(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

Barcode Registration to GDSN Synchronization

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

The following training is based on materials developed by 1WorldSync and GS1 and are used with their permission.

1WorldSync is a GS1 Global Data Synchronization Network™ data pool provider.

For more information, please visit www.1worldsync.com

Today's Presenters

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USAID Global Health Supply Chain Program

Today's Attendees

- Manufacturers

- Suppliers

- GHSC-PSM

- USAID

- GS1

- 1WorldSync

Meeting Objectives

- Build awareness of the upcoming GHSC-PSM GS1 deadlines

- Provide education on:

  – GHSC-PSM's initiative

  – GS1 standards

  – Master data & the GDSN

- Review timelines and required actions to get compliant

- Provide information about supporting resources

2018-2019 Timeline for Compliance

1

Now! Identification & Labeling

- Assign GTINs & GLNs
- COMPLETE GTIN & GLN Submission Form HERE
- Label your tertiary pack trade items*

2

Register for Data-pool

Data-pools are the mechanism for sending GTIN master data to GHS-PSM

Find List of Data Pools HERE

3

Publish Content to GHSC-PSM

- COMPLETE Trading Partner Form HERE
- Attribute Requirements
- GDSN Process and Communication

DEADLINE
30th December 2018

RECOMMENDED
30th January 2019

DEADLINE
30th December 2019

*Required for pharma, medical devices, sterile test kits, laboratory reagents only

USAID Global Health Supply Chain Program

Introduction & Progress

What is GHSC trying to achieve?

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

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

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

USAID Global Health Supply Chain Program

Global standards at GHSC-PSM

- Mandated by USAID in 2017

- Requirement formalized January 1, 2018 in Article 3 of the Standard Terms & Conditions

- Will be included in all new sourcing events / contracts; existing LTAs will be modified

- Accompanied by Global Standards Technical Implementation Guide and FAQ

- More information at ghsupplychain.org/globalstandards

April 25, 2017

TECHNICAL DIRECTION MEMORANDUM (TDM) 2017-03

TO: Anthony Savelli, Project Director, GHSC-PSM

FROM: Lindizgya Gutierrez, COR, GH/ID/MAL   /S/
           Sherif Mowafy, COR, GH/OHA/SCH   /S/
           Carmen Tull, COR, GH/MNCH/CHI   /S/
           John Vivalo, COR, GH/PRH/CSL

SUBJECT: Technical Direction Memo (TDM) Establishment of a strategic approach for the adoption of global standards for product identification

REFERENCE: Chemonics International - GHSC-Procurement and Supply Management USAID IDIQ No. AID-OAA-I-15-00004
Task Order 1 - AID-OAA-TO-15-00007, Task Order 2 - AID-OAA-TO-15-00009, Task Order 3 - AID-OAA-TO-15-00010, and Task Order 4 - AID-OAA-TO-16-00018

Background

To improve the safety and efficiency of supply chains in the countries in which it supports, and to improve the traceability of USAID funded commodities, USAID is implementing a strategic vision for adoption of global standards for supply chains. To advance this, USAID expects GHSC-PSM to implement a strategic and coordinated approach to adoption of global standards, namely GS1 healthcare standards, for product identification, data capture and data sharing across its global and in-country activities. This includes utilizing barcode technology in its supply chain and enabling its usage by national supply chains.

In January 2017, GHSC-PSM concluded a consultancy with RC Partners focused on adoption of global standards under the project. By May 25, 2017, GHSC-PSM shall submit to USAID a detailed plan for implementation of global standards for product identification and data capture to achieve the minimum targets set by each TO. This strategic plan shall detail milestones, risks, and resource requirements

Technical Directions

Below are the targets that have been established for T03. The targets for the remaining task orders will be provided in a later communication from the task order COR. The targets and objectives of this TDM are to focus on product identification and labeling. Further guidance will be provided on data sharing.

U.S. Agency for International Development
1300 Pennsylvania Avenue, NW
Washington, DC 20523
www.usaid.gov

The GHSC-PSM Procurement Requirement

- Phased in over time

- Identification (items & locations) within 6 months of new contracts

- Labeling requirements for pharmaceuticals, medical devices, laboratory reagents, and sterile test kits phased in between Dec 2018 – Jun 2022

- Master data exchange via the GDSN required by Dec 2019

SECTION NO. 2

OVERVIEW OF THE REQUIREMENT FOR PHARMACEUTICALS

The requirements specify the following **minimum** use of **GS1** identification keys and data carriers labeled on pharmaceutical products at various packaging levels:

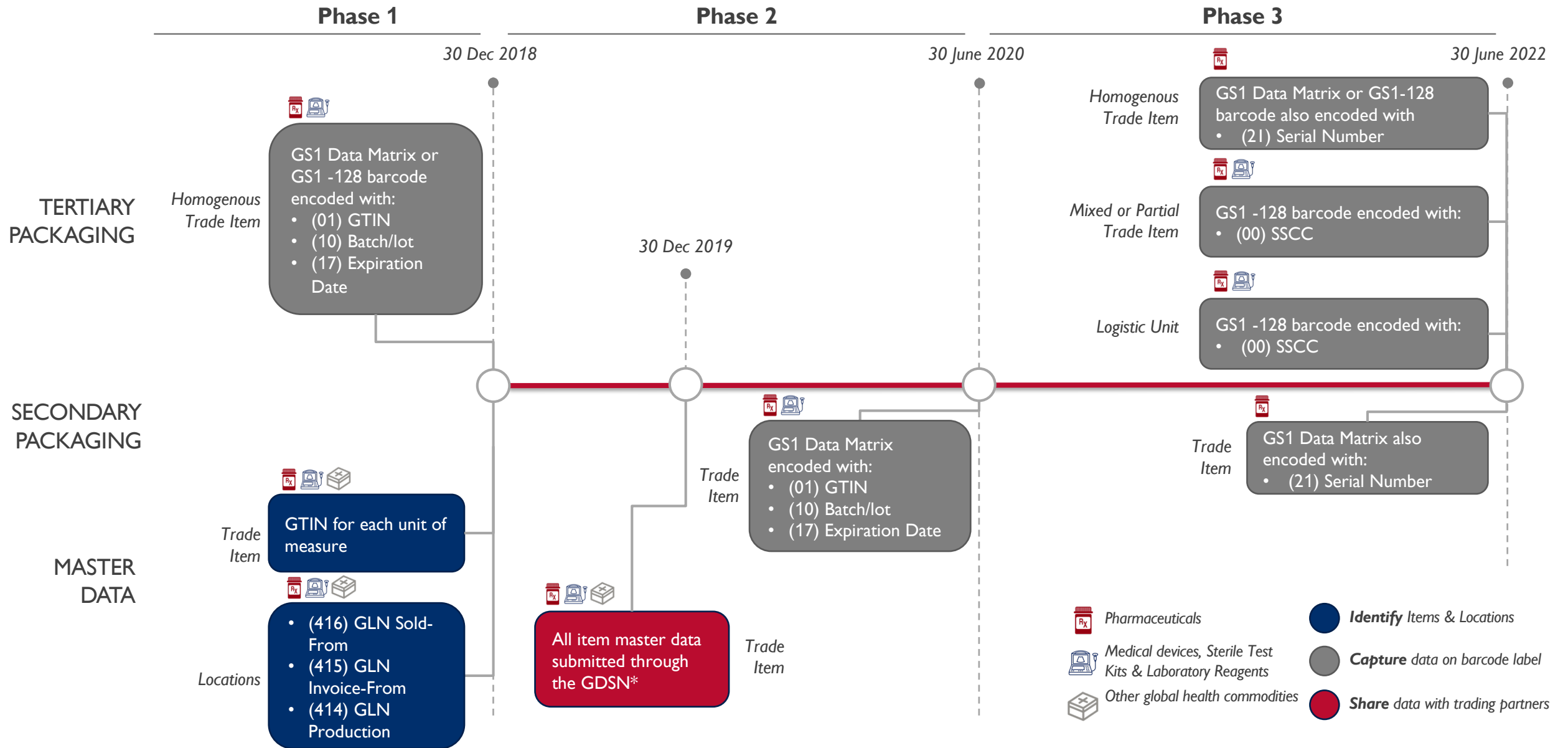| Packaging level	Packaging type	Requirement	Human readable interpretation (HRI)	Timeline
Tertiary: logistic unit		GS1-128 barcode[2] symbology encoded with: • Serial shipping container code (SSCC)	Information printed in human readable format: • SSCC	As soon as possible (ASAP) but no later than (NLT) June 30, 2022
Tertiary: trade item	Homogenous	GS1 DataMatrix or GS1-128 barcode symbology encoded with: • GTIN • Batch/lot • Expiration date • Serial number	Information printed in human readable format: • GTIN • Batch/lot • Expiration date • Serial number	For GTIN, batch/lot, and Expiration date, ASAP but NLT December 30, 2018 For serial number, NLT June 30, 2022
	Mixed or partial	GS1-128 barcode[3] symbology encoded with: • SSCC	Information printed in human readable format: • SSCC	ASAP but NLT June 30, 2022
Secondary: trade item		GS1 DataMatrix symbology encoded with: • GTIN • Batch/lot • Expiration date • Serial number	Information printed in human readable format: • GTIN • Batch/lot • Expiration date • Serial number	For GTIN, batch/lot, and Expiration date, ASAP but NLT June 30, 2020 For serial number, ASAP but NLT June 30, 2022
Primary: trade Item Optional; Required **only** when the product is supplied in carton-less packaging.		GS1 DataMatrix symbology encoded with: • GTIN • Batch/lot • Expiration date • Serial number	Information printed in human readable format: • GTIN • Batch/lot • Expiration date • Serial number	Optional

[2] If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.
[3] If and when the GS1 DataMatrix is recommended for use on the logistic unit in the GS1 General Specification, suppliers are permitted to use that data carrier to meet the GHSC-PSM logistic unit labeling requirement.
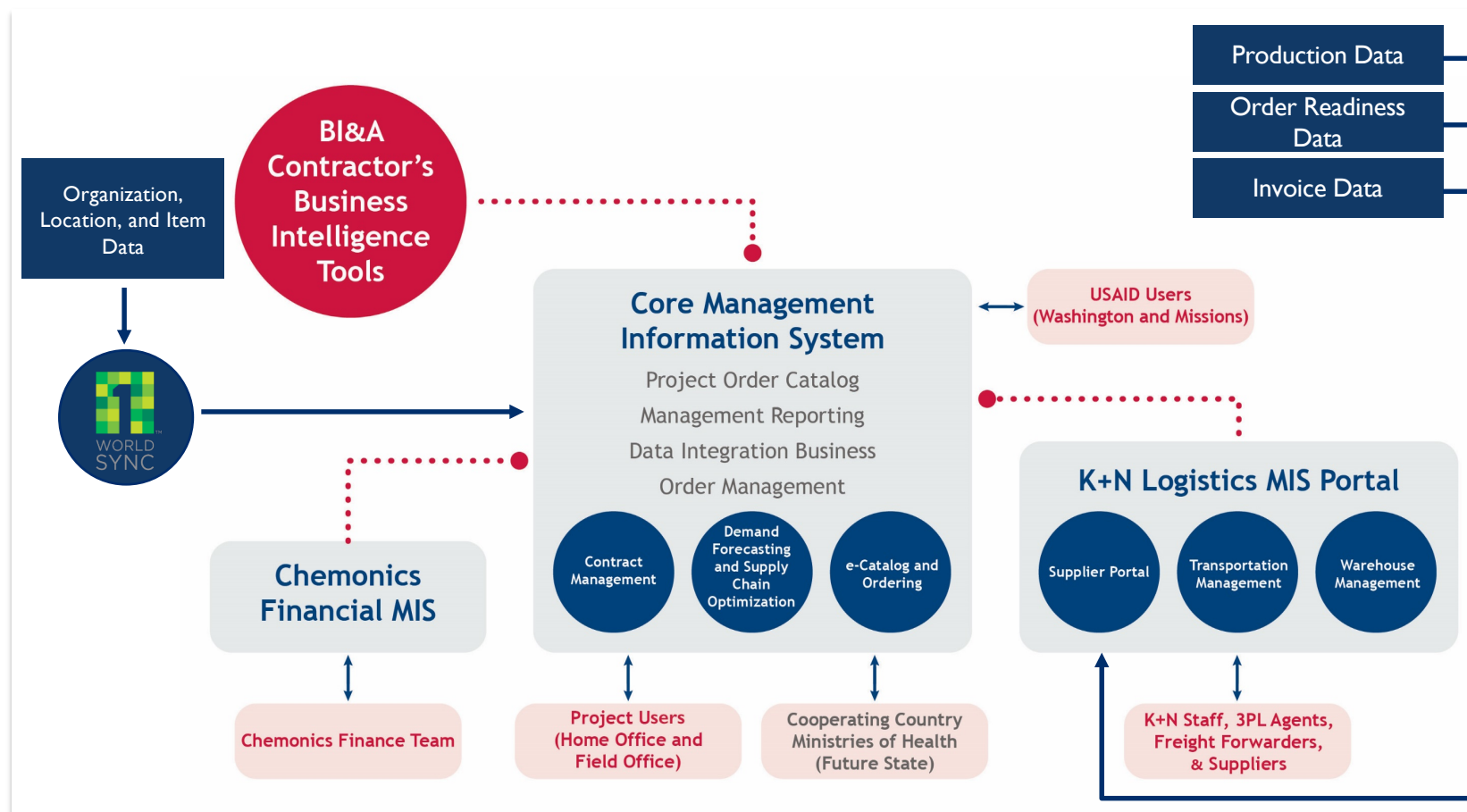
GHSC-PSM Global Standards Technical Implementation Guide | 6

More information available here

Summary of GHSC-PSM GS1 Global Standards Requirements

Phase 1 | **Phase 2** | **Phase 3**

30 Dec 2018 | 30 June 2020 | 30 June 2022

30 Dec 2019

TERTIARY PACKAGING

Homogenous Trade Item

GS1 Data Matrix or GS1 -128 barcode encoded with:
- (01) GTIN
- (10) Batch/lot
- (17) Expiration Date

Homogenous Trade Item

GS1 Data Matrix or GS1-128 barcode also encoded with:
- (21) Serial Number

Mixed or Partial Trade Item

GS1 -128 barcode encoded with:
- (00) SSCC

Logistic Unit

GS1 -128 barcode encoded with:
- (00) SSCC

SECONDARY PACKAGING

Trade Item

GS1 Data Matrix encoded with:
- (01) GTIN
- (10) Batch/lot
- (17) Expiration Date

Trade Item

GS1 Data Matrix also encoded with:
- (21) Serial Number

MASTER DATA

Trade Item

GTIN for each unit of measure

Trade Item

All item master data submitted through the GDSN*

Locations

- (416) GLN Sold-From
- (415) GLN Invoice-From
- (414) GLN Production

Legend

🔴 Pharmaceuticals

🔲 Medical devices, Sterile Test Kits & Laboratory Reagents

📦 Other global health commodities

🔵 **Identify** Items & Locations

⚫ **Capture** data on barcode label

🔴 **Share** data with trading partners

USAID Global Health Supply Chain Program

For more information on how to comply: www.1worldsync.com/customer-page/ghsc-psm
For more information on our requirements: http://ghsupplychain.org/globalstandards

GTIN: Global Trade Item Number   **GDSN**: Global Data Synchronization Network
GLN: Global Location Number   **SSCC**: Serial Shipping Container Code

GDSN data will feed into ARTMIS and form the basis of the GHSC-PSM product catalog
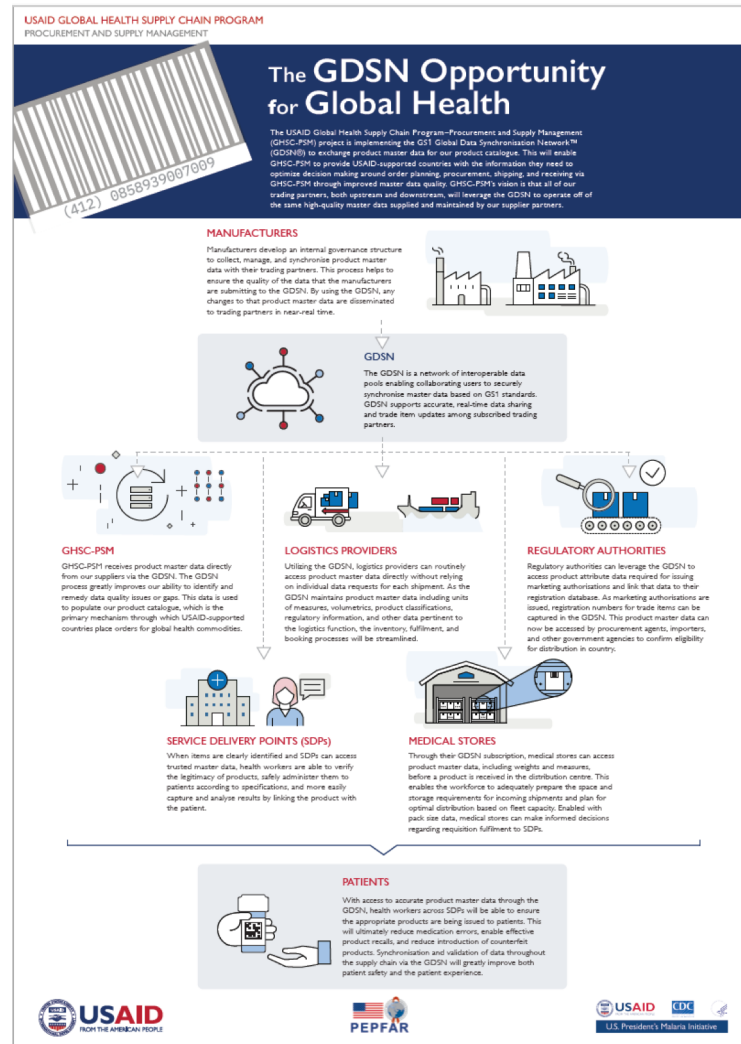
The GDSN opportunity for global heath

GS1 Global Data Synchronisation Network™ (GDSN®)
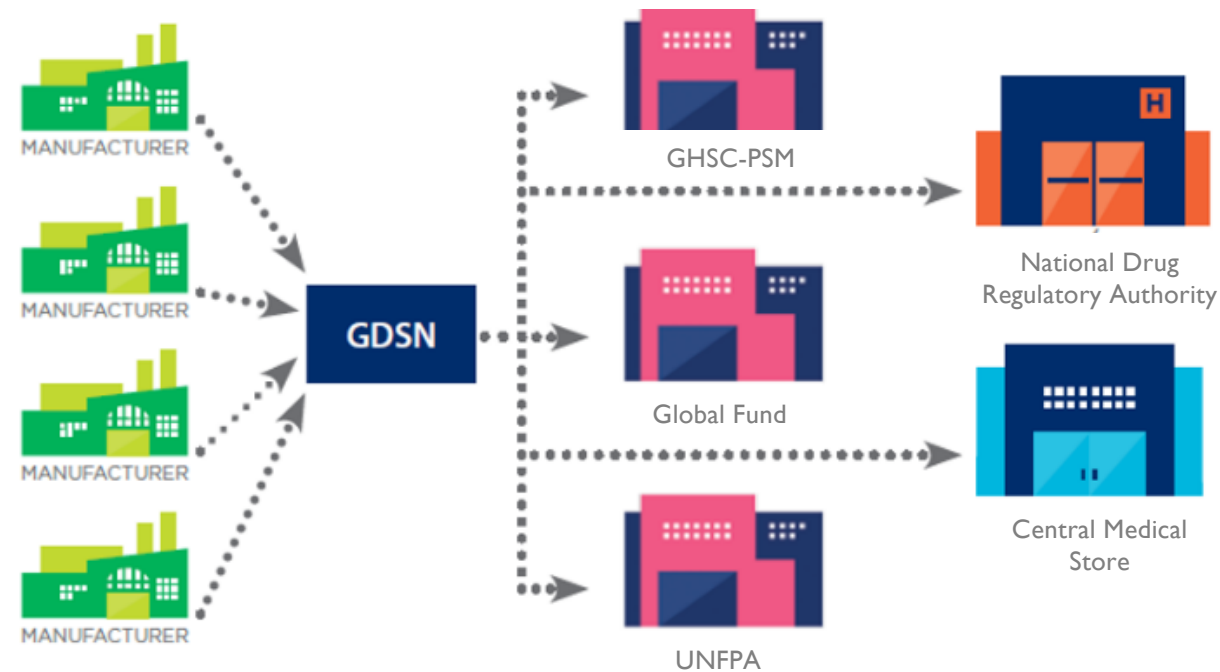
Manufacturers are able to provide data to all kind of databases and all kinds of customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.

USAID Global Health Supply Chain Program

Opportunities for GHSC-PSM with GDSN

- Information asymmetry is rampant in our supply chains. GDSN provides a single source of truth on Master Data – the supplier!

- Get a consistent set of attribute data from all trading partners

- Near real-time updates if product data changes

- Opportunity to receive registration (marketing authorization) information in a standard and consistent manner

- GHSC-PSM will have the same identifying data as UNFPA, Global Fund, and others, improving cross-agency procurement analytics

- Countries want to use GDSN data as the basis for a National Product Registry

In Summary…

- This is new to all of us!

  - We don't have all of the answers (yet)

  - We will work with you to figure it out

  - We are keen to start early and do testing with anyone who is ready to start

  - Communication will be key

- Countries are very interested in this service – lack of consistent identification and poor master data is central to supply chain challenges!

- We really believe that this will have a transformational in the global health community

GS1 in the Healthcare Industry

GS1 standards framework

Identify

Globally unique identification keys

Companies, Products, Locations, Patients, Providers, Logistics, Assets, Documents, Services, Shipments, Consignments

Capture

Automatic data capture

Barcodes and EPC-enabled RFID
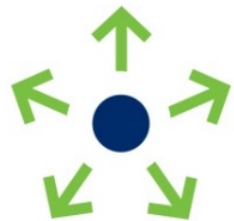
Share

Exchange of patient care & business critical information

Master Data, Transactional Data, Traceability & Event Data and Digital Content

The GS1 system of standards

The GS1 Global Company Prefix (GCP)

- The GS1 Global Company Prefix is the base component used to create a GS1 Key such as a Global Trade Item Number (GTIN).

- The GS1 Global Company Prefix is a license to create GS1 Keys and is issued by any one of the GS1 Member Organisations to companies who wish to use the GS1 system of standards

GS1 company Prefix

X X (X)* X X X (X)

GS1 Prefix
assigned by
GS1 Global Office

* the length can
be 2 or 3

Company number
assigned by GS1
Member Organization

Getting Started with GS1 Standards

GS1
The Global Language of Business

Ten steps to GS1 barcode implementation
User Manual

Issue 2.1, Final, December 2015
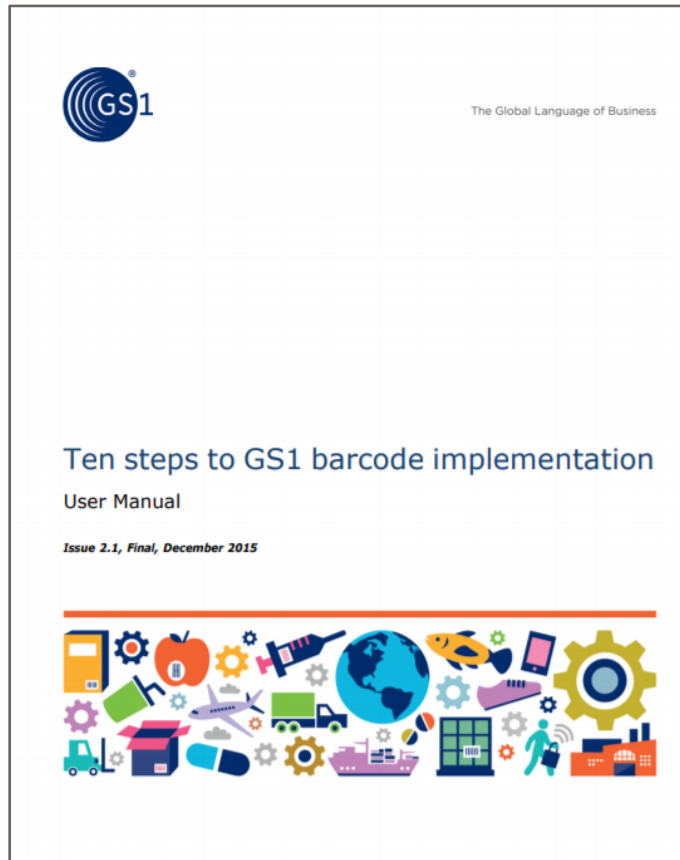
Ten Steps to Barcode Implementation

Step 1   Get a GS1 Company Prefix

Step 2   Assign numbers

Step 3   Select a barcode printing process

Step 4   Select a "primary" scanning environment

Step 5   Select a barcode

Step 6   Pick a barcode size

Step 7   Format the barcode text

Step 8   Pick a barcode colour

Step 9   Pick the barcode placement

Step 10   Build a barcode quality plan

https://www.gs1.org/standards/barcodes/10-steps-to-barcode-your-product/english

Packaging Level Hierarchies

Identification at all levels

| Pallet (Tertiary*) | Case / Shipper (Tertiary*) | Secondary package | Primary package | Single Unit package |
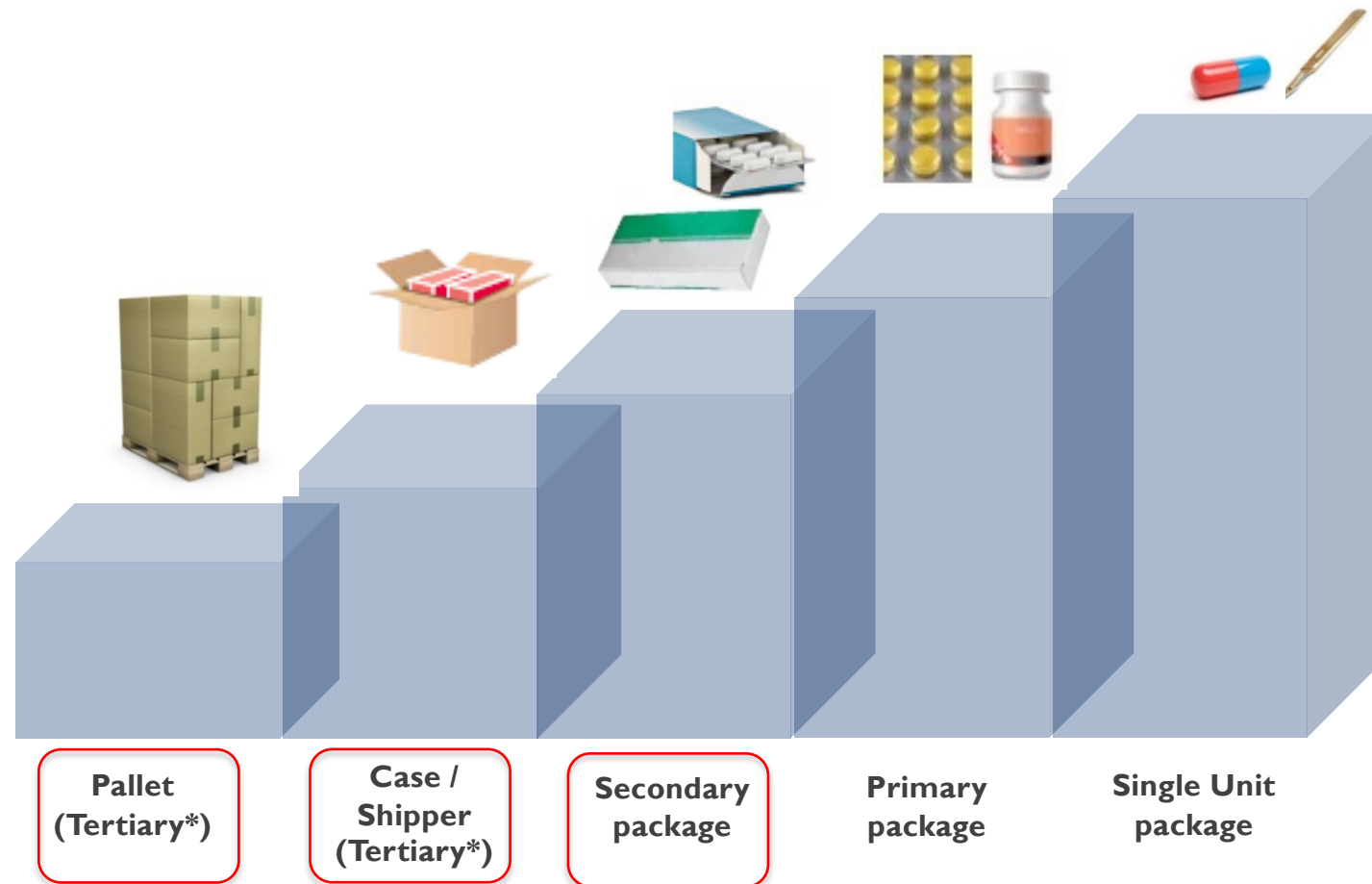
Note: * There is no globally standardized definition of "tertiary package"…

Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

USAID Global Health Supply Chain Program

GS1 Barcodes in a Healthcare Hierarchy

Check Digit

GTIN A (GTIN-14)
29504000059273

GTIN B (GTIN-14)
39504000059270

GTIN C (GTIN-14)
49504000059277

GTIN D (GTIN-14)
69504000059271

GTIN E (pallet as a Trade Item with GTIN-14)
89504000059275
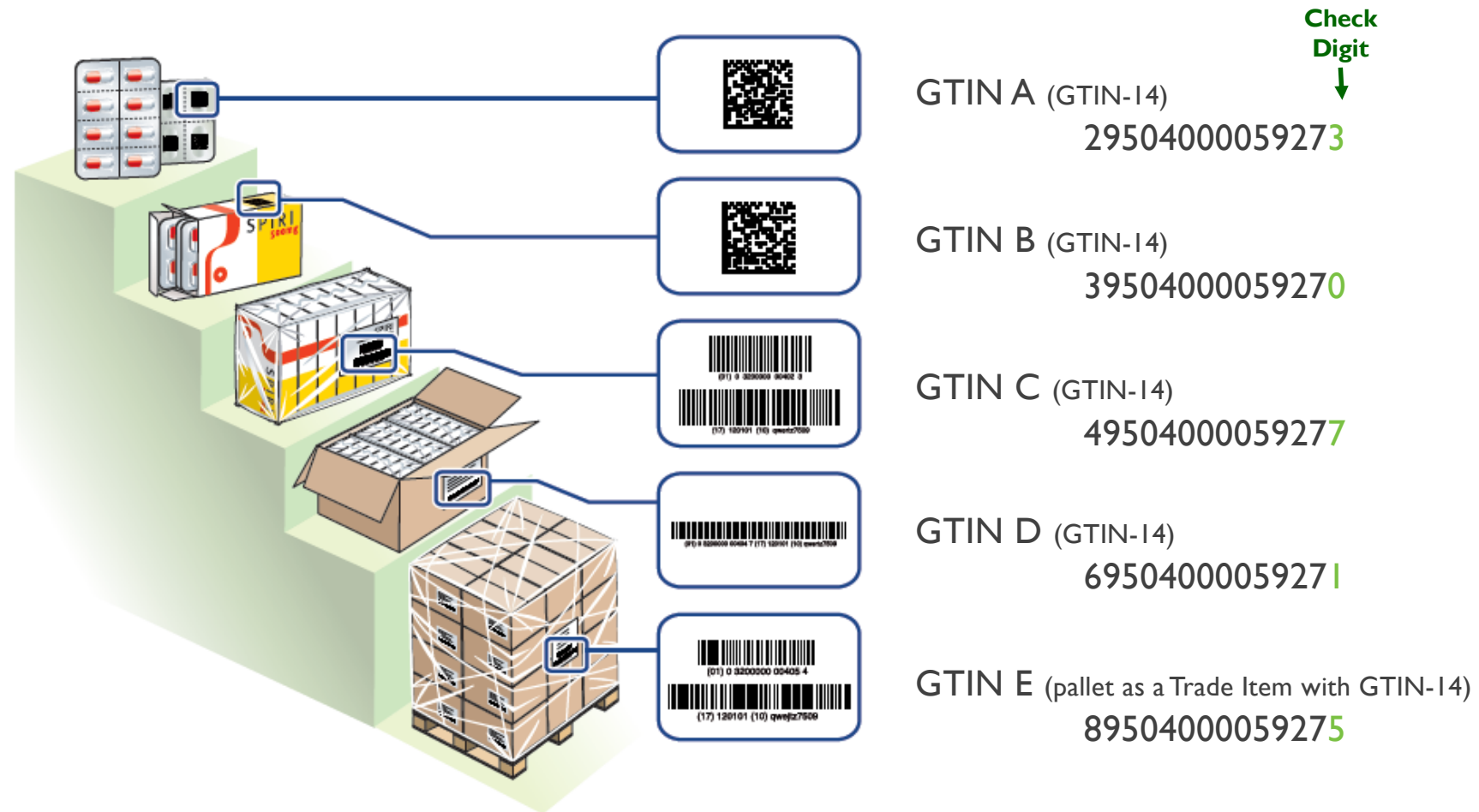
GS1 DataMatrix: The Favored 2D Carrier for Pharmaceuticals

(01) 08699546010011 → Product Identifier (GTIN)

(21) 583053774154 → Serial Number

(17) 151228 → Expiration Date

(10) TRT08E3 → Lot/Batch Number
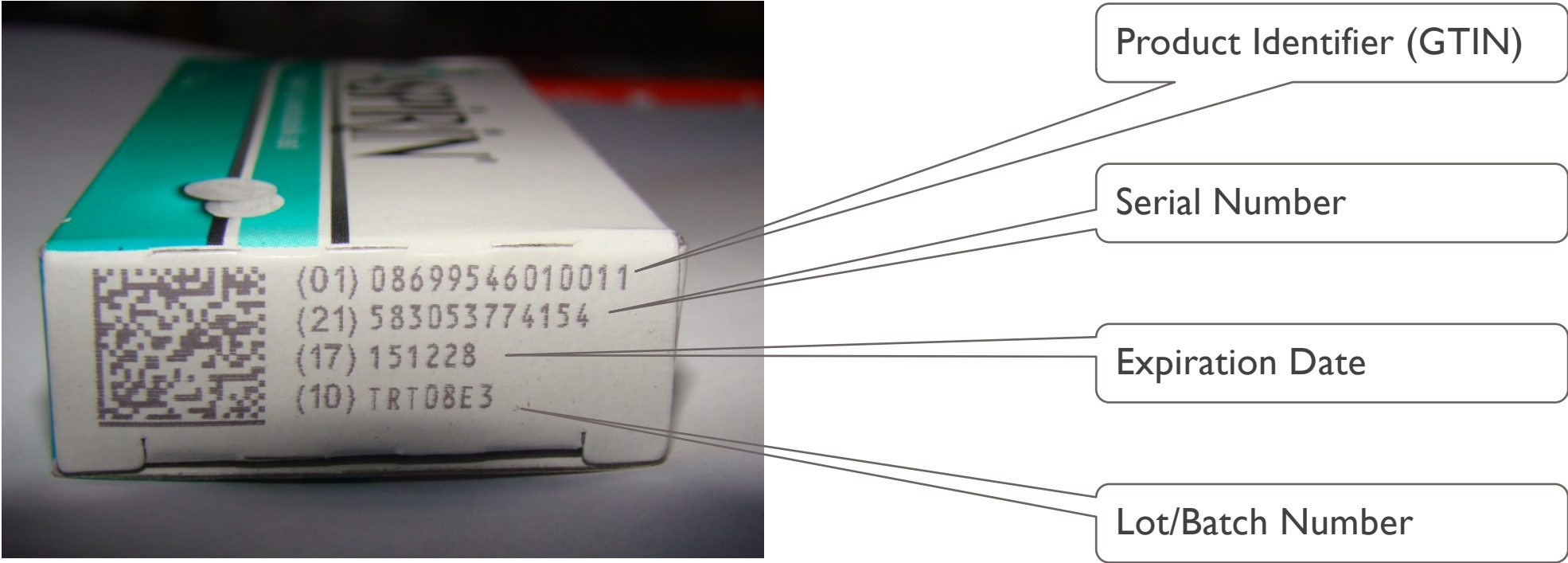
Note: These are the four data elements supported by regulators

Related GS1 Resources

- Healthcare GTIN Allocation Rules

  https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

- Healthcare GLN Guideline

  https://www.gs1.org/docs/healthcare/GLN_Healthcare_Imp_Guide.pdf

- GS1 General Specifications

  https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

GDSN: How it works & common misconceptions

Synchronizing Your Product Information

1) Is there a match?

**Manufacturers /
Wholesalers**

-Target Market
(Development Assistance)
-GLN
-GTIN

GS1 GLOBAL
REGISTRY®

-Target Market
(Development Assistance)
-GLN
-GTIN

**USAID
GHSC-PSM**

**Send
Information**

Yes

2) Synchronized

**Receive
Information**

Manufacturer /
Wholesaler
SOURCE DATA POOL

Chemonics
USAID GHSC-PSM
RECIPIENT DATA POOL
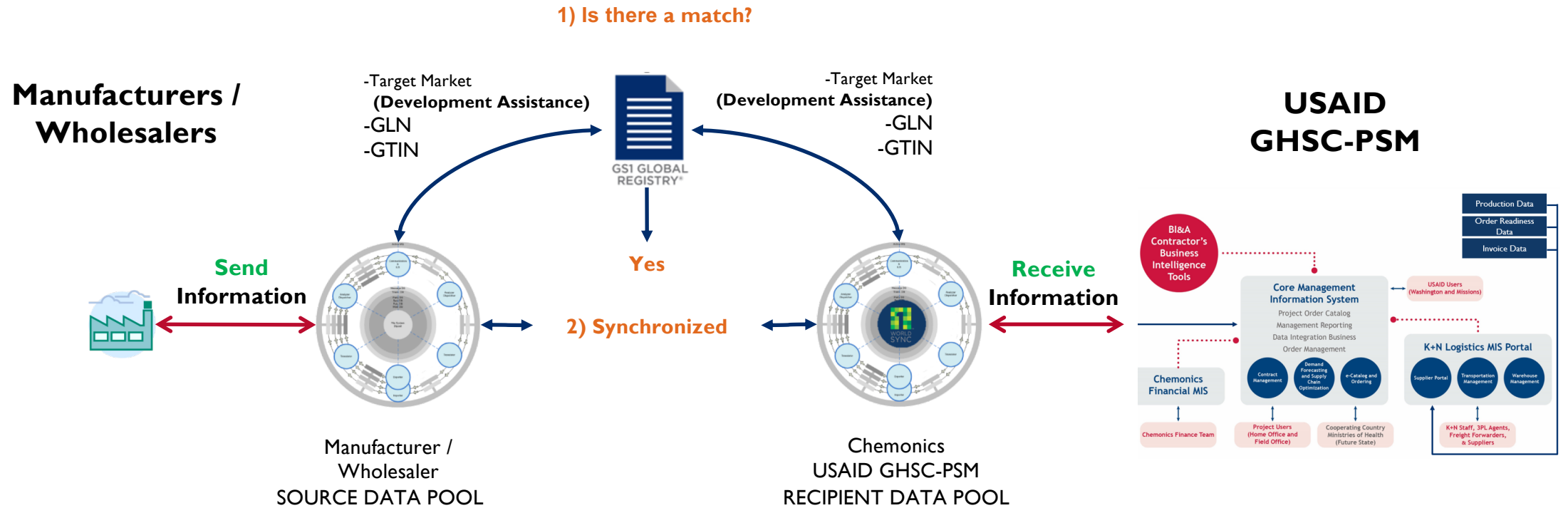
1) Secure connection established between supplier and recipient

2) Product content is shared (synchronized) and updated in real time

Product Information: Entering Information

1. The Attribute Guide

The attribute guide serves as a dictionary/reference to attributes that USAID GHSC-PSM needs to receive.

Attribute Guide Link

2. Product Content Entry and Publication

Once you register with a data-pool service provider, you will have access to a platform where you can enter the specific GHSC-PSM attributes as data entry fields.

This information is securely stored on the data-pool and the information provider chooses who to send (publish) the entered information to.

Preparing for GDSN: Internal Structure

2
Process Approved Content

1

TEAM

Approval of Product Content

- Executive Buy-in
  - Marketing/Sales Department
  - Regulatory/Legal Department
  - Supply Chain Department

Effective and Responsive Data Management Workflow

3

TEAM

Master Data Management Team

- Aggregates Information
- Owns the GDSN Process
  - Sends Content
  - Makes Corrections

Process Feedback Channels

4
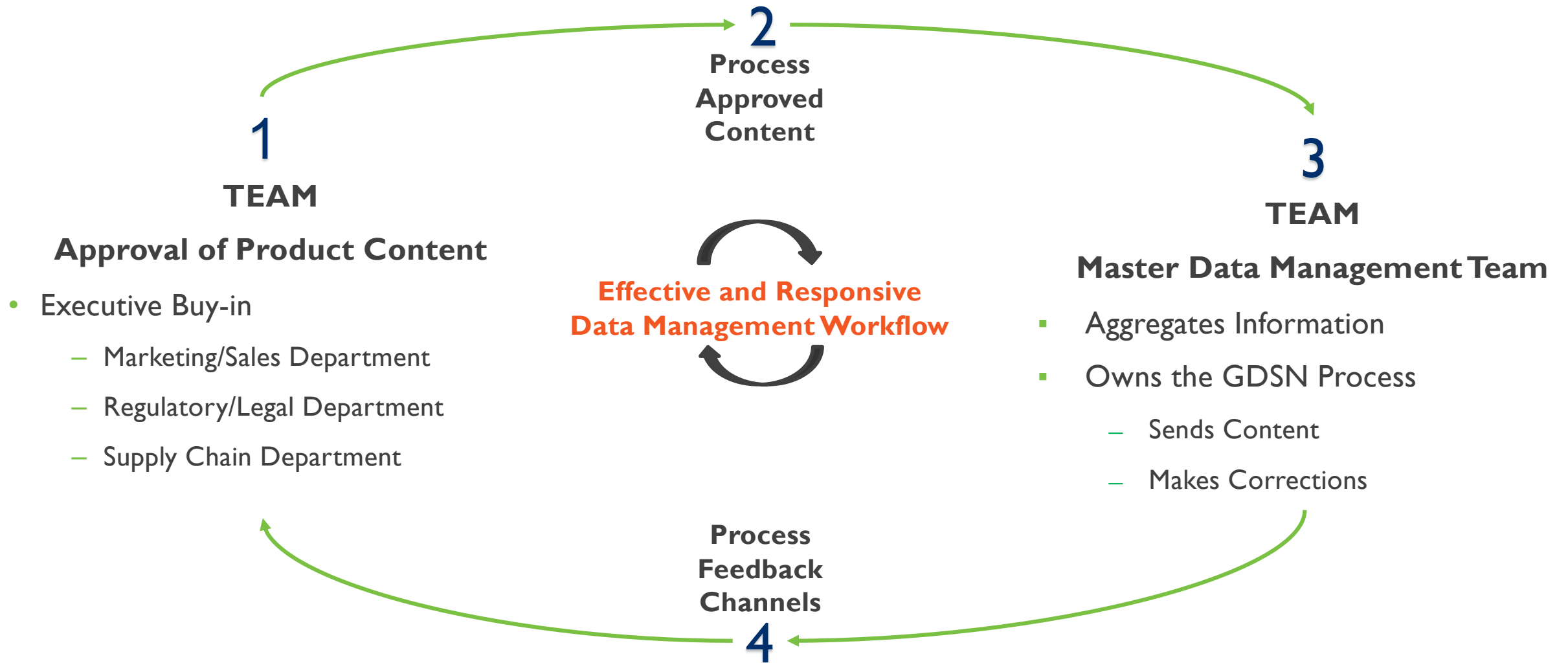
Once you are in, you can reach out to the broader industry

SOURCE
DATA POOL

US UDID

EUDAMED

USAID GHSC-PSM

GPOs

Hospitals / Providers
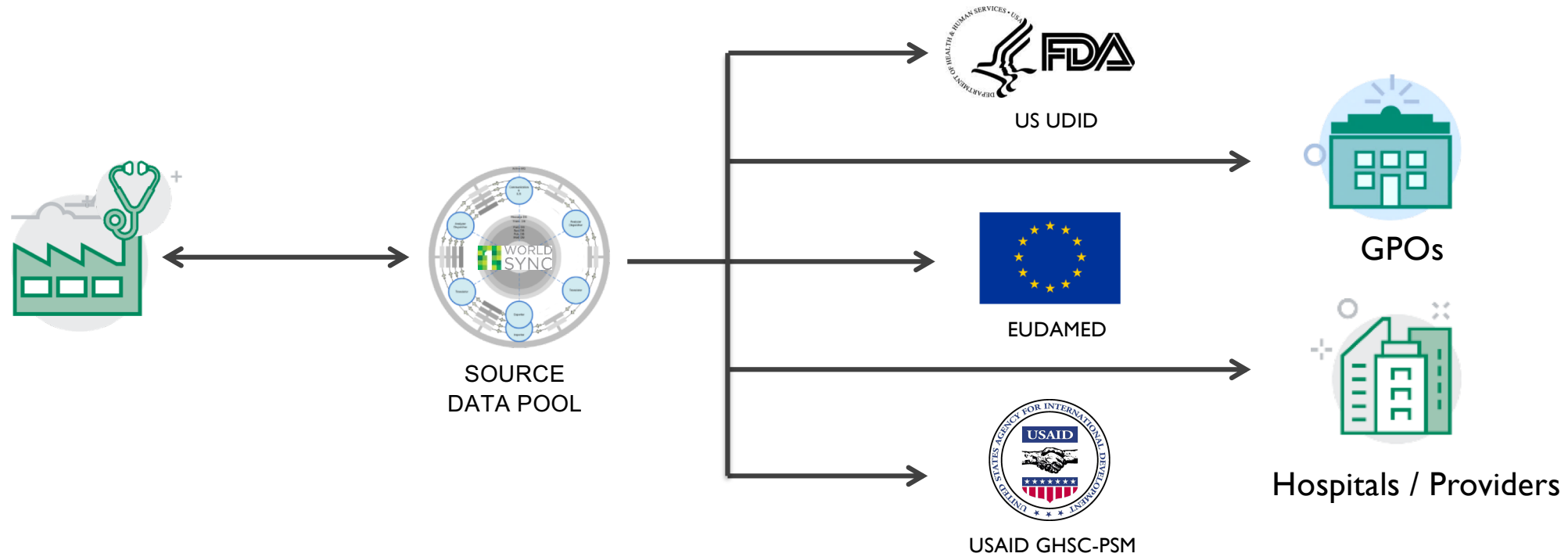
Misconception 1: *GTINs and GLNs can only be assigned to one Target Market*

- GTINs and GLNs can be assigned to multiple target markets!

- This GDSN model works off a basic principle:

  – The entire set of data attributes are assigned to a GTIN

  – Those attributes may vary depending on who provides the information (GLN)

  – Those attributes may vary by which target market (TM) the data is designed for

- The following attributes that **should not** change across GTIN, GLN, Target Market

✓ GTIN	✓ Variant	✓ Is trade item a base unit
✓ GPC Category Code	✓ Trade item unit descriptor	✓ Is trade item a consumer unit
✓ Brand Owner (GLN)	✓ Country of origin	✓ Is trade item a variable unit
✓ Brand	✓ Quantity of next lower level trade item	✓ Cancelled date
✓ Sub Brand	✓ Net content	
✓ Functional name	✓ Net content UOM	

Misconception 2: *The GDSN exchanges transactional information*

GS1 GDSN
The Global Data Synchronization Network

Item
GTIN: 00614141123452

Pack
GTIN: 10614141123459

Case
GTIN: 20614141123456

**What item is this?**

Master Data

- General Item Information / Classification
- Product Description Information / Images
- Unit Indicators/ Hierarchy

- Dimensions/ Packaging Information
- Contact Information/ Additional Trade Items

- Storage, Handling, Shelf Life
- Warranty Information

- Ingredient Information / Pharmaceutical
- URL Links to Additional Information
- Market Authorization / Hazardous Information

GS1 EDI
Electronic Data Interchange
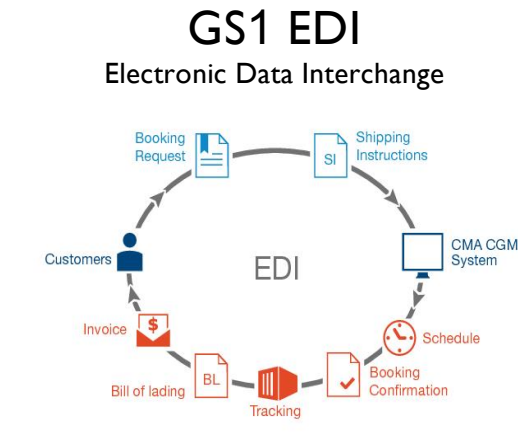
What did this cost?

Transactional Data

- Add Items GTIN & Quantities
- Change Orders (Price, Items & Dates)

- Product Activity Exchanged

- Shipment tracking numbers
- Order Level PO information

- Discounts
- Payment Terms
- Invoice Details

EPCIS / CBV
Electronic Product Code Information Services
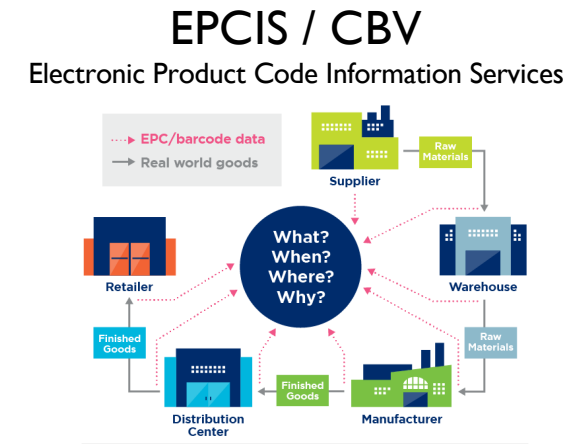
Who touched this along the way?

Event Data

What	• EPC Number leverages GTIN • Manufacturing Data (lot, batch, expiration date) • Transactional (PO, Shipment, Invoice)
Where	• Location (Leverage GLN)
When	• Event Time • Record Time
Why	• Business Process (Receiving, Shipping) • Product State (Active, In-Transit) • Current Condition (Temperature Being Stored)

USAID Global Health Supply Chain Program

Misconception 3: *Suppliers <u>must</u> use the same data pool as GHSC-PSM*

- GHSC-PSM suppliers can use any GDSN data pool

- As the world's largest data pool, 1WorldSync would love to partner with you to meet the GHSC-PSM requirement

Data Pool Providers
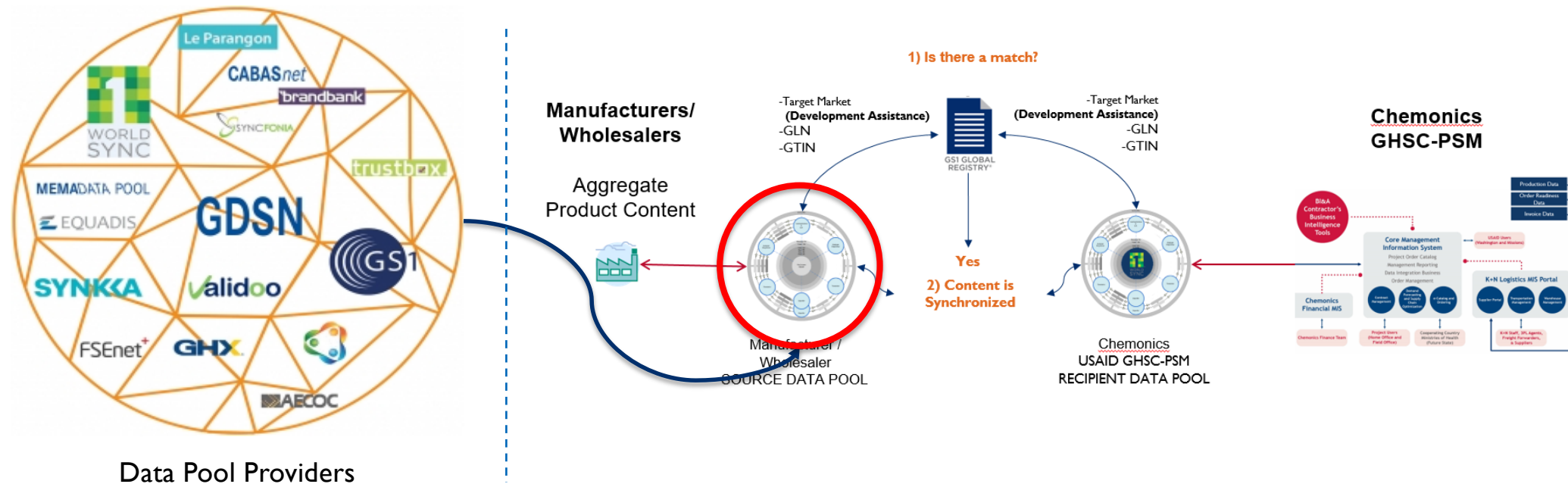
Timelines & Actions

2018-2019 Timeline for Compliance

1

Now! Identification & Labeling

- Assign GTINs & GLNs
- COMPLETE GTIN & GLN Submission Form HERE
- Label your tertiary pack trade items*

2

Register for Data-pool

Data-pools are the mechanism for sending GTIN master data to GHS-PSM

Find List of Data Pools HERE

3

Publish Content to GHSC-PSM

- COMPLETE Trading Partner Form HERE
- Attribute Requirements
- GDSN Process and Communication

DEADLINE
30th December 2018

RECOMMENDED
30th January 2019

DEADLINE
30th December 2019

*Required for pharma, medical devices, sterile test kits, laboratory reagents only

USAID Global Health Supply Chain Program

1. Identification & Labeling

1. Register with a GS1 Member Organization (MO) to obtain a GS1 Company Prefix

2. Assign a Global Trade Item Number (GTIN) to all items

3. Assign a Global Location Number (GLN) for relevant legal entities and locations

4. Fill out the GHSC-PSM GTIN and GLN Submission Form

   • https://www.ghsupplychain.org/sites/default/files/2018-08/20180812%20GHSC-PSMGTINSubmissionForm_V1.1_Final.xlsx

5. Follow the GS1 barcode implementation guidance to print barcode labels on your tertiary pack trade items*

DEADLINE
30th December 2018

*Required for pharma, medical devices, sterile test kits, laboratory reagents only

2. Register for Data Pool

1. Subscribe to a GDSN-certified data pool provider of your choice

   - A list of all GDSN-certified data pool providers can be found at https://www.gs1.org/services/gdsn/certified-data-pools

   - 1WorldSync has a special offer for GHSC-PSM suppliers to join the GDSN. For more information, contact +1-866-280-4013 or businessdevelopment@1worldsync.com

2. Internal Preparation

   - Work with existing or establish an internal master data management process

   - Get executive buy-in and create internal initiatives to allow you to invest time and resources in GDSN

RECOMMENDED COMPLETION
30th January 2019

3. Publish Content to GHSC-PSM

1. Complete Trading Partner form and GHSC-PSM will subscribe to your GLN in the GDSN
   - Available via http://www.1worldsync.com/customer-page/ghsc-psm/

2. Load the GTIN, GLN, and associated item data into your GDSN data pool solution
   - Reference the GHSC-PSM Data Synchronization Attribute Guide for a complete list of attribute requirements

3. Publish items to GHSC-PSM production GLN 0858939007009
   - Reference the GHSC-PSM Data Synchronization Implementation Guide for more detailed specifications related to publication

4. Continue to maintain items through the data synchronization process

DEADLINE
30th December 2019

Resources

GS1 Resources

- For a list of all GDSN-certified data pool providers:
    - https://www.gs1.org/services/gdsn/certified-data-pools

- For a list of all GS1 Member Organizations:
    - https://www.gs1.org/contact/overview

- To learn more about GS1, including implementation of the GDSN, register to attend one of the upcoming GS1 Healthcare Conferences
    - October 30 – November 1, 2018 in Bangkok, Thailand
    - March 26 – 28, 2019 in Noordwijk, Netherlands
    - November 5 – 7, 2019 in New Delhi, India
    - https://www.gs1.org/healthcare/events

USAID Global Health Supply Chain Program

GHSC-PSM Resources

- For more details on GHSC-PSM's requirement:
  - http://ghsupplychain.org/globalstandards

- GHSC-PSM's GDSN Landing Page:
  - http://www.1worldsync.com/customer-page/ghsc-psm/

- Key contacts:
  - GHSC-PSM Global Standards Team: globalstandards@ghsc-psm.org
  - GHSC-PSM Data Sync Team: datasync@ghsc-psm.org

1WorldSync Resources

- Website:

  – http://www.1worldsync.com/

- Key contacts:

  – businessdevelopment@1worldsync.com

  – +1-866-280-4013

- For upcoming events and training opportunities you can visit:

  – https://www.1worldsync.com/services/education-training/

Q&A

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THANK
YOU