partner to trading partner. Many stakeholders lack rigorous and formalized governance structures to manage how commodities are identified and how associated data about those commodities are managed, validated and exchanged.

Master data management is a combination of applications and technologies that consolidates, cleans and augments these master data and synchronizes the data with all applications, business processes and analytical tools. This process significantly improves operational efficiency, reporting and evidenced-based decision making.[3]

Scope

Three main types of data are managed in the supply chain: master data, transaction data and event data. The focus of this document is limited to product master data, which is the critical enabler for successfully leveraging the other types of data for supply chain decision making.

Table 2. Descriptions of Supply Chain Data Types

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

[3] Butler, D., Stackowiak, b. (2010), Master Data Management, An Oracle White Paper, June 2010. Retrieved from http://www.oracle.com/us/ciocentral/018876-396268.pdf

Product master data core information is about "what" is being traded in the supply chain. The "what" is identifying information about a given trade item, such as name, brand, description, size and unique identification number. These kinds of data underpin commerce and are used daily among trading partners to execute transactions in the supply chain and also by a broader value chain of health sector stakeholders, such as regulators. Supply chain transactions rely heavily on master and reference data; inaccurate data create inefficiencies in the procure-to-pay process and every other downstream supply chain function, and inhibit the ability to ensure that the six rights of logistics are achieved: the right goods, in the right quantities, in the right condition are delivered to the right place, at the right time, at the right cost.

Document Purpose

In response to these challenges, GHSC-PSM developed the PMDM Reference Guide to document an accessible and consistent approach to implementing a discipline for managing product master data, collectively known as PMDM. The guide will provide a point of reference for owners or custodians of product master data to evolve toward consolidated and standards-based management of product master data. It is supported by several resources and tools that are intended to assist users in quickly implementing the concepts described within their own environments.

While this document is not intended to be normative, it does contain normative references to standards and good practices with a specific focus on GS1 global standards for health care supply chains. Implementing these standards is a strategic priority for GHSC-PSM global and country programs. Leveraging standards creates the opportunity for efficiency gains and enables enhanced interoperability in a world that is increasingly digital and connected. Thus, the guidance in this document is underpinned by an assumption that readers are familiar with and leveraging GS1 global standards in their organizations.

Target Audience

The target audience for the PMDM Reference Guide is supply chain stakeholders—including governments and their implementing partners—who are managing a public health supply chain and seek to put in place a structured PMDM discipline within their organization supported by global standards and global best practices.

The PMDM Framework

The PMDM Reference Guide details six key components as the basis for a PMDM program: Governance, Architecture, Quality, Storage and Operations, Security, and Integration and Interoperability. This document will focus primarily on Governance, Architecture and Quality as the foundational components for formalizing a PMDM program. The components of Storage and Operations, Security, and Integration and Interoperability are largely tied to interventions supported through the broader information systems environment and are described at a more conceptual level.

Table 3. Product Master Data Management Key Components

Data Governance	Data Architecture	Data Quality	Data Storage and Operations	Data Security	DI&I
– Data Governance Organization – Data Governance Strategy – Data Governance Operations	– Master Data Terminology Strategy – Reference Data Model	– Data Quality Strategy – Data Quality Audits – Data Validation Rules and Reasonability Checks	– Data Operations and Configuration Management – Data Lifecycle Management – Data Auditing, Logging and Reporting	– Privacy, Access Control, Authentication – Data Sharing Agreements	– Platform Architectural Approach – Architectural Standards – Integration and Data Sharing – Historical Data, Archiving, and Retention

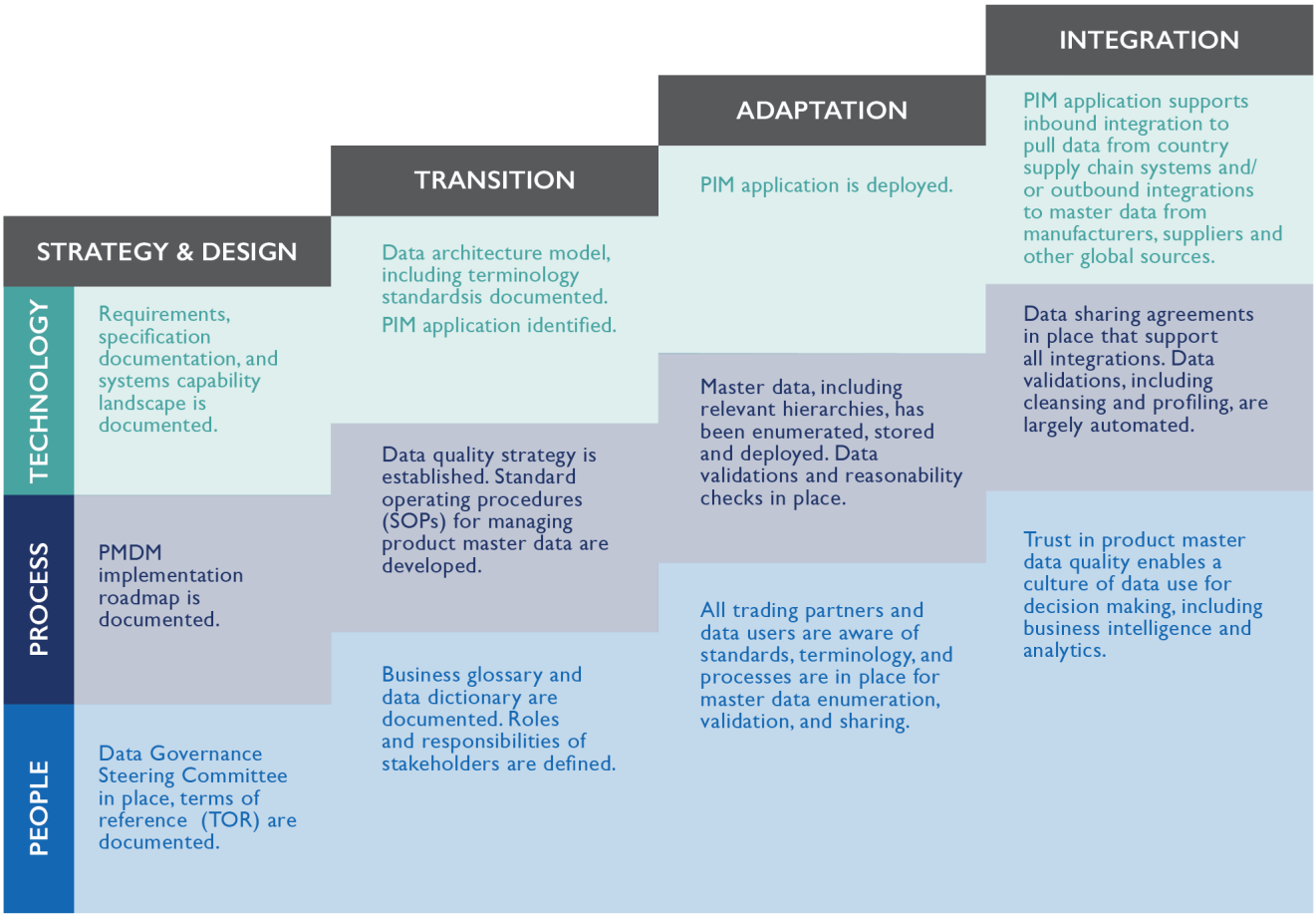
Collectively, these key components of PMDM deliver a comprehensive and consistent view of master data across a standalone or integrated product information management (PIM) function. Ultimately, consistently applying PMDM prepares a trading partner to fully leverage the benefits of GS1 standards for identifying, capturing and exchanging data in support of enabling data visibility, verification and traceability of trade items as they move through the supply chain.

Product Master Data Management Progression Model

PMDM is an approach that requires a combination of people, process and technology[4] to create, maintain and manage a product master data enterprise. GHSC-PSM has defined four progressive levels of implementation of PMDM, from strategy and design through full integration, that encompass the six PMDM components. Implementers are encouraged to review the model to understand the full spectrum of PMDM progression and can leverage it to assess the current state of a PMDM program and/or as a guide to create their own roadmap to full integration.

[4] GTIN Adoption & Usage Model Implementation - Roadmap for U.S. Healthcare Supply Chain. (2017). Retrieved from https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=830&language=en-US&PortalId=0&TabId=134.

Figure 3. PMDM Progression Model



Overview of General Concepts

This section describes several general concepts that are referenced frequently throughout the document.

GS1 Global Standards

GS1 is an international standards organization that develops and maintains a comprehensive system of data standards for health supply chains, including identifying locations, legal entities, trade items, and logistic units; capturing data through specific data carriers, such as barcodes; and sharing data through standards for master, transaction and event data exchange, as summarized in Figure 4.[5]

Figure 4. Summary of the GS1 System of Standards for Identify, Capture and Share

The three most referenced GS1 standards in the PMDM Reference Guide are the Global Trade Item Number (GTIN), the Global Location Number (GLN), and the GS1 Global Data Synchronization Network™ (GDSN®).

[5] GS1. (2014, December 23). GS1 Standards in Healthcare. Retrieved from https://www.gs1.org/industries/healthcare/standards.

Table 4. Most Relevant Standards Included in the PMDM Reference Guide

Standard	Definition	Relevance to PMDM Reference Guide
GTIN[6,7]	The GS1 identification key used to identify trade items—any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered or invoiced at any point in any supply chain.	The GTIN will be referenced as the primary unique global identifier for trade items that pairs the physical product with the master data about that product in a PIM through use of a data carrier (e.g., through scanning a barcode).
GLN[8]	The GS1 identification key used to identify physical locations or parties.	While the GLN has a broader application in the context of location and legal entity master data, in relevance to this document on PMDM, the GLN will be referenced only as an attribute associated with a GTIN, such as the GLN associated with the brand owner, manufacturer or manufacturing location of a trade item.
GDSN[9]	A network of interoperable data pools enabling collaborating users to securely synchronize master data based on GS1 standards. GDSN supports accurate, real-time data sharing and trade item updates among subscribed trading partners.	GDSN will be referenced in relation to data integration and sharing. GDSN speaks to the highest level of maturity for a PMDM, whereby standardized product information is synchronized globally by trading partners.

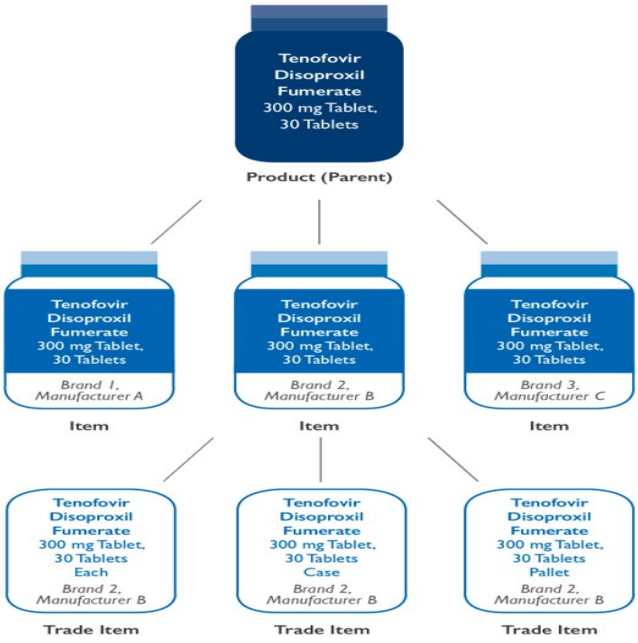
Product and Trade Item Hierarchy

The terms "product" and "trade item" are often used interchangeably, but in practice and for the purpose of the PMDM Reference Guide, the two concepts have differentiating characteristics that are important to understand to effectively manage commodities in the health supply chain.

In general, a product refers to a general concept of a commodity, whereas the trade item refers to a commercialized instance of that commodity by a specific manufacturer. Products have a set of defining characteristics, often defined by a local entity that may include active ingredients, dosage, dosage form and pack size. Trade items are instances of products with unique characteristics, such as manufacturer, brand name, shelf life, and net content. Trade items will be assigned GTINs unique to each packaging level—products will not. An entity's product master data should be able to support and manage both concepts as well as the hierarchy or relationship between the two, sometimes referred to as a parent-child relationship. An example of this concept is provided in Figure 5.

[6] GS1. (December 5, 2014). Global Trade Item Number (GTIN) - ID Keys. Retrieved from https://www.gs1.org/standards/id-keys/gtin.
[7] For more information about the allocation of GTINs specifically in the health care context, please refer to the GS1 Healthcare GTIN Allocation Rules, available: https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
[8] GS1. (December 5, 2014). Global Location Number (GLN) - ID Keys. Retrieved from https://www.gs1.org/standards/id-keys/gln.
[9] GS1. (September 26, 2016). Global Data Synchronization Network (GDSN) - Services. Retrieved from https://www.gs1.org/services/gdsn.

Figure 5. Relationship Analysis: GTIN Parent-Child Relationship



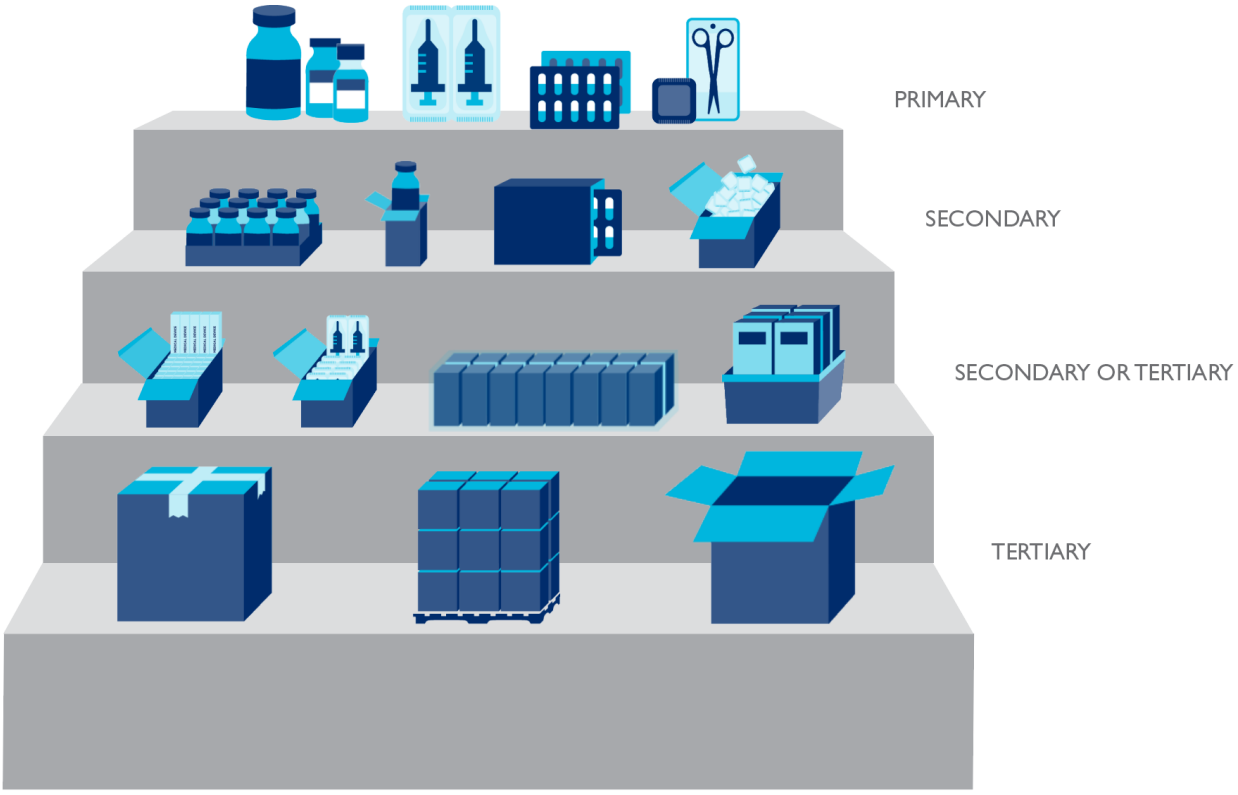
In public health supply chains, planning and requisitioning are functions that are generally executed using the generic concept of a product, while procurement, order fulfillment and all subsequent processes are executed with the specific instance of a trade item.

Trade Item Packaging Hierarchy

Any level of packaging that can be priced, ordered or invoiced throughout the supply chain is considered a trade item. An "each" is often packed in an "inner pack" with multiple inner packs packed into a "case." Each level of packaging can be considered a trade item; therefore, each is also to be assigned a GTIN. The definition of trade item packaging configurations and the relationship between those different levels is called the trade item packaging hierarchy.[10] Part of the process for aligning master data to manage trade items at different packaging levels as they move through the supply chain (e.g., receive items into a warehouse at the case level, pack them at an inner pack level) is managing each trade item uniquely but establishing the parent-child relationships between those trade items in the product master data. The barcode on the physical package containing the GTIN is what links the physical item with the master data about that item in the system.

[10] GS1 Spain. (2015, June). GS1 Standards Implementation Guide Healthcare Deployment Guide. Retrieved from https://www.sergas.es/Recursos-Economicos/Documents/23/SuppliersLoadingBookletHealth_GS1_1_1C.pdf.

Figure 6. Example of the Trade Item Packaging Hierarchy for Health Care Products



Trade item master data should be managed in a way that links the primary, secondary and tertiary GTINs of each trade item and its variants. This creates a hierarchical, parent-child relationship between a containing object (i.e., parent) and one or more objects (i.e., children) that are contained. Table 5 demonstrates how GTINs can be associated with one another to represent a packaging hierarchy.

Table 5. Example for GTIN Hierarchy Attributes for a CASE with Four Packs of 50 Each

Pack Level	GTIN	Child GTIN	Quantity of next level trade item	Net content
Case (CA)	20614141123456	10614141123459	4	200
Pack (PK)	10614141123459	00614141123452	50	50
Each (EA)	00614141123452	N/A	N/A	1

Product Classification Hierarchy

GS1 defines product classification as a form of cataloguing, or identifying, items and can be defined as a process for grouping items into categories based on similar properties and relationships between them.[11] Classification provides trading partners with a common language and methodology for the

[11] GS1. (2015, April). Product Classification in Healthcare. Retrieved from https://www.gs1.org/sites/default/files/docs/healthcare/product_classification_in_healthcare.pdf.

grouping of items. It improves the integrity of master data, breaks down silos in the communication of item information, and enables roll-up or drill-down of product categories to support business intelligence and analytics.

A classification system is used to group products into categories such as medical devices, versus pharmaceutical drugs at various levels of detail. Classification systems commonly used in health care are the GS1 Global Product Classification (GPC), United Nations Standard Product and Services Code (UNSPSC), Global Medical Device Nomenclature and Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD), among others.[12] Table 6 below provides an example of widely used classifications in health care.

Table 6. Examples of Classification Systems

Classification System	Definition	Examples	Levels
UNSPSC	United Nations open standard taxonomy classification of products and services that covers medical equipment, accessories and supplies; drugs and pharmaceutical products; and health care services	Drugs and pharmaceutical products	Segment
		Amebicides, trichomonacides and antiprotozoals	Family
		Antiprotozoals	Class
		51101908, artemether	Commodity
GPC	GS1 mandatory category classification methodology for GDSN that covers Over the Counter Products: Family Planning, Health Enhancement, Health Treatments and Aides and Home Diagnostics	Health care	Segment
		Family planning	Family
		Barrier contraception	Class
		10000460, condoms	Brick
ATC	WHO classification system divides the drugs into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties	Antiparasitic products, insecticides, repellents	Level 1
		Antiprotozoals	Level 2
		Antimalarials	Level 3
		P01BE, artemisinin and derivatives, plain	Level 4

[12] GS1. (2015, April). Product Classification in Healthcare. Retrieved from https://www.gs1.org/sites/default/files/docs/healthcare/product_classification_in_healthcare.pdf.

DATA GOVERNANCE

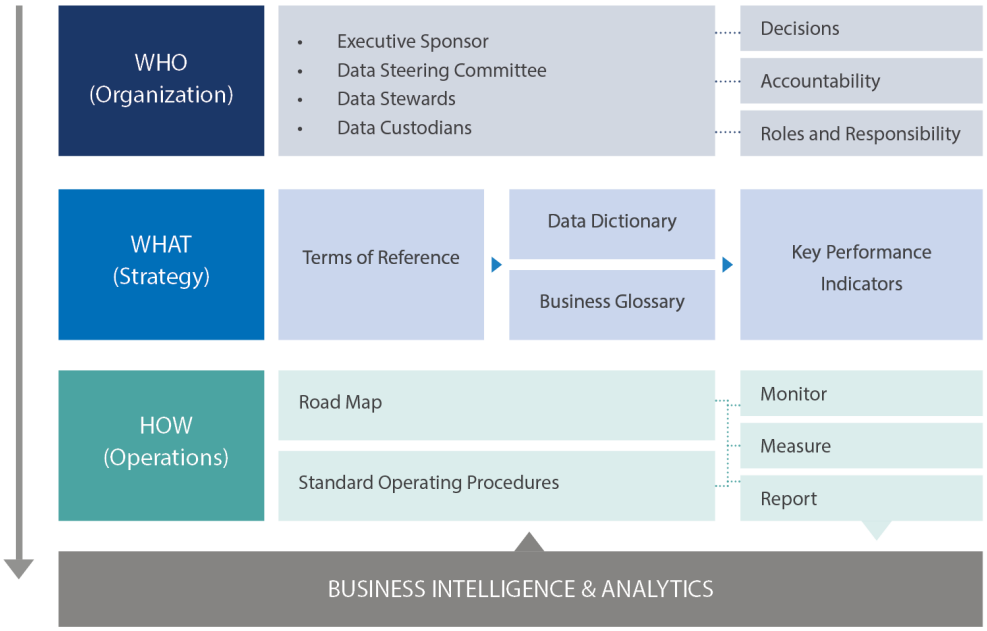
This section introduces the concept of product master data governance and the three key components that should be considered as part of data governance implementation, as summarized in the table below.

Table 7. Data Governance Overview

DATA GOVERNANCE	A set of business processes that manages actions, methods, timing and responsibilities for supporting master data within an organization.
Subcomponents	Data Governance Organization; Data Governance Strategy; Data Governance Operations
Tools	Governance Terms of Reference Template; Illustrative Governance Roles and Responsibilities Matrix; Responsible, Accountable, Consulted, Informed (RACI) Matrix Template; Illustrative PMDM Implementation Roadmap; Illustrative Standard Operation Procedure (SOP) for New Product Introductions

Data governance can be described as a set of responsibilities, practices, policies and procedures used by an agency's executive to provide strategic direction, ensure objectives are achieved, manage risks and use resources in a responsible and transparent way.[13] Functionally, a data governance framework captures the "what?," "who?" and "how?" of instituting a master data management program from a strategic and operational perspective, as depicted in Figure 7.

Figure 7. PMDM Governance Framework



[13] State of Queensland (Department of Education and Training). (March 2018). Corporate Governance Framework. Retrieved from https://qed.qld.gov.au/det-publications/managementandframeworks/Documents/corp-governance/corp-governance-framework.pdf.

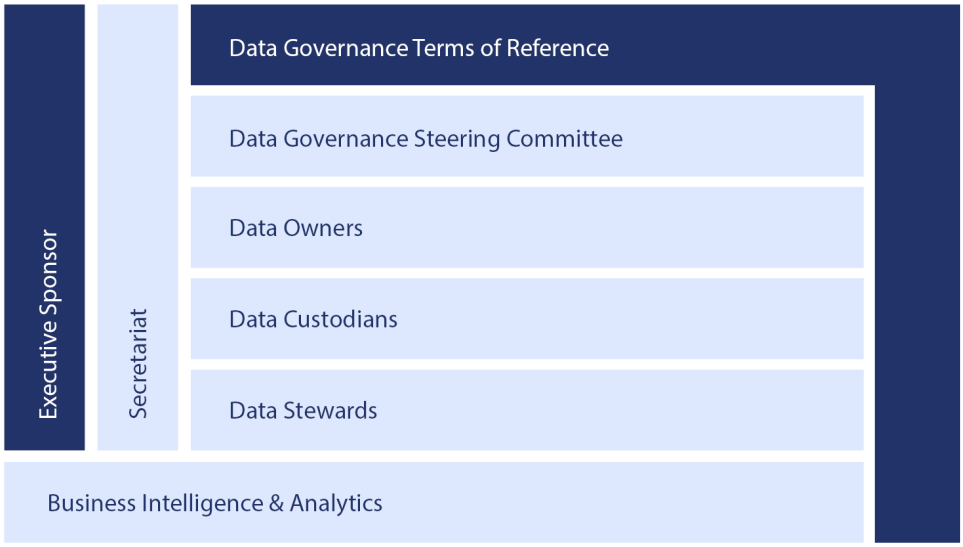
Data Governance Organization

One of the most important objectives of a data governance function is defining the organizational structure under which the PMDM program will function, including the roles and responsibilities of the different individuals and teams required to establish and execute the PMDM program. A strong data governance program formalizes accountability for data management across the PMDM program. This is usually spearheaded by an executive sponsor (e.g., organizational lead, influencer) who will galvanize and engage the relevant stakeholders required to implement a PMDM program. Different approaches for engaging stakeholders may be employed by the executive sponsor as is appropriate for the environment.[14] Some of the approaches that may be used include:

- The "Call to Action" model: Stakeholders are asked to address an urgent objective for data visibility or quality, with the vocal support of the sponsor.
- The "Influence the Influencer" model: Executive sponsor involves only a few influential stakeholders initially in developing the governance structure of the program and then grows participation with the shift from planning to implementation or the maturity of the program.
- The "Organic Growth" model: Stewardship activities are positioned as natural extensions to other tasks.

An outcome of the stakeholder engagement process is the formation of a Data Governance Steering Committee whose main purpose is to establish the governance strategy. Also, core roles and responsibilities for executing the PMDM program need to be defined. At a minimum, these should include the individuals serving in the role of data custodian, data steward, and data owner and their decision making and implementation rights. As roles are defined, it is critical to document the participation required in completing tasks and deliverables for the overall PMDM program, as shown in Figure 8.

Figure 8. PMDM Organizational Framework



[14] Thomas, G. (2014, April 26). Engaging Stewards and Stakeholders. Retrieved from http://www.datagovernance.com/engaging-stewards-and-stakeholders/.

Annex 1.2, Illustrative PMDM Governance Roles and Responsibilities Matrix, and Annex 1.3, RACI Matrix Template, are common tools for documenting tasks and the role of various resources compared with one another in assigning decision-making powers and ensuring accountability among stakeholders.

Data Governance Strategy

A data governance strategy sets direction and communicates purpose, priorities, outcomes, values and performance measures of success.[15] It enables accountability in a PMDM program through supporting documentation, such as a terms of reference, to define the purpose and way of working, key performance indicators (KPIs) to ensure accountability against goals, and a data dictionary to ensure that all stakeholders involved in managing the product master data speak the same language. Collectively, these will articulate a shared mission of the desired end state for the PMDM program.

Terms of Reference

The TOR documents the working arrangement for the PMDM program and important information about the program, including its vision, purpose, sponsor, membership, broader stakeholder engagement, and program implementation. The TOR should be broadly linked to an organization's strategies to describe how the PMDM program supports the organization's overall functions to ensure that it is not a standalone activity, but rather is integrated as part of the mission. The TOR is a living document that will require ongoing maintenance as the dynamics of the organization and its interactions with internal external stakeholders evolve.

Functionally, the TOR authorizes the parties responsible for the PMDM program to enact and be accountable for the policies, procedures and standards developed for product master data. Annex 1.1, Governance Terms of Reference Template, is an example of a TOR that can be adapted to a given organization's PMDM implementation.

Data Dictionary

A data dictionary is a collection of names, definitions and attributes about *data* elements that are being used in the PMDM program. A data dictionary is important for establishing a common language to ensure consistency in the way attributes are managed. Simply put, it helps normalize product data. A functional data dictionary will incorporate standards-based metadata, where available, and accommodate additional requirements, such as national coding standards (e.g., marketing authorization or health care reimbursement codes) or local data attributes (e.g., associated health program information), as necessary to be comprehensive to a given environment. Normalization ensures that each data attribute, such as Brand, Description and Net Content, appears exactly once in a record to avoid data anomalies and preserve space. Typically, normalized data exist only in computer systems and do not match the original business representation of the data.[16] For example, the description of a medication may include a reference to "fluid ounces." If there is no predefined way of creating item descriptions and their use, it may be possible that more than one data entry can occur for the same item (i.e., 12 fluid ounces, 12 fl. ounces, 12 fl oz).

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[15] State of Queensland (Department of Education and Training). (2018, March). Corporate Governance Framework. Retrieved from https://qed.qld.gov.au/det-publications/managementandframeworks/Documents/corp-governance/corp-governance-framework.pdf.

[16] Malaika, S., & Nicola, M. (2011, December 15). The history of business records. Retrieved from https://www.ibm.com/developerworks/data/library/techarticle/dm-1112normalization/index.html.

If a standards-based process is in place for creating master data, the likelihood of issues and related errors, inconsistencies and inefficiencies being introduced is greatly reduced. This normalization process also enhances the quality of the data that is managed and shared. The GS1 Global Data Dictionary (GDD)[17] is a repository of the data elements defined across the GS1 system of standards and can be used as a starting point for product master data attributions.

Business Glossary

While a data dictionary is a normalization document for technical users, a business glossary[18] is targeted at business owners. A business glossary is a repository with definitions of key concepts and terminology, used to gain consistency and agreement between and among stakeholders interacting with a common system or implementing common business processes. In the PMDM program, business terms must be documented and communicated to ensure that the same nomenclature and definition are used and understood by any stakeholder interacting with the data (e.g., product and trade item), either within a given organization such as a central medical store (CMS) or across multiple health sector stakeholders.

Key Performance Indicators

Key performance indicators are data values used to monitor and measure the effectiveness of the PMDM program. KPIs should be tied to the short, intermediate and long-term vision of what success looks like to a given organization. As such, the governance body should spearhead the process of defining KPIs and setting target measures and timelines. As with any KPIs, PMDM success measures should be specific, measurable, assignable, realistic and timebound, or SMART. Examples of KPIs that may be adopted by a PMDM program include percent of:

- Registered products available in the PIM application
- Trade items with a validated GTIN populated
- Trade items with all mandatory attributes populated
- Products mapped to a given classification system
- Trade items that meet validation checks

Data Governance Operations

Governance operations details the mechanisms and interactions through which the principles defined through the governance function is put into action.[19] An operating model supplies the "how" that the Steering Committee can leverage to implement policies and guidelines through an implementation roadmap and SOPs.

Implementation Roadmap

The first aspect of developing an operations model is articulating high-level timelines for intended outcomes. The roadmap for the PMDM should be developed by the Steering Committee and endorsed by all stakeholders involved in the implementation process. The roadmap should consider the current

[17] GS1. (n.d.). Global Data Dictionary . Retrieved from http://apps.gs1.org/gdd/SitePages/Home.aspx.
[18] An example of GHSC-PSM's global standards business glossary can be found: https://www.ghsupplychain.org/glossaryofterms
[19] https://www.hwaalliance.com/what-is-governance-operating-model-development/

state (start where you are) as well as maturity consideration (desired state). It should be a living document, reviewed periodically by the Steering Committee. Annex 1.4, Illustrative PMDM Implementation Roadmap, is an example, with phasing and key milestones presented against a timeline.

Standard Operation Procedures

An essential component of PMDM is the institution of the SOPs for entering, aggregating, consolidating, removing duplication, standardizing and maintaining data.[20] SOPs allow for implementing the PMDM program through a consistent methodology for providing ongoing maintenance of master data. The scope of SOPs implemented will depend on the scope of the implementation, but we recommend considering at a minimum the following:

- Introduction of a new product
- Introduction of a new trade item
- Phase-out of a legacy product or trade item
- Change to attribute
- Audit procedures for data quality
- Inspection of a physical product

Annex 1.5 includes an illustrative SOP for New Product Introduction.

[20] Davis, W. (2016, November 18). Best Practices for Developing a Master Data Management Strategy. Retrieved from https://www.trifacta.com/blog/master-data-management-strategy/.

DATA ARCHITECTURE

This section introduces the concept of product master data architecture and its subcomponents that should be considered as part of architecture design, as summarized in the table below.

Table 8. Data Architecture Overview

DATA ARCHITECTURE	Models, policies, rules and standards that define how data are stored, managed and used in an information system
Subcomponents	Master Data Terminology Strategy; Data Reference Model
Tools	Illustrative Product Master Data Attributes; Sample Logical Produce Master Data Reference Model

Data architecture is composed of models, policies, rules and standards that define how data are stored, managed and used in a product information system(s).[21] A well-defined data architecture ensures data integrity by standardizing the structure for product data by unifying product identifiers and attributes in conformance with existing standards, such as GS1. It describes how this information is stored and accessed and how it interfaces with external systems such as the logistics management information system, warehouse management system, and drug regulatory information system. It also provides a formal approach to creating and managing the flow of product master data and how data are processed in a PIM application. In the context of this document, a PIM application may be either a single system's internal product master data module or a cross-organizational tool such as a national drug registry. GS1 standards for system architecture promote technology independence and a layered approach, with the ability to support unique product and trade item identification keys and supporting hierarchies as the foundation of the data architecture.[22] In this context, product data should be defined independently of the PIM application through which it is implemented, as the method should not alter the fundamental characteristics and relationships of the structured data.

The end goal for product master data architecture is to enable a central "source of truth" for product master data and establish interdependencies and relationships between different data types and sources. It will reside in a chosen PIM application.

Master Data Terminology Strategy

A master data terminology strategy provides a system with a common language and identifiers for information about products, and in this instance, anchored in global standards. Alignment with global standards enables the common identification of trade items through communication about products from the time they are manufactured to the point of dispense or use. Terminology strategy deployed

[21] Lewis et. al.(2001) Carnegie Mellon. An Enterprise Information System Data Architecture Guide. Retrieved from https://resources.sei.cmu.edu/asset_files/technicalreport/2001_005_001_13877.pdf
[22] GS1. (2016) GS1 Architecture Principles. Retrieved from https://www.gs1.org/docs/architecture/GS1_Architecture_Principles.pdf

will need to be flexible to accommodate for local requirements, use of national and global classifications, and specific requirements set by governing regulations.

Nomenclature

Nomenclature is a system of rules used to provide common descriptions to products that have the same performance characteristics and thereby can be substituted for one another (e.g., two syringes with differing product descriptions from two different manufacturers that are designed for the same purpose or use).23 Key stakeholders will need to align and agree on a common nomenclature to use for item and product descriptions. This helps ensure that products and trade items are consistently defined and minimizes risk of duplication. The convention developed should follow a set of clear rules defined by the user group (e.g., imperial versus metric measures) and should be based on a globally recognized standard (e.g., International Nonproprietary Names (INN),24 United States Food and Drug Administration (USFDA) Nonproprietary Naming of Products,25 EphMRA New Form Code (NFC)) where possible.

An example of the nomenclature used by the GHSC-PSM project for pharmaceuticals can be considered in this context and includes the following elements:

- Generic name (based on INN)
- Strength (metric measures)
- Formulation (based on EphMRA NFC or USFDA)
- Pack size (number of base units)
- Packaging level
- Brand owner name
- Brand name (where applicable)

In practice, as described in detail earlier, this is represented through the following product and trade item descriptions in the product master data:

Table 9. Example of Product and Trade Item Nomenclature

Hierarchy	Item Description
Parent 1 (Product)	Acetaminophen 325 mg tablet, 100 tablets
Child 1.1 (Trade Item)	Acetaminophen 325 mg tablet, 100 tablets, each [Johnson & Johnson] [Tylenol]

[23] GS1. (2015, April). Product Classification in Healthcare. Retrieved from https://www.gs1.org/sites/default/files/docs/healthcare/product_classification_in_healthcare.pdf.
[24] WHO. (December 5, 2018). International Nonproprietary Names. Retrieved from https://www.who.int/medicines/services/inn/en/.
[25] Center for Drug Evaluation and Research. (January 2017). Nonproprietary Naming of Biological Products Guidance for Industry. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/nonproprietary-naming-biological-products-guidance-industry.

Child 1.2 (Trade Item)	Acetaminophen 325 mg tablet, 100 tablets, each [GlaxoSmithKline] [Panadol]

Identification

To enable use of the GS1 data carrier on commodities as available, data architecture development should be guided by conformance with GS1 standards for trade item identification. Conformance with the GTIN standard for trade items and the GLN standard for locations and legal entities associated with that trade item enables interactions with external trading partners (e.g., manufacturers, distributors, procurement agents, donors, export clients) and allows for interoperability across disparate systems by supporting a common reference key across different stakeholder groups. Use of GTIN as a trade item identifier also enables use of the GDSN to exchange trade item master data between suppliers and recipients.

Although brand owners are increasingly deploying GTINs to identify trade items, it is important to design the data architecture to accommodate internal product and trade item keys, as GTINs may not be widely used as a form of identification. We recommend using the GTIN as a secondary identifier for items where available, with the goal of capturing GTINs for all trade items over time. The internal trade item key can be mapped or "anchored" to GTINs and other identification keys already being used in the supply chain (e.g., marketing authorization codes, health insurance reimbursement codes, warehouse stock-keeping unit (SKU) codes) to enable linkages across the health sector ecosystem.

Table 10. Example of Trade Item Identification

Identifier	Value
Internal Trade Item Key	XXX-001
GTIN	00300450501813
Trade Item Description	Acetaminophen 325 mg tablet, 1,000 tablets, each [Johnson & Johnson] [Tylenol]
CMS SKU	22981392
FDA Registration Code	NDC 50580-600-03
NHIA Code	ACETA223

Over time, the GTIN becomes the single identification key linking the physical trade item (through the barcode) to the information about that trade item in the system. This process reduces the complexity of fragmented identifiers caused by varying codes used by different stakeholders in the supply chain ecosystem. The identification mapping process is critical for allowing different stakeholders to continue to use their code structure while leveraging the benefits of a central repository that collects and manages codes from across stakeholders aligned with the GTIN.

Product Hierarchies

Classification systems enable creating product hierarchies, which are the foundation of commodity analytics and improve the ability to roll up or drill down into commodity-related information. Many global classification structures for health care are in use today, each with its own strengths and constraints. [26] Multiple classification structures can be maintained within a master data structure to enable various business processes (e.g., spend analysis, financial analysis, procurement, strategic sourcing, tendering, enterprise resource planning, asset management). The ability to manage multiple classification systems is a global best practice. It enables flexibility because these systems are often limited in scope to a subset of commodities (e.g., pharmaceuticals or medical devices) and their attributes.

We recommend adopting, at a minimum, a global classification structure that aligns with most commodities being managed through the health supply chain[27] to enable reporting and analytics. Different classification systems will be required for different use cases: pharmacists are often trained to use ATC/DDD; GDSN subscriptions require use of GPC; UNSPSC enables reporting on spend and consumption at various levels of detail across a large number of product categories, including pharmaceuticals, medical devices and consumables. Relevant national classification systems may already be in place that should be supported (e.g., national health insurance reimbursement codes, program-specific classifications). The extent to which these different classification structures are required to be incorporated and managed through the PMDM program will need to be determined by the users.

Data Attributes

Attributes are characteristics of a product or trade item that distinguish it from other similar concepts or commodities. Attributes will be unique at various levels of a hierarchy; an example of attributes can be found in Table 11 and a more comprehensive set of attributes to be considered at the product, trade item and trade item packaging level can be found in Annex 2.1, Illustrative Product Master Data Attributes.

Table 11. Sample Attributes at Various Levels of Product and Trade Item Hierarchy

[26] GS1. (2015, April). Product Classification in Healthcare. Retrieved from https://www.gs1.org/sites/default/files/docs/healthcare/product_classification_in_healthcare.pdf.

[27] USAID has led a significant effort to create a global product classification master leveraging the UNSPSC system down to Level 4 classification and has extended that system to include a Level 5 to capture the differentiation in various packaging configurations. More information about this system can be found: http://ghsupplychain.org/index.php/GHSC-Program-Product-Master

Product	Trade Item	Trade Item Packaging Level
Product description	Item description	GTIN
Generic name	Brand name	Unit description
Strength	Manufacturer name	Depth
Product form	Manufacturer location	Height
Active ingredient	Country of origin	Width
Dosage form	Shelf life	Weight
Route of administration	Storage instructions	Net content

More than 3,000 attributes are defined by GS1 through the GDSN standards.[28] The number and complexity of the attributes captured have a direct impact on the level of effort required to source and maintain the associated data. As a result, we recommend identifying a minimum number of attributes required to support core functions to start and evaluate the need for additional "nice-to-have" data in the future as the PMDM program matures.

Attribute values should be defined and maintained by the brand owner or manufacturer of the trade item. Stakeholders will be required to identify which attributes should be captured and maintained to manage trade items in the scope of the functions supported by the PIM application and capture those attributes and their definitions in the data dictionary.

Data Reference Model

A data reference model is an abstract model that organizes data elements and standardizes how they relate to one another.[29] In this context, the reference data model should formalize the concepts of identification, attributes and relationships in a logical representation. The model will organize and describe the relationships between data to support requirements and configuration of a PIM application and will be supported by the data dictionary. The process for developing a reference model is focused on aligning codes, hierarchies (including product/ trade item, product classification, and trade item packaging levels), attributes and definitions. If master data are intended to be sourced through an internal integration, for example, the GDSN, relational management of these data should also be considered as part of the data model design.

At a minimum, the reference data model should support three main concepts: product attributes, trade item attributes, and trade item packaging level attributes. An example of a reference data model supporting GS1 standards, multiple classification hierarchies, and GDSN can be found in Annex 2.2, Sample Logical Product Master Data Reference Model.

[28] GS1 US. (2019). GS1 Global Attribute Explorer. Retrieved from https://www.gs1us.org/tools/gs1-attribute-explorer.
[29] Main Features of SQLdbm Modeling Tool. (2018, January 9). Retrieved from http://blog.sqldbm.com/main-features-of-sqldbm-modeling-tool/.

DATA QUALITY MANAGEMENT

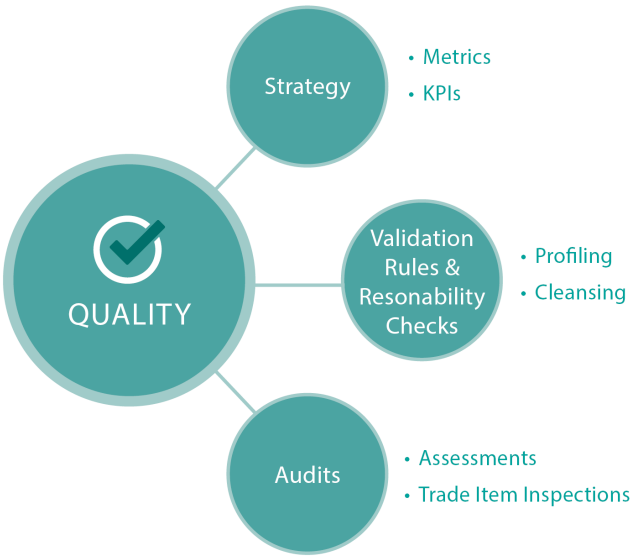
This section will introduce the concept of quality management for product master data and the three key components that should be considered as part of a quality program, as summarized in the table below.

Table 12. Data Quality Overview

DATA QUALITY	A series of documented, periodically reviewed procedures implemented to maintain and support the production of good-quality data
Subcomponents	Data Quality Strategy; Data Quality Audits; Data Validation Rules and Reasonability Checks
Tools	Data Quality Strategy Outline; Illustrative Data Quality Assessment Scorecard; Illustrative Trade Item Physical Inspection Protocol

Data quality management (DQM) is a series of documented, periodically reviewed procedures implemented to maintain and support the production of good quality data.[30] A DQM program is critical for consistent, high-quality product master data. It includes a data quality strategy (planning), data quality audits (assurance), and data quality validation rules and reasonability checks (control.)

Figure 10. Data Quality Management Pillars



[30] GS1. (2014, December 23). Data Quality Framework. Retrieved from https://www.gs1.org/services/data-quality/data-quality-framework.

Data Quality Strategy

A data quality strategy is a set of documented policies and procedures to plan, operate and control DQM processes. It is aimed at ensuring good-quality data, including accuracy, timeliness and completeness of product master data. As a reference point, GS1 DQM looks at a wide spectrum of an organization's functional areas, including stewardess, policies and standards, business process and system capabilities all harmonized in a single DQM strategy.[31] The strategy proposed in this reference guide assumes PMDM quality functions will be a subset of existing monitoring and evaluation functions. It also assumes that resources are already in place to support the supply chain system and thus focuses on metrics required to maintain quality product data. It should be considered with close reference to the Data Governance and Data Architecture components of the PMDM. Annex 3.1, Data Quality Strategy Outline, details what information should be documented as part of the strategy.

Data Quality Metrics

While KPIs measure overall program performance against goals, data quality metrics assess conformance of master data for each product or trade item against defined parameters. Data quality metrics are a core tenant of the data quality strategy to indicate a "minimum threshold" of compliance. To ensure data quality metrics stay relevant, data maintenance must be deliberate and ongoing. Data quality for a given product or trade item against these metrics should be measured routinely.

Characteristics that should be used to guide development data quality metrics are shown in Table 13.

Table 13. Characteristics of Data Quality Metrics[32]

Characteristic	Description
Complete	All products and trade items must have an identifier and the minimum set of mandatory attributes.
Consistent	Data definitions must align with the data dictionary and be applied across the entire dataset.
Accurate	All data must be correct and truthful. Accuracy can and should be measured at various levels, including overall item accuracy, but also accuracy of specific business-critical attributes, such as dimensions and weights or hierarchies.
Time stamped	All data must be marked with the data time-to-value, that is, the expectation for availability and accessibility of information to the intended users.
Standards-based	All metrics must conform to adopted standards (e.g., relevant components of the GS1 standard) and national (e.g., nomenclature) standards.

[31] GS1. (2010, October). GS1 Data Quality Framework. Retrieved from https://www.gs1za.org/wp-content/uploads/2016/10/Data-Quality-Framework-v3.0-Issue-2.pdf.
[32] GS1 Ireland. (2019). What is good quality data? Retrieved from https://www.gs1ie.org/data-quality/.

Data Quality Audits

To maintain a cycle of continuous data accuracy and completeness, periodic internal audits of product data are needed. A process for determining the criteria, scope, frequency and methods for executing internal audits of the data must be set by the data stewards in consensus with data owners. Conducting internal audits at least once a year is generally good practice. Audit results should be documented, and corrective action taken if required. A process should be in place to track any changes to the data, with records of previous versions dated and archived. Where required, changes in data should be communicated to all relevant stakeholders to ensure product data attributes are updated in external systems.

Two methods for conducting internal audits are considered for PMDM: (1) data quality assessments, which are focused on measuring conformance to standards and performance measures, and (2) trade item inspections, which are focused on accuracy of the master data as compared with the observable physical characteristics of the trade item itself.

Data Quality Assessments

Data quality assessments (DQAs) are a standard practice for assessing data quality, documenting any limitations in data quality, and establishing a plan for addressing those limitations. A key aspect of DQAs is the measurement of metrics against conformance levels to set thresholds. An example of a threshold may include the extent to which product data complies with GS1 standards for packaging measurements and tolerances.

Steps in conducting PMDM-DQAs are outlined in Table 14.

Table 14. DQA Steps

Step	Description
1	Develop the PMDM DQA framework, including the purpose and frequency of the assessments.
2	Define the scope of the DQA, including metrics and conformance parameters.
3	Form an assessment team and develop an assessment questionnaire and scorecard.
4	Raise internal awareness of the PMDM DQAs.
5	Apply assessment questionnaire and record results in scorecard.[33]
6	Consolidate, analyze results and develop draft improvement plan. The first-time application should be considered the benchmark.
7	Communicate results to the relevant parties and finalize an improvement plan with stakeholders.

[33] It is recommended to use and/or adapt the Self-Assessment Questionnaire & Scoring Model of the GS1 Data Quality Framework, available: https://www.gs1.org/services/data-quality/data-quality-framework

8	Implement action; if changes are made to the master list, date and archive the old version.

The results of a DQA can be reflected in a scorecard or dashboard against assigned metrics and aggregated to inform KPIs. Annex 3.2, Illustrative Data Quality Assessment Scorecard, is a template for building out a scorecard. It was adapted from GS1 Australia.[34]

Trade Item Data Inspections

Trade item data inspection is a procedure for enhancing data accuracy by applying a standardized methodology for the physical inspection/comparison of a physical trade item with master data maintained in a PIM application.[35] Trade item inspections are intended to measure the degree to which the product master data are consistent with the physically observable characteristics of the trade item. The directly observable attributes of a physical package are known as data accuracy metrics. Inspections should include all three categories of metrics where possible.

Table 15. Trade Item Data Inspection Priorities

Category	Attribute Description	Attribute
Foundational	Attributes that constitute the most foundational differentiating characteristics of a given trade item and are required for managing uniqueness of the trade item in a PIM.	• Product key • Manufacturer • Brand name • Strength • Dosage form • Net content
Logistics	Attributes that constitute the most critical characteristics for managing a trade item in a supply chain.	• Packaging level unit of measure • Linear dimensions[36] • Volume • Gross weight
Business Process	Attributes that measures the extent to which the business processes are adhered to, such as the SOP, and introducing or retiring products or trade items.	

A stepwise approach to implementing trade item inspections is provided in Annex 3.3, Illustrative Trade Item Physical Inspection Protocol.

Trade item inspections are not intended to be used as a solution for data accuracy but rather, to verify objectively and reliably the quality of the master data being managed. Applying this inspection procedure must be accompanied by other elements of a data quality management system described in this section.

[34] GS1 Australia. (n.d.). Data quality in focus. Retrieved from https://www.gs1au.org/download/gs1au-scorecard-healthcare-data-quality-program-self-assessment.xlsx/file

[35] GS1. (2010, October). GS1 Data Quality Framework. Retrieved from https://www.gs1za.org/wp-content/uploads/2016/10/Data-Quality-Framework-v3.0-Issue-2.pdf.

[36] It is recommended to consult the GS1 Package Measurement Rules Standard for guidance on how to measure all levels of packaging in different forms: https://www.gs1.org/docs/gdsn/3.1/GS1_Package_Measurement_Rules.pdf

Data Validation Rules and Reasonability Checks

Validation rules should be implemented and reasonability checks should be performed to ensure uniqueness of data and compliance with set standards.[37] Some validation rules can be automated, that is, configured and deployed through a PIM application, while others may be manual. Automated validations are usually preventative and should be considered as requirements are being developed for sourcing a PIM application. Manual validations may be considered corrective and generally demand more resources. This document will focus on manual validations, namely, data profiling and cleansing.

Data Profiling

Data profiling is the process of uncovering defects and anomalies in the product master data. The process consists of multiple analyses that investigate the structure and content of data to make inferences on their conformity.[38] Profiling techniques should help to discover formats and pattern inconsistencies and may be classified under three different types of analysis: structure, content, and relationship analysis as described in Table 16.[39]

Table 16. Approaches to Data Profiling

Type	Description
Structure analysis	Structure analysis is the simplest form of profiling involving exhaustively analyzing product master data to validate that the data are formatted consistently and correctly. To implement a structure analysis, one common method used is "pattern matching." It assesses whether the data conform to the intended structure, e.g., whether they are text or number based, contain the expected range of values, and other format-specific parameters.
Content analysis	A more rigorous profiling method that takes a closer look at the data to ensure it is aligned with adopted standards. Content analysis profiles the values provided for each attribute and their conformity to the broader parameters for those attributes, e.g., the extent to which the specified code list adheres to the specified nomenclature. For example, does the product key have the correct number of digits?
Relationship analysis	Master product data must demonstrate the relationship between a product and a trade item. Relationship analysis checks the data's conformity with the agreed-upon hierarchies for use for the item description in the master file.

[37] GS1. (2018, May). How to Write GDSN Validation Rules. Retrieved from https://www.gs1.org/docs/gdsn/How_to_Write_GDSN_Validation_Rules.pdf.
[38] Bauman, J. (n.d.). What is data profiling and how does it make big data easier? Retrieved from https://www.sas.com/en_us/insights/articles/data-management/what-is-data-profiling-and-how-does-it-make-big-data-easier.html.
[39] Bauman, J. (n.d.). What is data profiling and how does it make big data easier? Retrieved from https://www.sas.com/en_us/insights/articles/data-management/what-is-data-profiling-and-how-does-it-make-big-data-easier.html.

Data Cleansing

Data cleansing is a process that directly follows profiling, through which data are corrected, including deduplication and removal of anomalies or errors in data. Data cleansing does not just involve eliminating data that might be inaccurate or out of date; it also means organizing the data efficiently and reducing the possibility of other errors, such as duplicate, missing and misfiled data, from occurring again.[40] The following are examples of data cleansing in its simplest form:

- Remove extra spaces
- Select and address blank fields
- Convert numbers stored as text into numbers
- Remove duplicate entries
- Highlight data errors
- Adjust text to the proper case (upper/lower)
- Spell check

While some of these steps may be automated through application configuration through the construction of rules, others may require more complex transformations of data.

[40] Ramati, P. (2019, April 1). Data Cleansing is Critical to Business Success. Retrieved from https://ibmsystemsmag.com/IT-Strategy/04/2019/data-cleansing.

DATA STORAGE AND OPERATIONS

This section addresses storage and operations requirements for the PIM application that will manage the product master data information assets, as summarized in the table below.

Table 17. Data Storage and Operations Overview

DATA STORAGE AND OPERATIONS	The technical infrastructure needed to create the foundation for the integration and interoperability of the PMDM
Subcomponents	Data Operations and Configuration Management; Data Lifecycle Management; Data Auditing, Logging and Reporting

Data Operations and Configuration Management

A technical infrastructure is needed to support the requirements defined in the data architecture. Many existing commercially available supply chain information systems may have the capabilities to meet the requirements for PMDM based on GS1 standards but may not be configured to fully leverage the desired architecture. Table 18 lists the steps for creating and maintaining the PIM application infrastructure.

Table 18. Steps to Configuration Management

Step	Notes
Acquisition/selection of PIM	An instance of some type of system of storage and methodologies where product master data can be managed.
Initial setup/configuration	Establishment of instances of the storage system(s) and any type of preliminary setup of the operation and minimum monitoring and maintenance needs.
Product catalog setup	May require transitioning existing data to the product catalog(s) that the country is currently using.
Monthly hosting	Costs may be associated with hosting the system or possible additional existing functionality.
System administration	Some amount of time may be required to ensure everything is working correctly.
Ongoing maintenance	Upgrades and enhancements would need to be applied to systems, including maintenance of the standards and guidelines.

We recommend maintaining an updated reference guide to include all components, specifications and versions of the application. As configuration occurs or changes are made, the reference guide must also stay current and be accessible by those who require access to that information.

Data Lifecycle Management

A PIM application will need to support the master data lifecycle through product and/or trade item transitions, for example, the transition from a legacy to a new first-line HIV/AIDS treatment. As new items are introduced into the supply chain affect existing items, the transitional impact must be addressed (i.e., what commodities are still eligible to be ordered, distributed or returned, which will change through this transition). A PIM application should provide the capability for an item to be "replaced by" another item at the end of its lifecycle and allow for a new item to "replace" the old item.

Data Auditing, Logging and Reporting

To enable accountability of the responsible parties in managing product master data quality—including both completeness and accuracy—we recommend that a PIM application include the capability to audit and log how (i.e., who, what, when) product master data are being added, changed or corrected. The ability to manage the overall PMDM program relies heavily on accountability for data quality, which relies in part on the ability to report on what changes have occurred.

Figure 11. Product Master Change Log

Data Attribute Change Log										
Ref #	**Date / Time**	**Added / Changed By**	**Changed Attribute**	**GS1 Attribute Name**	**Previous Value**	**Description**	**New Value**	**Description**	**Approver**	**Approval Date/Time**
124	5/4/2018 10:22:45 AM	John Smith	Allergen Type Code	allergenTypeCode	BB	Benzyl Benzoate	BA	Benzyl Benzoate	Mary Reynolds	43225.38316
125	9/19/2018 2:11:23 PM	John Doe	Dosage Recommendation	dosageRecommendation	Take 2 tablets every 4 hours	Take 2 tablets every 4 hours	Take 2 tablets every 6 hours	Take 2 tablets every 6 hours	Mary Reynolds	43363.14045
126	4/14/2019 4:10:17 PM	Joseph Jones	Prescription Type Code	prescriptionTypeCode	SPECIALIST_ PRESCRIPTION_ REQUIRED	Specialist Prescription Required	PRESCRIPTION _ UNDER_ MONITORING	Prescription Under Monitoring	Rita Brannigan	43570.4305

These lifecycle concepts may also be leveraged in transitioning from legacy system(s) to a new system or PIM application.

DATA SECURITY

This section addresses business processes for ensuring security of product master data. The section's main content is summarized in Table 19.

Table 19. Data Security Overview

DATA SECURITY	A set of business processes governing the assurance of secure, up-to-date and correct data
Subcomponents	Privacy, Access Control and Authentication; Data-Sharing Agreements

Product master data are generally not sensitive in comparison to other types of supply chain (e.g., negotiated prices, volumes) and health care (e.g., patient records) related data. A large proportion of product master data can be sourced in one way or another publicly—either by reading the product packaging or on company websites. However, the use of quality product master data in business processes relies heavily on leveraging complete and accurate data through authorized "source of truth" channels to maintain data integrity. If master data are used in high-level business processes (planning, ordering, logistics, reconciliation, etc.) and are not accurate, errors can be introduced that can cost time and money, compromise data visibility and introduce risk, including delays and errors in medicine delivery and dispense.

Privacy, Access Control and Authentication

A key element of ensuring data integrity is managing access of the users authorized to create and manage product master data, as well as the access of that data for consumption by internal and potentially external data recipients. A master data management framework comprises processes to manage privacy, access control, and authentication from a practical perspective. Processes usually enable creating a set of roles that are assigned a set of permissions that tie directly into what functions that user can perform. The governance organization should determine which product data will need to be secure; not all data need —to be protected at the same level. These permissions should be enabled and secured through the system's ability to enable controls on access and authentication.

Data-Sharing Agreements

A data-sharing agreement is a formal contract between two parties that documents what data are being shared and how the data are intended to be used. Data-sharing agreements have two purposes: first, to protect the party providing the data by ensuring that the data will not be misused; and second, to prevent miscommunication between the provider party and recipient party by ensuring that parameters around data sharing and use are discussed and agreed upon.

We recommend that some level of data-sharing agreement be put in place with any external party or system that may have access to product master data. Agreements should be in place for how and with whom the master data should be shared. Different stakeholders, internal and external, should have clear definitions of their ability to share and use the data for the necessary business processes. By

establishing clear direction and guidance, the risks associated with the various stakeholders and users of the data, internal and external, should be minimized.

In the PMDM context, the data may be shared with other parties, either receiving master data into a system or sharing it externally with other parties. These parties need to be identified, such as manufacturer, distributor, donor or regulatory agency. Parameters should be put in place on how data are shared among them, the nature of the data being shared, the required permissions, and intended use. We recommend setting up a data-sharing agreement with each party detailing these parameters and monitoring/enforcement mechanisms for use or misuse.

The process and rigor associated with establishing data-sharing agreements between two parties will vary based on the extent of data being shared and the nature of the relationship. For example, data sharing through the GDSN as a formal network for synchronization is highly formalized,[41] whereas a data-sharing agreement among warehouses or franchise partners may be less rigorous or formal.

[41] GS1. (n.d.). GDSN Terms of Participation Agreement for U.S. Trading Partners. Retrieved from https://www.gs1.org/docs/gdsn/support/GDSN_Terms_of_Participation_US_Agreement.pdf.

DATA INTEGRATION & INTEROPERABILITY (DI&I)

This section introduces high-level concepts for data integration and interoperability. Key content in this section is summarized in Table 20.

Table 20. DI&I Overview

DATA INTEGRATION AND INTEROPERABILITY (DI&I)	Requirements and management standards required to stand up technology that will need to be acquired or licensed for managing PMDM information assets
Subcomponents	DI&I Platform Architectural Approach; DI&I Architectural Standards; DI&I Integration & Data Sharing; DI&I Historical Data, Archiving and Retention

DI&I is a key consideration as the PMDM program becomes more adaptive and integrated. This is usually attained when there is a shift from a single enterprise to an integrated environment. Some examples of this include a shift to a cross-enterprise platform (e.g., a hospital managing for their whole network, a company managing for their pharmacy franchises), or a cross-sectoral platform (e.g., national product catalog or drug registry).

DI&I Platform Architectural Approach

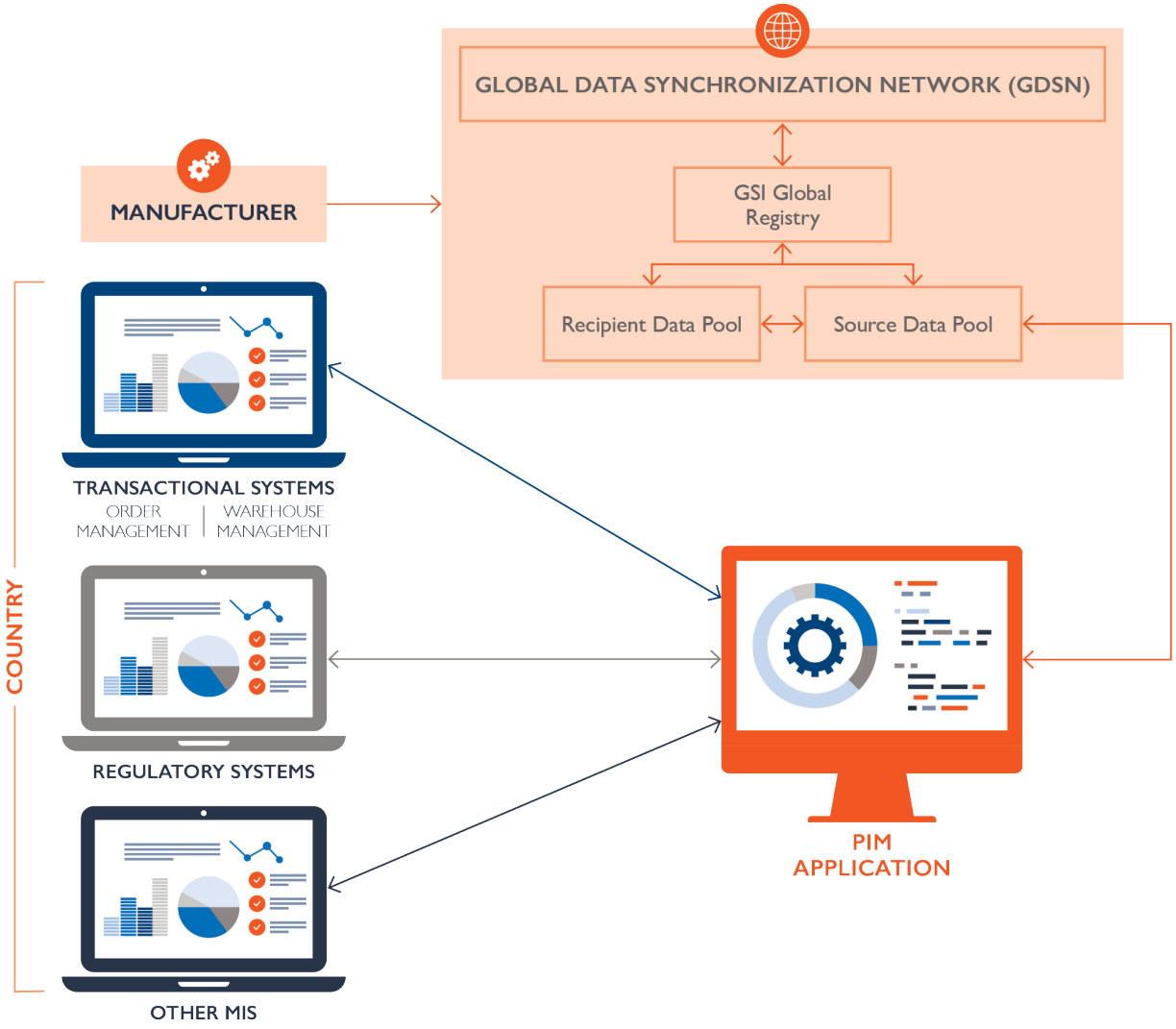
In an integrated state, the product master data architecture can leverage a product master data module on an existing system, a standalone tool interacting with a single system, or a broader cross-enterprise application. The requirements for such an approach will be determined by the enterprise owner/executive sponsor and reflect the user requirements across stakeholder groups who will rely on the PIM application for their master data. This may require stakeholders to revisit and expand on the foundational elements of the product master data architecture to address a broader set of applications. The PIM system may be configured to conduct validation checks on the information to ensure it is properly defined and formatted per the data reference model.

DI&I Architectural Standards

A significant amount of work has been done in developing open architectural standards for various types of health information systems in the global health community.[42] A key focus in developing registries is the interoperability layer than enables access to and exchange of data across any number of external systems.

[42] See, for example, Open Health Information Enterprise (OpenHIE): https://ohie.org/

Figure 12. Interoperability Layers Enable Exchange of Data



We recommend that cross-enterprise or cross-sectorial PIM application consider using an open architecture standard and enable integration through an interoperability layer for access. This approach facilitates management of the security infrastructure and implementation of data governance rules that enable access to various systems and services. The approach provides a mechanism for error tracking and management, enabling the capturing metrics for monitoring the flow of data across different supply chain and health information systems.[43] These processes also formalize the approach to creating and managing the flow of product master data to and from various internal and external sources.

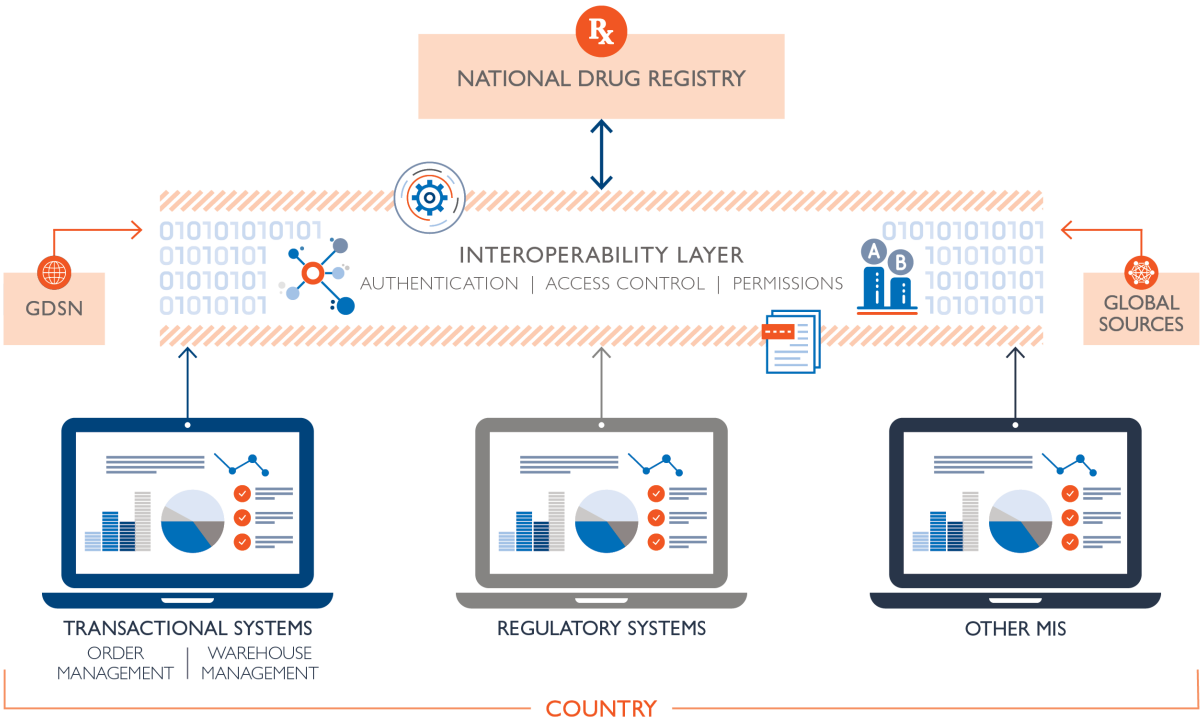
[43] OpenHIE. (n.d.). OpenHIE Architecture Specification. Retrieved from https://ohie.org/#arch.

DI&I Integration and Data Sharing

A PIM application will manage data from different sources, but one global source of information that is commonly deployed is the GDSN. The basic premise of GDSN is to ensure that the item that is identified and described by a set of master data attributes by the owner (usually the manufacturer) is also identified and described with the same set of master data by all supply chain partners.

The goal is to have all trading partners leveraging the GDSN for near-real time synchronization of product master data, generated by the brand owners of a given trade item. However, even recognizing the focus on deployment of GS1 standards, including GDSN, a PIM application must be flexible to receive and maintain data that come from other sources, such as donor information systems and potentially other external sources of data.

Figure 13. Example of a National Level PIM Application Leveraging GDSN



DI&I Historical Data, Archiving and Retention

The ability to maintain the historical information related to the master data, including creation date/time, source, validation, changes/corrections, and discontinuation, should remain part of the record of each product concept and trade item. The integration points with external systems are critical for lifecycle management, as the actual trade items and their related master data are owned and managed by brand owners, with whom there is a reliance for their data. The overall lifecycle of the product for the manufacturer is often different from the lifecycle of the product in an organization's own management of that product (e.g., even if a manufacturer stops producing a specific item, it could remain in the supply chain for several more years until all available stock is used or returned). As a result, business process workflows will be built around the lifecycle of product information that increases in complexity with the number of users reliant on those data. There will be correlations between items that are "replaced by"

other items and similarly, items that "replace" other items, referencing each other in their respective master data.

In this context, stakeholders will have to consider the amount of storage required to maintain data through this lifecycle. The amount of data that stays active in the system, especially in a database or master data transaction capacity, depends on the cost/benefit analysis of storage versus costs. The retention periods for data will vary depending on need, with two to five years an average in the health care and life sciences industry.[44] The retention period should be considered in the context of any government or related regulations and in accordance with common information technology practices. A process should be put in place to remove data after the period of retention passes.

[44] Fisher, G., & Herbst, A. (2009). Information Management Along the Lifecycle of Data and Application Systems: Challenges and Solution Approaches. Retrieved from https://pdfs.semanticscholar.org/aeda/52ebde6300e1a78cf5019c4374076d7cff3c.pdf.