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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

TraceNet Recommendations V2.0 – Activity Review

May 2, 2024

Agenda

Topic	Estimated Time	Speakers

• GS1 101
  • What – Introducing GS1 Global Standards
  • Why – Leveraging GS1 as the Global Standard used for TraceNet and Global Health
  • How – Operationalization of standards
	10 minutes	Jackson Moser

• TraceNet V2.0 Technical Working Group
  • TraceNet Overview
  • PMI Nigeria Verification Pilot
  • Document Changes & High Priority Topics
  • V2.0 Finalization
	15 minutes	Jackson Moser

• ITN Use Cases Overview
  • TraceNet Community-Defined Use Cases
  • Use Case Deep Dives
	20 minutes	Violet Ketani

• Q&A	5 minutes	All

GS1 Global Standards

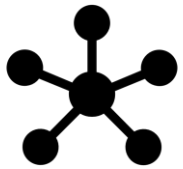
GS1 is a Global Standards Organization

- Neutral & Not-for profit
- User driven
- Global & Local
- Inclusive & Collaborative

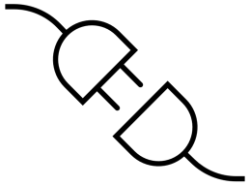
Content Source: GS1 Global Office

The Benefits of Global Standards

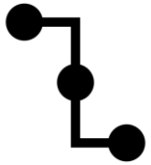
National identification and classification structures may exist for pharmaceuticals and related health commodities, but global standards provides a **common language** to efficiently interact with external trading partners (e.g. manufacturers, distributors, procurement agents, donors, export clients)



Within a country, global standards **enable interoperability across disparate systems** (e.g. drug regulatory information system (DRIS), logistics management information systems (LMIS)) in a given sector by having a single reference code to associate items or products across different stakeholder groups.



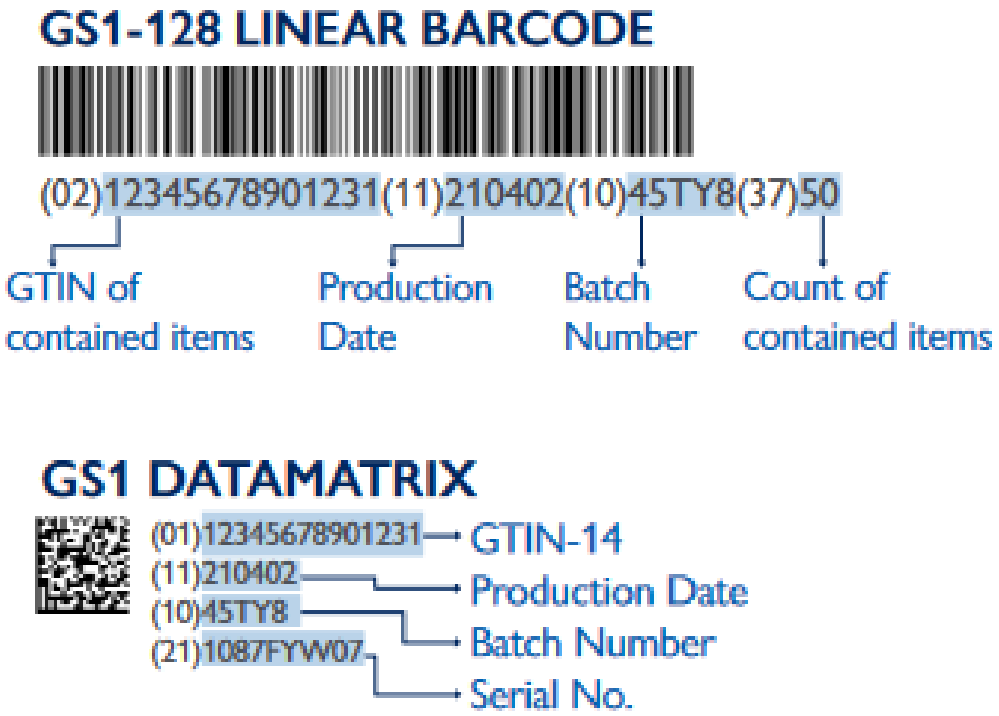
Rules and specifications are needed to enable data exchange among different supply chain stakeholders.



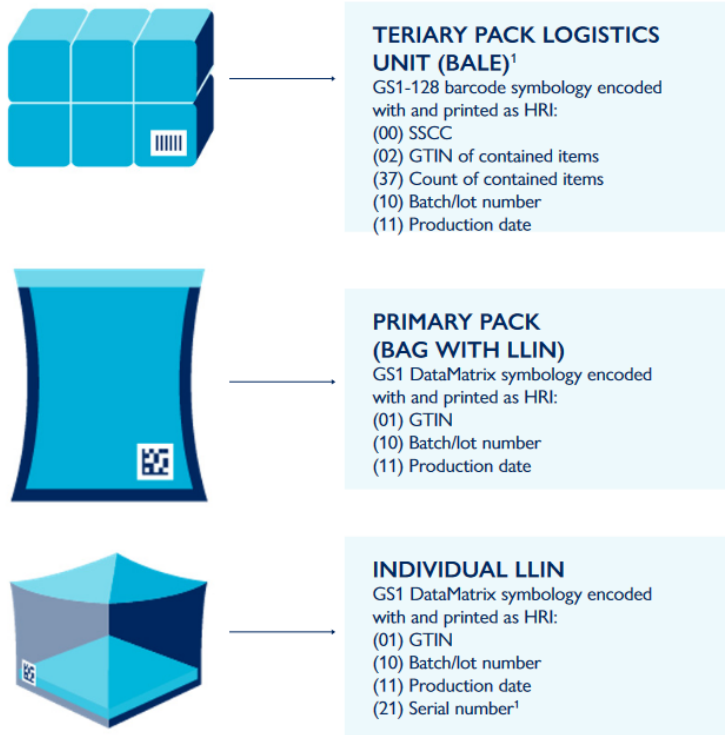
Global standards – **a common language for identification, data capture, and data exchange – are the basis for global trade, verification, and traceability.**

GS1 Barcode Types & Required Application Identifiers (AI)

GS1 128-Linear and GS1 DataMatrix Barcodes



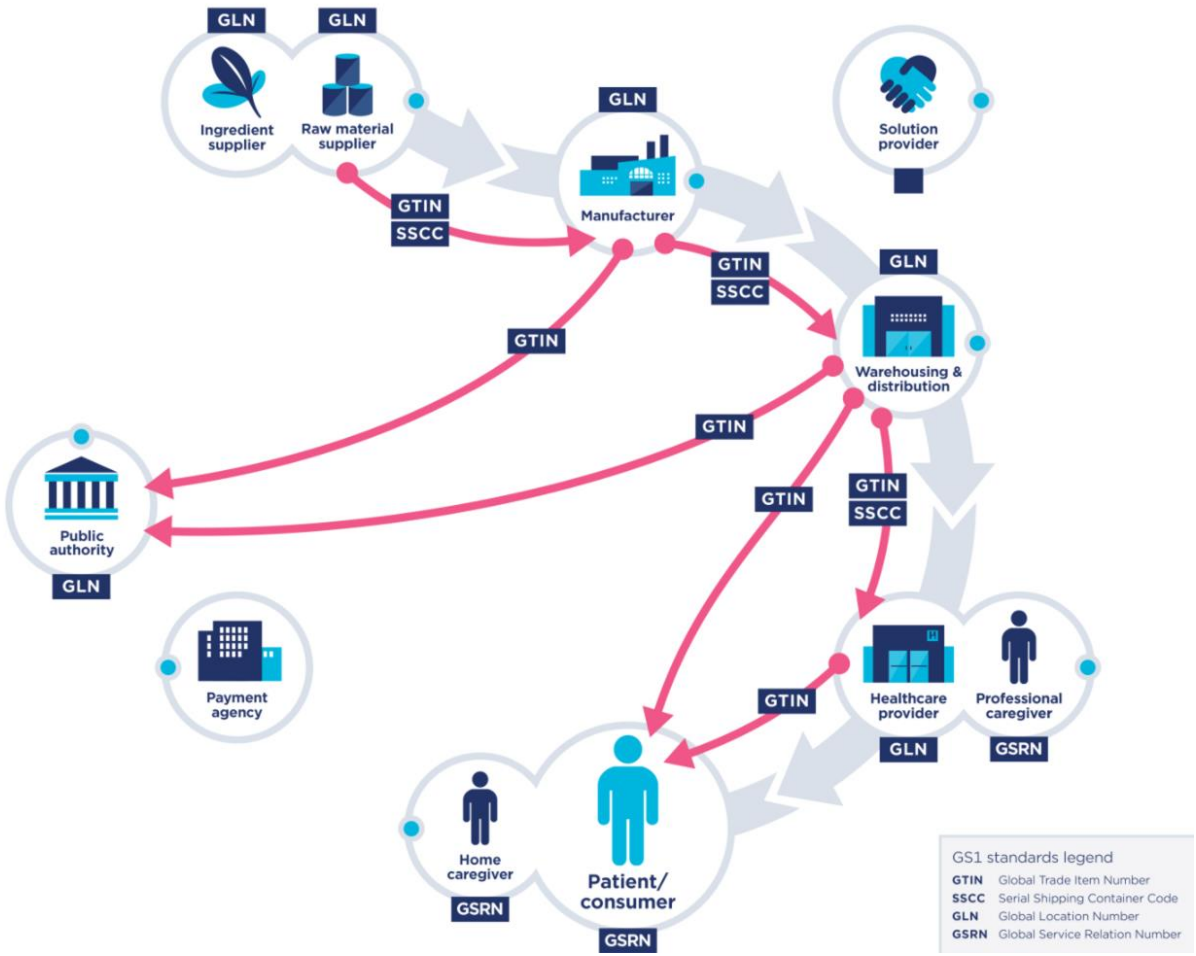
Across the ITN hierarchy



Leveraging GS1 as the global standard used for TraceNet and Global Health:

Data Visibility	Enable end to end data visibility through globally unique item and location identification and increasingly mature master data management practices, which create opportunities for improved systems interoperability
Automated Data Capture	Identify and implement supply chain efficiencies through use of automatic identification and data capture (AIDC) (e.g., barcode) technology across donors, procurement agencies, and donor-supported country supply chains
Security	Ensure supply chain security through chain-of-ownership or chain-of-custody product management that identifies risk and incident of product loss, expiry, and diversion
Safety	Increase patient safety through use of serialization to enable improved controls against substandard and counterfeit medicines

Enabling a Digital Thread



There are three kinds of data that is shared in a supply chain

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

Example: Product Master Data for Warehouse Operations

58904093822198

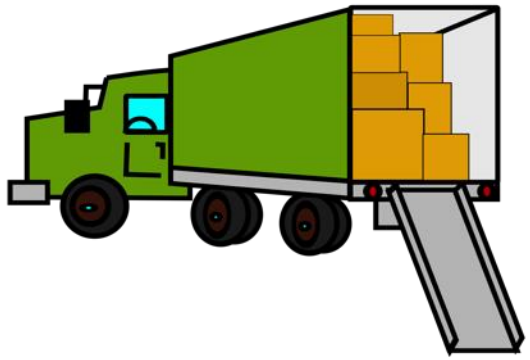
Query database

NPC/LMIS/WMS

Retrieve volumetric information

case

Optimize Truck Loading Space



Subset of GTIN attributes

GTIN Number	NatPharm Product Code	Description	Shelf Life	UOM	Length	Length UOM	Width	Width UOM	Height	Height UOM
58904093822198	FP0074	Ethinylestradiol/Levonorgestrel 0.03/0.15 mg Tablet, Blister, 28 Tablet, Case [Mylan] [Zinnia F]	36	CS	0.50	m	0.30	m	0.15	m

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TraceNet V2.0 Overview

Nigeria PMI LLIN Campaign Verification Pilot – Objectives

01

Increase understanding of how barcode scanning for data capture can improve the timeliness and accuracy of Long-Lasting Insecticide-Treated Net (LLIN) campaign distribution data.

02

Determine how to use GS1-based identifiers to facilitate the detection of LLINs not intended for the campaign.

03

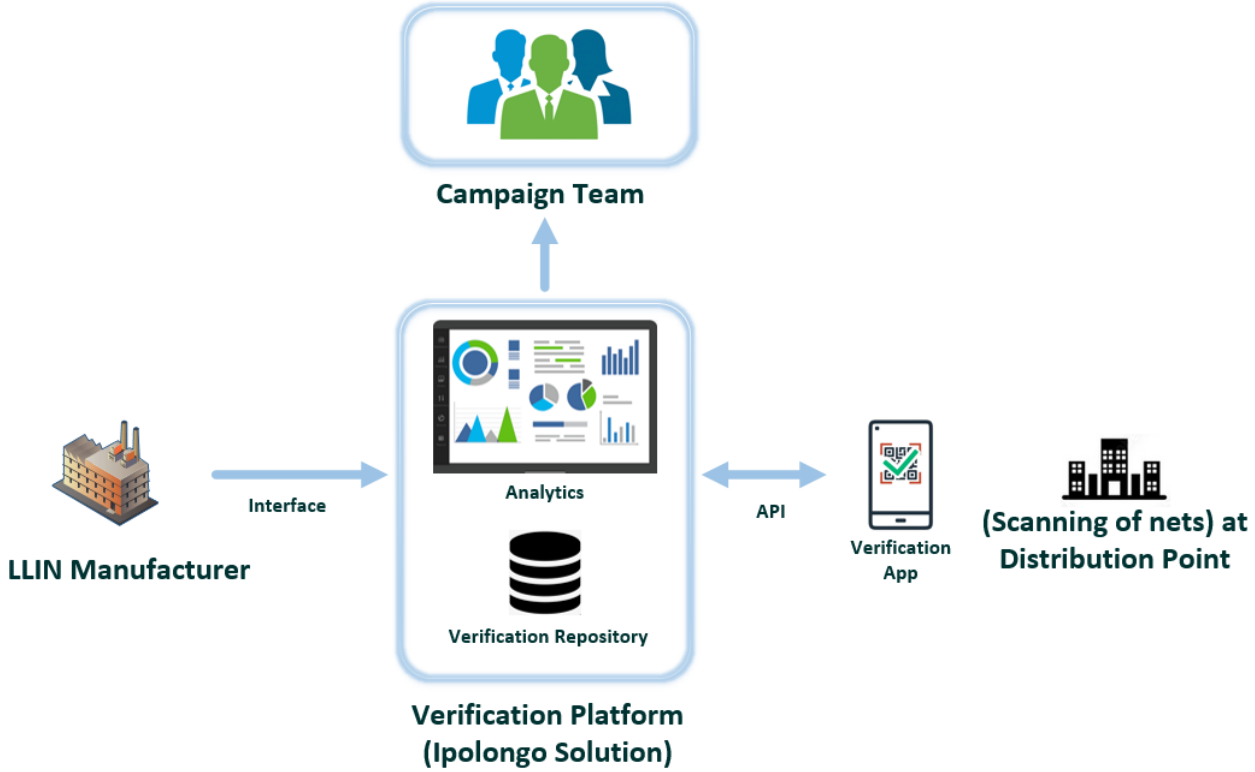
Understand how information systems anchored in GS1 Healthcare Standards can improve campaign distribution timeliness and increase the net visibility in the supply.

High Level Flow

(01)12345678901231
(11)210402
(10)45TY8
(21)1087FYW07

Master Data
GTIN: 12345678901231
Item Name: Long-Lasting Insecticidal Net
Packaging: Each
Brand Name: Lab Limited
Manufacturer name: LLIN Manufacturer

Transactional Data
GTIN: 12345678901231
Production Date: 04/02/2021
Batch: 54TY8
Serial number: 1087FYW07



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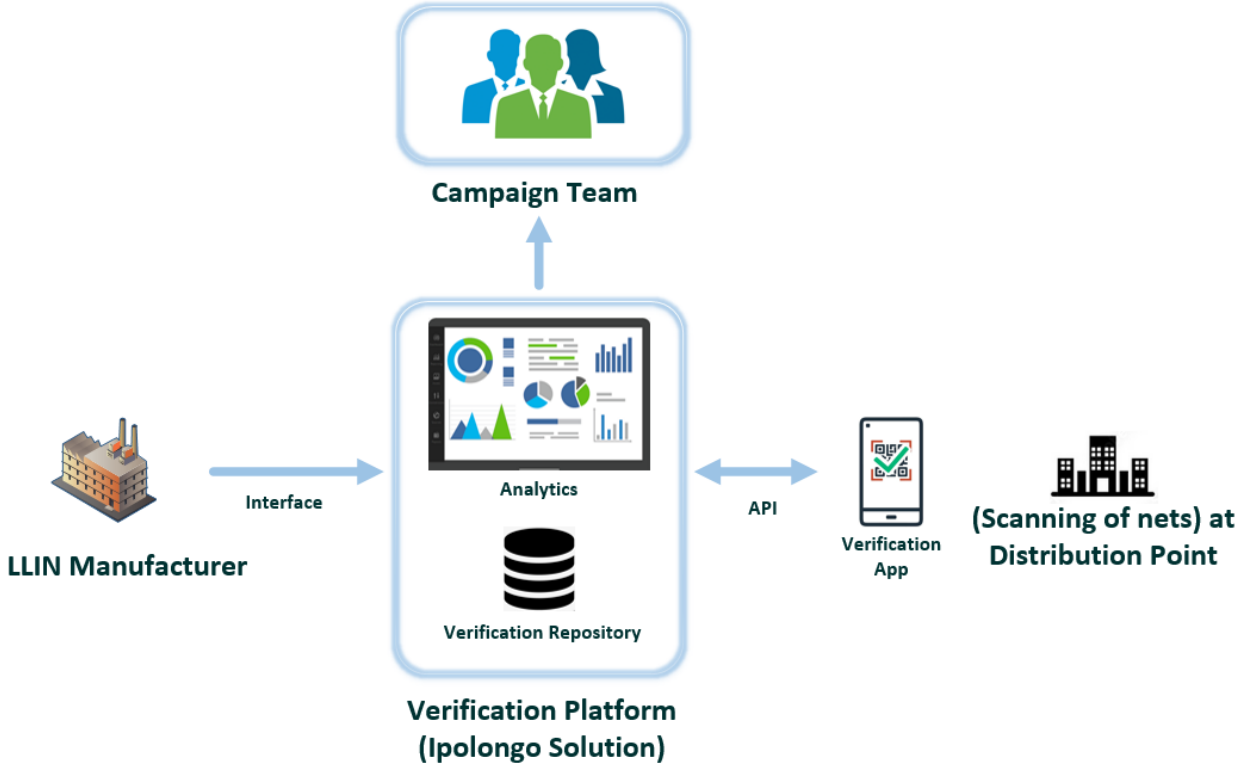

Verification Pilot – Key Takeaways

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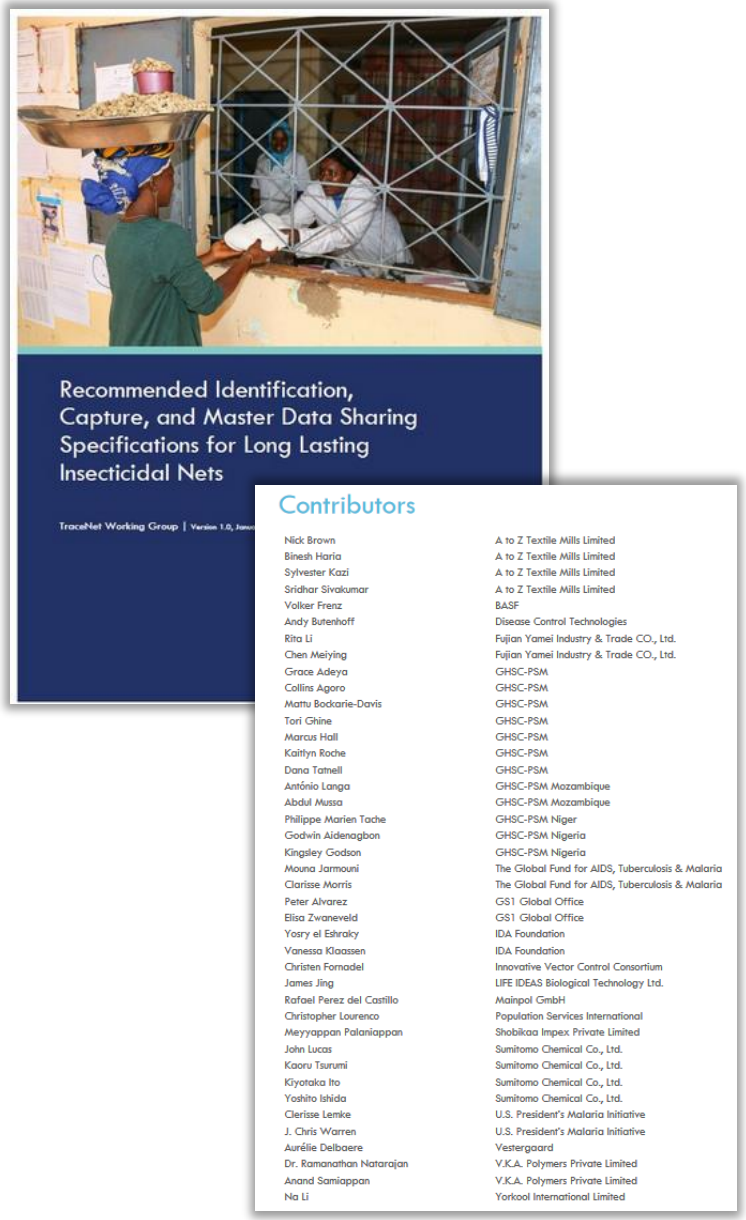
CDC

- Simplicity in Scanning Process
- Data Carrier Sizing
- Data Carrier Placement
- Low Light Capabilities
- Damage and Distortion
- Serial Number Reconciliation
- Duplicate Serial Numbers

TraceNet TWG Overview

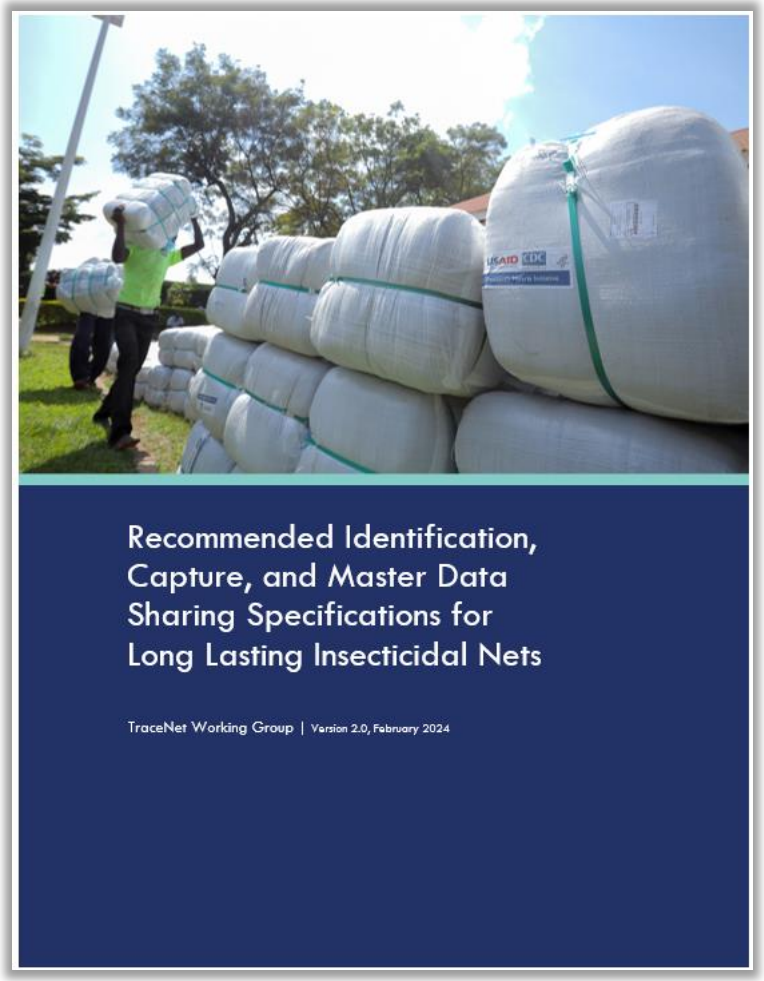
- TWG initially co-convened in 2019 by USAID PMI and the Global Fund—focused on seeking industry input to help shape the product identification, data capture, and data sharing standards for LLINs.
  - V2.0 Kickoff, topical discussions, workshops, use cases, drafting
- As standards have been operationalized over the last 4+ years, the TWG has been reconvened to update guidance in reflection of implementation lessons learned by IPAs and manufacturers.
- TraceNet V2.0 has been informed by 24 different organizations, 4 of which are new participants (UNICEF, AMF, AMP, eGov).



High Priority Topics

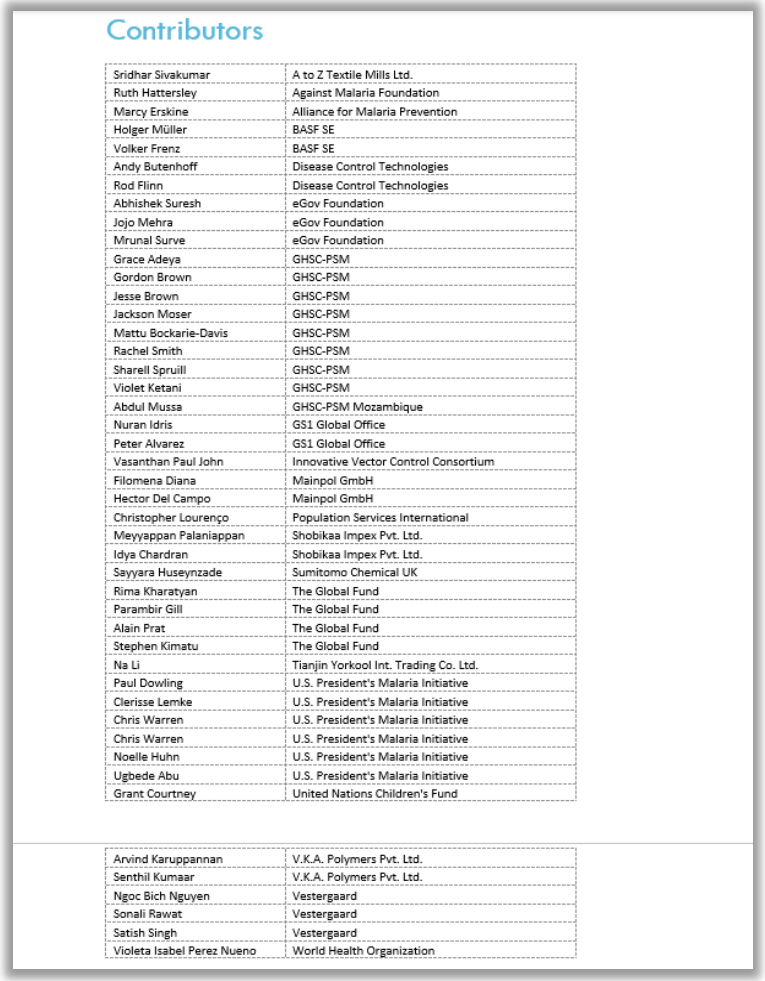
- Data Carrier Sizing and Label Material
  - Need for alignment on the technical categorization in which LLINs are to be identified under the GS1 General Specifications, as well as defined QA/QC minimum requirements for label adhesion and print ink
    - Categorization informs the requirements for minimum and maximum x-dimensions for DataMatrix
    - Considering the importance of scanning process in the field/across the value chain, suggested by GHSC-PSM to categorize as "*Trade items scanned in retail pharmacy and general distribution or non-retail pharmacy and general distribution*", per GS1 Gen Specs
    - TWG members to continue to meet under ongoing forums to create above-mentioned QA/QC baseline standards
- Release Date Calculation
  - Key challenges in determining AI(11) with certitude [AI(11) captures *Production Date*, but in the context of LLINs, it is to capture *Release Date*]
    - Historically, certain manufacturers look to Extrusion date to capture production date, whereas others look to Sampling date.
    - In recommending the capture of Release date, manufacturers voiced concern around the unpredictability of actual release date—product is often made-to-order, and commonly subject to long holding periods (3 mo. – 1 yr.)
    - Tangential to this holding period challenge, guidelines were also revised to recommend SSCCs not be re-used for a minimum of 3 years (was previously 1 year, which is the minimum recommended per the GS1 Gen Specs)
- Printing of multiple Bale barcodes
  - Per the GS1 guidance, it is recommended to print multiple barcodes on the logistic unit (bulky product) for increased data carrier visibility for scanning-based distribution/storage use cases
    - In the context of LLINs, this guidance applies to the Bale level
    - Recommended that manufacturers and procurement agents work closely together to determine an approach

Thank you to all TWG partners for you inputs!



Recommended Identification, Capture, and Master Data Sharing Specifications for Long Lasting Insecticidal Nets

TraceNet Working Group | Version 2.0, February 2024



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The recommended data carrier on the bag is the GS1 2D DataMatrix. The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

- (01) GTIN
- (11) Production date[17]
- (10) Batch/Lot

The HRI detailing the encoded data should be written adjacent to (i.e. under or next to) the data carrier. Data carriers, with associated HRI, should be positioned directly onto the exterior of the bag.

An example of the data carrier encoded with the required data for the bag containing an individual LLIN is included:

(01)10857674002017
(11)201231
(10)NYFUL01

3.3 Bale

The bale, containing a variable number of trade item units for logistic purposes, is considered a logistic unit. The recommended data carrier is the GS1-128 linear barcode. A GS1 2D data carrier may be included in addition to the GS1-128 symbol. When used, the GS1 2D symbol shall include all element strings included in the GS1-128 symbol(s) and may include additional element strings. Labels that are applied directly to the product should use an adhesive that is strong enough to adhere to the label for an extended shelf life.[20]

Per the GS1 General Specifications, two barcodes representing the same GTIN are recommended in instances where warehouse or general distribution scanning is necessary—especially in instances where heavy or bulky product, such as bales, are being handled.[18]

The minimum GS1 identification key, AI, and HRI recommended for inclusion are:

- (00) SSCC
- (02) GTIN of trade items in logistic unit
- (37) Count of trade items contained inside of a logistic unit
- (11) Production date[18]
- (10) Batch/lot

The HRI should be written adjacent to (i.e. under or next to) the barcode symbol data carrier. Data carriers, with associated HRI, should be included on a label that is adhered to the exterior of the bale. A sample logistic label for LLINs is included in Annex A.

An example of the data carrier encoded with the SSCC for the bale is included:

(00) 00614141123456789 0

An example of the data carrier encoded with the additional variable information for the bale is included:

(02) 10857674002017 (37) 50 (11) 201231 (10) NYFUL01

[17] Per Section 1.1.1, AI (11) Production date should be encoded as the release date
[18] Per Section 1.1.1, AI (11) Production date should be encoded as the release date

TraceNet-Defined ITN Use Cases

TraceNet Community-Defined Use Cases

Summary:

Use Cases

- TraceNet Working Group participated in activities to discuss and identify a set of use cases that the community can align around use of GS1 Healthcare Standards to address pain-points in LLIN distribution at the country level.
- Four unique use cases were identified and prioritized by the group.
- **aggregation is not considered a capability in the use cases designed

Visibility of where product has been and currently should be in the LLIN supply chain
Global health trading partners track chain of custody (CoC) and/or chain of ownership (CoO) of LLINs at the batch level through to delivery at the household.

Inventory management
Improve accurate data capture and aggregate view of LLINs for inventory, usage, shelf-life management and wastage within a LLIN supply chain

Avoidance and detection of shrinkage and diversion
Improve the ability to identify points in the in-country supply chain where diversion, leakage, and shrinkage occurs and triangulate data for investigations.

Monitoring & use
Improve the ability to record matching between unique nets issued and post-distribution monitoring including planning for repurposing and end of life

Use Case Description

Visibility of where bale is in the LLIN supply chain

Trading partners can track chain of custody (CoC) and/or chain of ownership (CoO) of LLIN commodities at the batch level through to delivery the household

Benefits and Outcomes

- Reverse logistics for nets in the event of a QA event
- Tracking of movement of leftover campaign nets
- Improved supply chain security
- Improved visibility into incidents such as leakage
- Mitigate against theft and diversion
- Improved data quality and accuracy leading to trust in data

Business Activity	Processes
Manufacturer commissions nets and assigns SGTIN, Batch/Lot, and SSCCs are assigned to each bale with AI (02) and AI (37)*	• Manufacture and label GS1 compliant product and define master data • Preparation of data
Traceability data is shared to a national repository prior to import Share SGIN, B/L, Exp, SSCC	• Trading partner responsible for import will share a traceability event to a national LLIN Campaign management system at dispatch using GS1 tools such as EDI or EPCIS
National warehouse shares chain of custody (CoC) or chain of ownership (CoO) events as required at receiving and shipping) with regional level warehouses via LLIN tracking tool/system Same identifiers	• Receive inbound event messages • Scan data carriers on logistic units and at receiving and shipping • Share event data to regional warehouse • Regional WH confirm receipt and share consumption from region/DP data with national system
[If verifying at the household level] Ownership/custody transferred to household Verify SGTIN against system of record	• Net distributors scan data carriers on nets at distribution point • Distribution centers confirm receipt and share consumption data with regional WH • Serial numbers paired with household identifier • Net distributors decommission net serial number once transferred to household • Reconciliation of net scanned against event data • In case of safety recall and/or return of unused nets to higher level storage facility, net distributors leverage scanned barcode data and event data to manage reverse logistics

*Visit the GS1 Application Identifiers site for all definitions here: https://ref.gs1.org/ai/

Use Case Description

Inventory Management

Improve accurate data capture and aggregate view of LLINs in (inventory, usage, shelf-life management, wastage) within a LLIN supply chain

Benefits and Outcomes

- Certitude of LLINs at receipt
- Visibility of quantities of which bales are contained in each container
- Record reconciliation at destuffing of containers
- Stock positioning
- Cross validation against Microplanning
- Reduce shrinkage
- System interoperability

Business Activity	Processes
Manufacturer commissions nets and assigns GTIN, Batch/Lot, Production Date and Serial SSCCs are assigned to each bale with AI (02) and AI (37)*	• Manufacture and label GS1 compliant product and define master data • Preparation of data • Trading partner responsible for import will share unique SSCCs for each container at dispatch using GS1-based tools such as GS1 XML
National warehouse receives bales and tracks movement to regional hubs	• National warehouse receives shipment , validates container ID against ePL, prepares for shipment to regional warehouse • SSCCs recorded on Despatch Advice for shipments to regional hubs
Regional national warehouse receive bales and tracks movement to and returning from distribution points	• In-country warehouses and distributors scan the barcode on bale or net and verify against Despatch Advice / system of record • SSCCs recorded for shipments to distribution points • Beginning balance and shipments receipts are recorded in system
Distribution points unpack bales and prepare for distribution to household	• Record received SSCCs from regional hubs • AI (37) used to target movement of bales to the household • Scan GS1 2D DataMatrix on each net and record against household ID • SGTIN is decommissioned in system of record • Beginning balance and nets distributed recorded in system of record

*Visit the GS1 Application Identifiers site for all definitions here: https://ref.gs1.org/ai/

Use Case Description

Shrinkage and Diversion

Improve the ability to identify points in the in-country supply chain where diversion, leakage, and shrinkage occurs—overall, detecting (un)intentional loss—and triangulate data for investigations.

Benefits and Outcomes

- Enables proactive investigation of diverted products
- Tracking of leftover campaign nets
- Track loss of goods through the supply chain
- Increase visibility below the central warehouses
- Understand points in the supply chain where bed nets are leaving the legitimate supply chain

Business Activity	Processes
Manufacturer commissions nets and assigns GTIN, Batch/Lot, Production Date and Serial SSCCs are assigned to each bale with AI (02) and AI (37)*	• Manufacture and label GS1 compliant product and define master data • Preparation of data • Trading partner responsible for import will share unique SSCCs for each container at dispatch using GS1-based tools such as GS1 XML
National warehouse receives bales and tracks movement to regional hubs	• National warehouse receives shipment , validates container ID against ePL, prepares for shipment to regional warehouse • SSCCs recorded on Despatch Advice for shipments to regional hubs
Regional national warehouse receive bales and tracks movement of shipped-to and returned nets from DPs Diversion tracking	• In-country warehouses and distributors scan the barcode on bale or net and verify against Despatch Advice / system of record • SSCCs recorded for shipments to distribution points • Beginning balance and shipments receipts are recorded in system
Distribution points unpack bales and prepare for distribution to household Send reconciliation reports of bales received (serial reconciliation) – shrinkage	• Record received SSCCs from regional hubs • AI (37) used to target movement of bales to the household • Scan GS1 2D DataMatrix on each net and record against household ID • SGTIN is decommissioned in system of record • Beginning balance and nets distributed recorded in system of record

*Visit the GS1 Application Identifiers site for all definitions here: https://ref.gs1.org/ai/

Use Case Description

Monitoring & Use

Increase granularity of data to uniquely identify nets and household during durability monitoring post-distribution to household

Benefits and Outcomes

- Ability to follow up with household over a period of time to determine survival rates (potency, durability, conditions)
- Knowing which households are using the same ITNs as intended

Business Activity	Processes
Manufacturer commissions nets and assigns (01) GTIN, (10) Batch/Lot, (11) Production Date* and (21) Serial Number**	• Manufacture and label GS1 compliant product and define master data • Preparation of data
SGTIN information is shared to a national repository prior to import	• Trading partner responsible for import will share SGTIN to a national LLIN Campaign management system at dispatch using GS1 tools such as EPCIS
Ownership/custody transferred to household	• Net distributors scan data carriers on nets at distribution point • SGTIN paired with household identifier
Durability monitoring team revisits household after 36 months to monitor use and after-life repurposing	• Scan GS1 2D DataMatrix and verify against household information • Prepare durability monitoring report, recording the presence of distributed net

*In the context of LLINs, Release Date is to be captured as AI (11)
**Visit the GS1 Application Identifiers site for all definitions here: https://ref.gs1.org/ai/