Global Standards for Supply Chain Data Visibility

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

01 November 2018

USAID FROM THE AMERICAN PEOPLE

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

USAID FROM THE AMERICAN PEOPLE CDC U.S. President's Malaria Initiative

GS1

The following training is based on materials developed by GS1 and are used with their permission. We would like to gratefully acknowledge GS1's support.

GS1 is a not-for-profit organization that develops and maintains global standards for business communication.

For more information, please visit GS1.org.

Agenda

- GHSC-PSM's Vision
- Why do we care about global standards?
- Overview of the GS1 system of standards
- Automatic Identification & Data Capture (AIDC)
- Master Data Management (MDM) and Master Data Exchange

[Break Time!]

- GHSC-PSM implementation of global standards
- Electronic Data Interchange (EDI) in healthcare
- Event-based traceability in healthcare
- Global regulatory environment
- Global health developments

Requests of participants

- Be present!
- Participate!
  - Ask questions
  - Share experiences

Objectives

- To develop an awareness that GHSC-PSM is implementing GS1 standards and what those standards can help us to achieve
- To provide a baseline understanding of the GS1 system of standards to enable all staff to be conversant with suppliers, implementing partners, and other donor agencies
- To inform GHSC-PSM staff on our strategy for implementation, including immediate next steps
- To provide resources for staff to continue building their understanding of GS1 standards
- To elevate the visibility of the global standards as a cross cutting technical approach within GHSC-PSM

GHSC-PSM's Vision

The Challenge

- Poor data visibility because items and products are identified in non-standard ways
  - Proprietary identification numbers that are reassigned at various points in the supply chain
  - Identification inconsistent across procurement agencies and supply chain stakeholders through to the end user
- Lack of standardization in processes and operations because of inconsistent packaging labels
  - Multiple barcodes
  - Different types of barcodes
  - No barcodes

…WHICH RESULTS IN RISK TO SUPPLY CHAIN SECURITY

Why are global standards relevant?

Global Standards

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

GS1 Standards

- Develop and maintain global standards for business communications
- Provide a common language to identify, capture, and share supply chain data
- Specific focus on applicability of standards for healthcare supply chain

Supply Chain Data Visbility

- Enabled through common nomenclature, processes, and data sharing interoperability across all stakeholders in the global health supply chain

The journey to today

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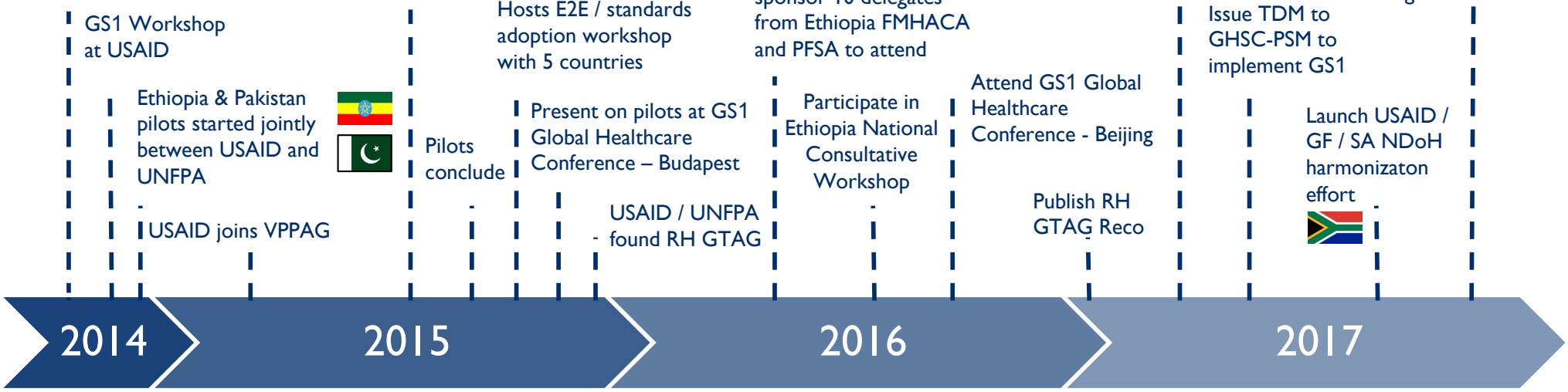
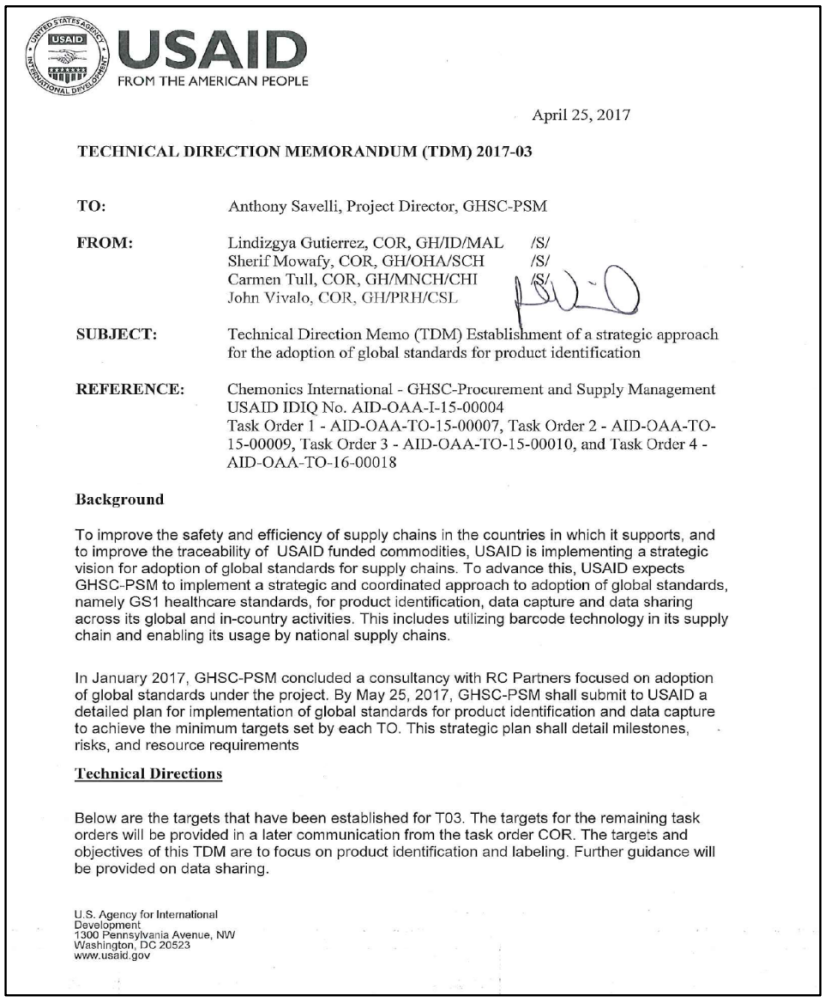


GHSC-PSM

USAID Technical Direction Memorandum (TDM)



USAID
FROM THE AMERICAN PEOPLE

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

In April 2017, USAID issued a Technical Direction Memorandum to the GHSC-PSM Project for establishment of a strategic approach for the adoption global standards for product identification, data capture and data sharing.

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

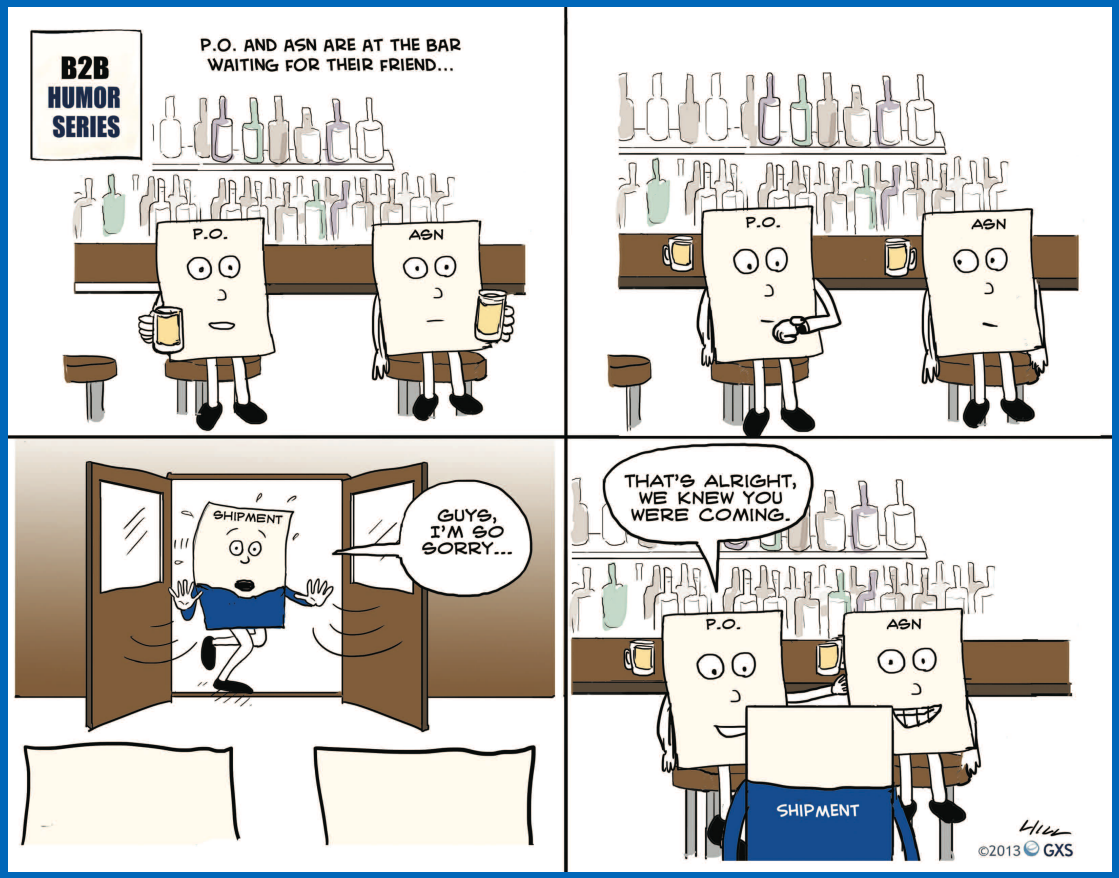
- To enable end-to-end data visibility
- To identify and implement supply chain efficiencies
- To ensure supply chain security
- To increase patient safety

Successes in health supply chains

- St. James Hospital System in Ireland
  - Removed €5 million in stock
  - Mock recall can identify 100% of pharmaceuticals in 10 minutes
  - Product wastage reduced from €90,216 to zero in the year post service implementation
- UK NHS
  - Reduced emergency consignment stock orders thanks to improvements in forward demand/stock planning plus €1.1 million savings
  - 4:1 ROI on Inventory alone
- Netherlands Hospital Systems
  - ROI Year 3 of € 2.5million
  - 20% reduction in inventory
- Bernhoven Hospital
  - Track and trace supports better asset control
  - 25% reduction in stock levels
  - 80% reduction in expired stock
  - Reduced indirect costs of staff
- Canada – Alberta Health System
  - Price harmonization and consolidated, strategic sourcing
  - ROI of 7:1 over three years – savings of $261,500,000

Source: GS1 Healthcare Conference Chicago, October 2017

Why do we care about global standards?



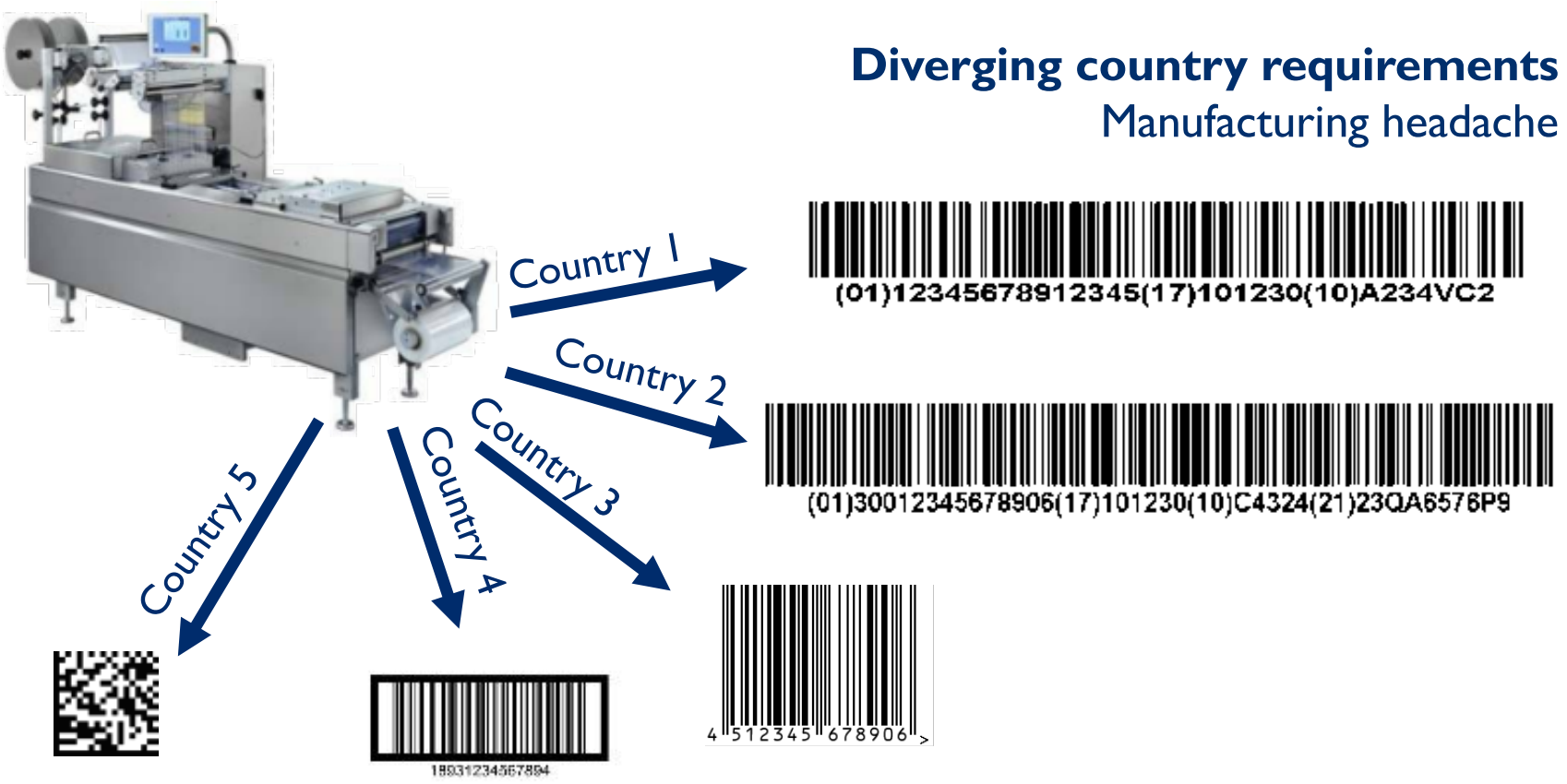
What if standards in grocery stores worked like they do in the healthcare supply chain?

Lack of standards in daily life is inefficient and annoying…

..in healthcare it is inefficient and dangerous!

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – **inconsistency; incompatibility**
- No bar code – need to bar code; re-package; re-label

The need for global standards in healthcare



Diverging country requirements

Manufacturing headache

"CUSTOMIZED ACTIONS MEAN COSTS!!

Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering – otherwise complexity and cost will continue to raise"

Senior Executive, MD company

GS1 – an international standards organization

1 million	150 countries	6 billion	112 MOs
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 6 billion times per day globally	112 Member Organisations around the world

GS1 is both global and local

GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

GS1 Member Organisations

Local offices in 112 countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

Recognized NGO status by the UN

UNITED NATIONS NATIONS UNIES

DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS

Office for ECOSOC Support and Coordination – NGO Branch

DC1-1480, 1 UN PLAZA, NEW YORK, N.Y. 10017

Tel: (212) 963-8652 • Fax: (212) 963-9248
www.un.org/ecosoc/ngo

1 August 2011

Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant Special consultative status to your organization "GS1". On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.

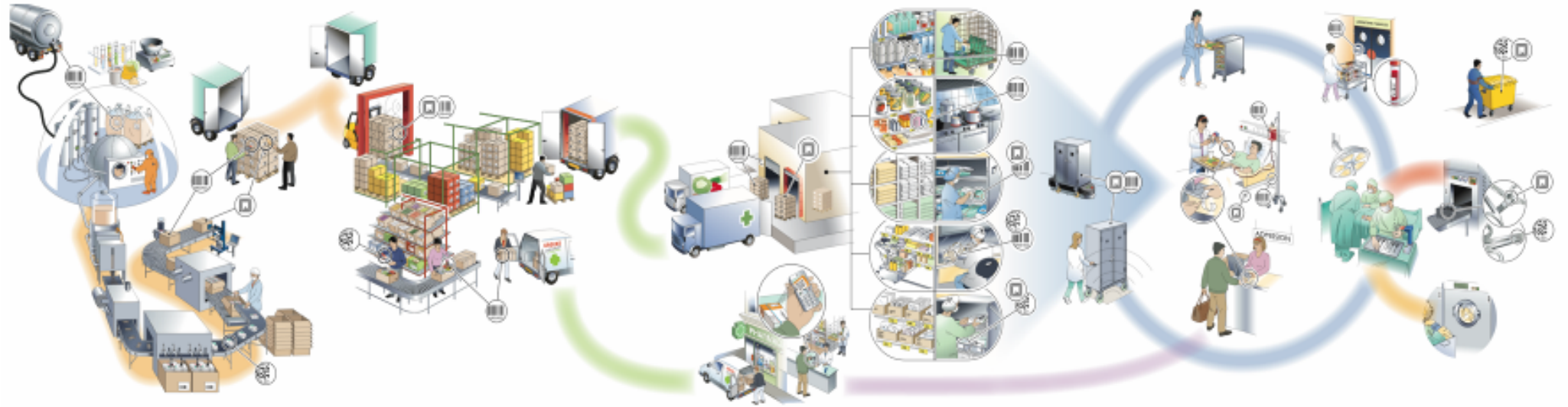
Global automatic identification standards

GS1 Standards …

6 billion 'beeps' per day

Product identification in healthcare should be as ubiquitous as it is in the retail and grocery industries!

Voluntary, global healthcare user group



To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.

Our vision 2005

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for

patient safety

supply chain security & efficiency

traceability

product data

GS1 healthcare is an expanding, committed community of globally engaged stakeholders…

…and there are many more companies working with GS1 at a local level

Working with global organizations…

International Organisation for Standardisation

European Committee for Standardization

Health Level 7 International

International Health Terminology SDO

Clinical Data Interchange Standards Consortium

Integrating the Healthcare Enterprise

Digital Imaging and Communications in Medicine

Joint Initiative Council

World Health Organization

World Customs Organization

International Hospital Federation

International Council for Commonality in Blood Banking Automation

International Society for Quality in Healthcare

European Association of Hospital Pharmacists

European Federation of Pharmaceutical Industries and Associations

European Medical Devices Industry Association

…as well as with leading healthcare providers to implement…

…GS1 in healthcare around the world!

Manufacturers
- 3M Healthcare
- Abbott Laboratories/AbbVie
- Allergan
- Actelion Pharmaceuticals Ltd
- Amag Pharmaceuticals, Inc
- Amgen Europe B.V.
- Astra Zeneca
- B. Braun Melsungen AG
- Baxter
- Bayer
- BD (Becton)
- Biogen Inc.
- Bristol Myers Squibb
- Cook Medical Europe Limited
- CSL Behring GmbH
- Edwards Lifesciences
- Eli Lilly and Company
- F. Hoffmann-La Roche Ltd
- Fresenius
- GE Healthcare
- Gilead Sciences, Inc
- GlaxoSmithKline
- GW Pharmaceuticals plc
- Johnson & Johnson
- Medtronic
- Merck
- Merckle/Teva
- Novartis
- Pall Pharmaceuticals
- Pfizer
- Pierre Fabre
- Santhera Pharmaceuticals Ltd
- Septodont
- Shire
- Smiths-Medical
- Takeda
- Teleflex Inc.
- UCB Pharma S.A.

Solution provider
- 1WorldSync, Inc.
- 4XScience
- Adents Software
- Advanco
- AXWay
- Be4ward Ltd.
- Blue Sphere Health Ltd.
- BPCompass GmbH
- Excellis Health Solutions LLC
- Frequentz
- GHX
- Innovit Europe Ltd
- LANSA Ltd.
- Mettler Toledo PCE
- Movilitas Consulting AG
- OCS Checkweighers GmbH
- Optel Group
- Oracle
- RfXcel Corporation
- SAP
- Sicpa S.A.
- Supply Chain Wizard, LCC
- Systec & Services
- Systech International
- Tracelink
- US Data Management LLC
- Vesdo AG
- Videojet Technical Suisse GmbH
- Zebra Technologies

Distributors/Healthcare providers/GPOs/T&L
- AmerisourceBergen Corporation (US)
- Australian Digital Health Agency
- Bernhoven Hospital (Netherlands)
- CHI Robert Ballanger (France)
- DHL (UK)
- Erasmus MC Rotterdam (NL)
- Filip Vtori (Macedonia)
- Hong Kong Hospital Authority
- HUG Geneva (Switzerland)
- Iberia Rehab Hospital (US)
- International Hospital Federation (IHF)
- King FAISAL Specialist Hospital & Research Center (Saudi Arabia)
- McKesson
- Norfolk and Norwich NHS Trust
- Ramsay Health Care (Australia)
- South West Healthcare (Australia)
- St. James Hospital (Ireland)
- The Ottawa Hospital
- UMC Groningen (NL)
- Universitätsklinikum Schleswig-Holstein (DE)
- UPS
- Wiener Krankenanstaltenverbund (Austria)

Non-voting members
- AHRMM
- Cladimed
- EDQM – Council of Europe
- FDA USA
- Instituto Brasileiro de Ética Concorrencial – ETCO
- Public Health Agency of Canada
- US DoD
- Healthcare Distribution Management Association (HDMA)

Manufacturers
- 3M
- Bayer
- Becton Dickinson
- Boehringer Ingelheim
- Coloplast
- Draeger Medical
- Hospira
- Kimberly-Clark
- Novo Nordisk
- Pierre Fabre
- Purdue Pharma
- Sanofi Aventis
- Smith and Nephew
- St. Jude Medical
- Stryker
- Terumo
- Upsher-Smith

Distributors/Wholesalers
- Aexxdis
- Alliance Unichem (Netherlands)
- Amerinet
- AmerisourceBergen
- Brocacef (Netherlands)
- CH2
- Depolabo
- Galexis
- GAMMA Wholesale
- Geodis
- McMahon
- Mediq (Netherlands)
- Owens & Minor

Healthcare providers/Retailers
- AMC Amsterdam (Netherlands)
- Antonius Ziekenhuis Nieuwegein (Netherlands)
- Ascension Health (US)
- Bernhoven Ziekenhuis Uden (Netherlands)
- Capital District Health (Canada)
- CH René Dubos Pontoise (France)
- CHRU Strasbourg (France)
- CHU de Québec (Canada)
- CHU DIJON (France)
- Deventer Ziekenhuis (Netherlands)
- Erasmus Medical Center (Netherlands)
- HealthShare NSW Health
- HUG Geneva (Switzerland)
- London Drugs (UK)
- Maxima Medisch Centrum (Netherlands)
- Mayo Clinic (US)
- Sisters of Mercy (US)
- Sobeys Pharmacy (UK)
- UHBS (Switzerland)
- UHCS Augusta VA (US)
- UMC Nijmegen (Netherlands)
- UMC Utrecht (Netherlands)
- VU medical center (Netherlands)
- Walgreens (US)
- Walmart (US)

Associations
- AHA (US)
- CHeS (US)
- CNOP (France)
- EFPIA (Europe)
- Eucomed (Europe)
- FENIN (Spain)
- GIRP (Europe)
- HDMA (US)
- International Hospital Federation
- JFMDA (Japan)
- LEEM (France)
- NACDS (US)
- Patient Safety Foundation (US)
- SNITEM (France)

Others
- GCS UNI H A (France)
- NEHTA (Australia)
- RESA IDF (France)

… and many more

GS1 Healthcare is directed by users

Leadership Team 2017/2018

Tri-Chairs:

- Feargal McGroarty, St. James's Hospital
- Scott Mooney, McKesson
- Mike Rose, Johnson & Johnson

LT Members:

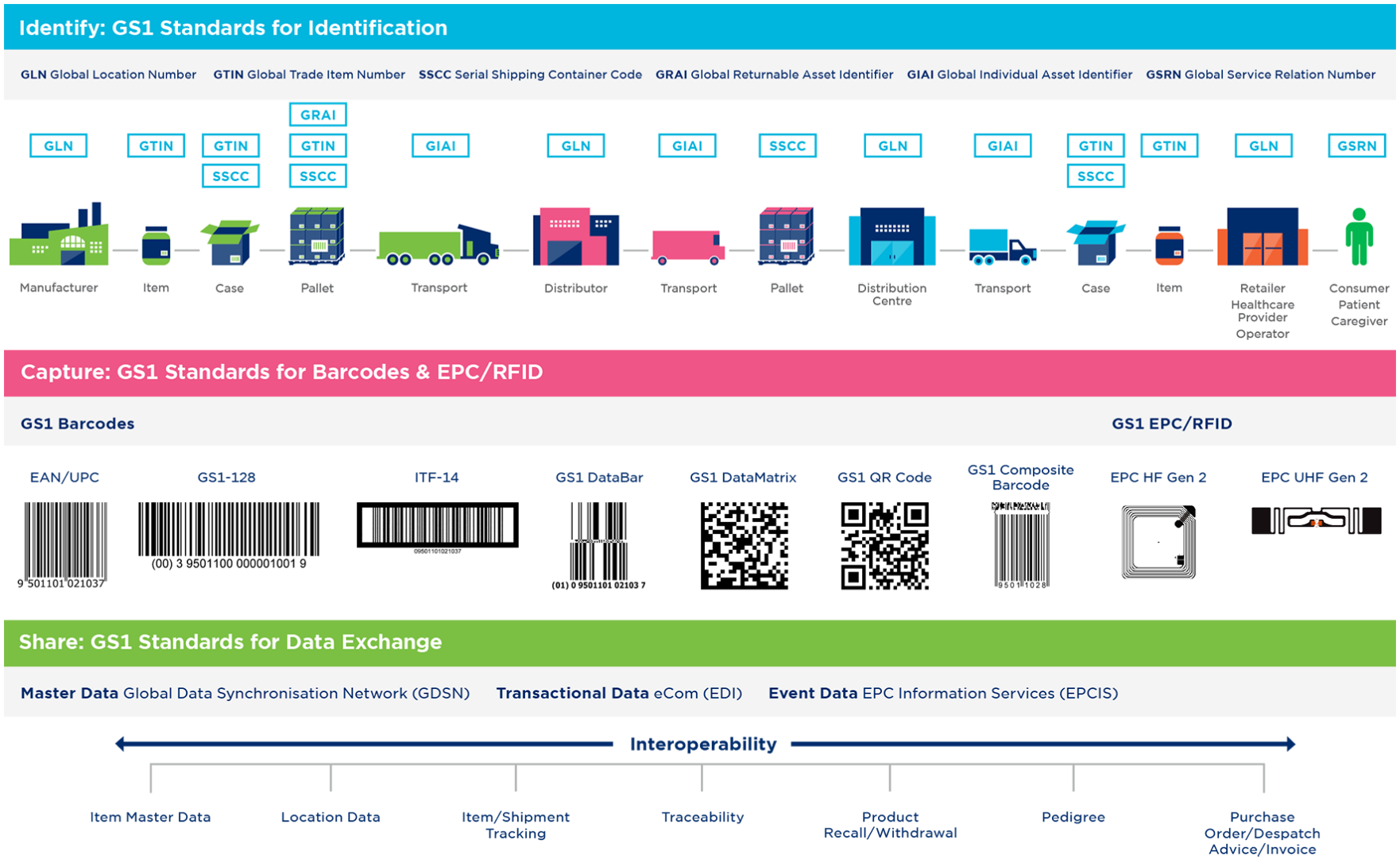
- Nick Manzo, 1WorldSync
- Charity Hovey, 3M
- Cyndi Poetker, Abbott
- Jeff Denton, Amerisourcebergen
- Volker Zeinar, B. Braun
- Stefan Artlich, Bayer
- Dennis Black, BD
- Justin Bitter, Bernhoven Hospital
- Bill Bobbie, Cook Medical
- Mike Meakin, DHL
- Sébastien Langlois-Berthelot, F. Hoffmann-La Roche
- Karen Conway, GHX
- Grant Courtney, GSK
- Jean-Michel Descoutures, IHF
- Steve Capel, Medtronic
- Pascal Aulagnet, Pfizer
- Mark Hoyle, Teleflex
- Grant Hodgkins, USDM
- Catherine Koetz, GS1 Australia
- Ana Paula Maniero, GS1 Brazil
- Arthur Smith, GS1 Canada
- Valérie Marchand, GS1 France
- Hans Lunenborg, GS1 Netherlands
- Rami Habbal, GS1 UAE
- Glen Hodgson, GS1 UK
- Greg Bylo, GS1 US

Quiz time!

- How many offices does GS1 have around the world?
- Is GS1 a for profit or not for profit organization?
- What type of solution provider is GS1?

Overview of the GS1 System of Standards

GS1: a global system of standards



GS1 standards across the entire supply chain

Manufacturer

Transport provider

Distributor or Wholesaler

Transport provider

Hospital or Clinic

Patient

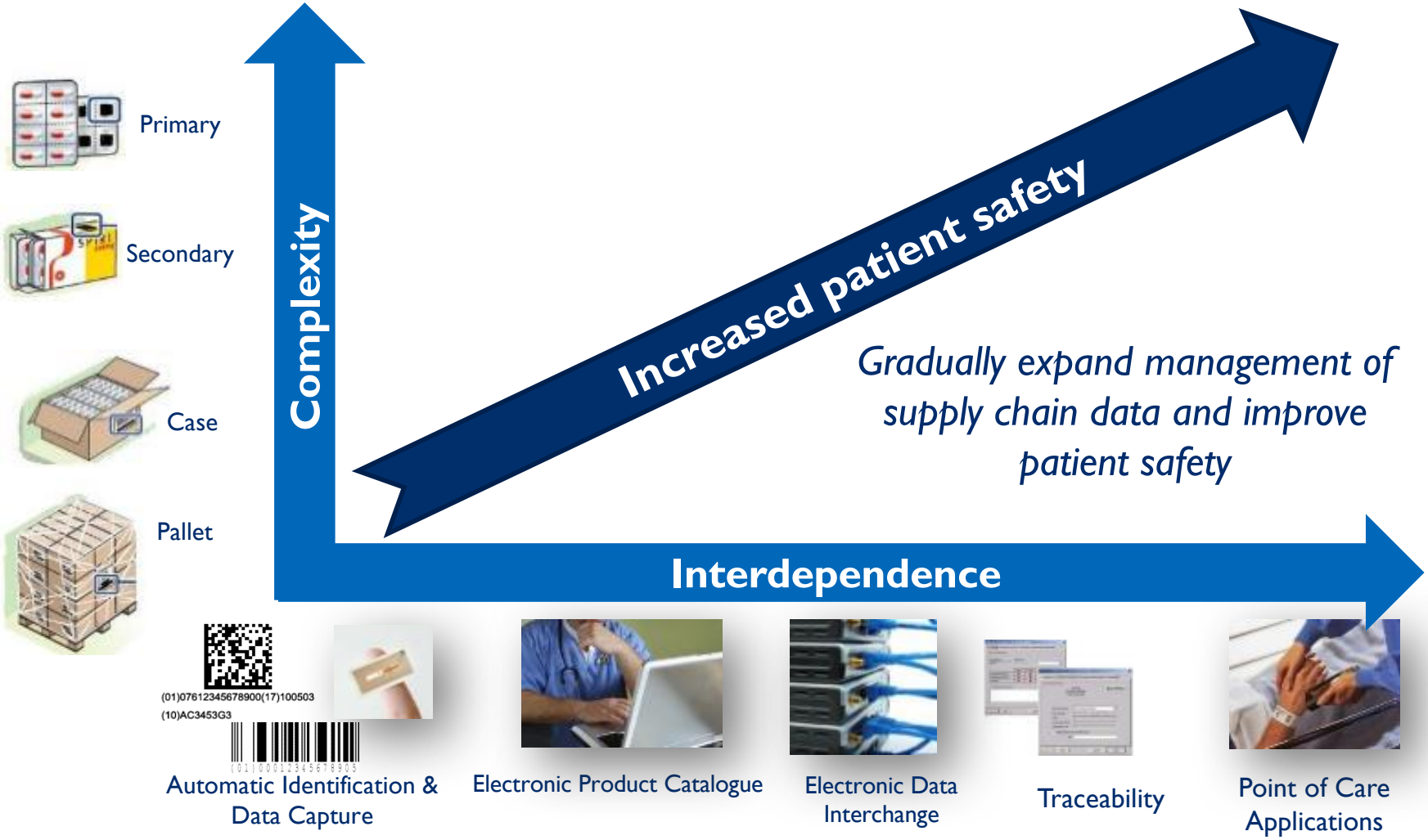
Improved production, packaging and supply processes

Simplification and accuracy improvement in warehousing, distribution, and logistics processes

Automatic verification in dispensing and administration processes, reducing medical errors

- More accurate and efficient supply chain management
- Enabling traceability and authentication (counterfeiting, product recalls, etc.)
- Enabling regulatory compliance
- **Improving patient safety and supply chain efficiency**!

For a secure healthcare supply chain



Quiz time!

- What are the three main areas of GS1 standards?

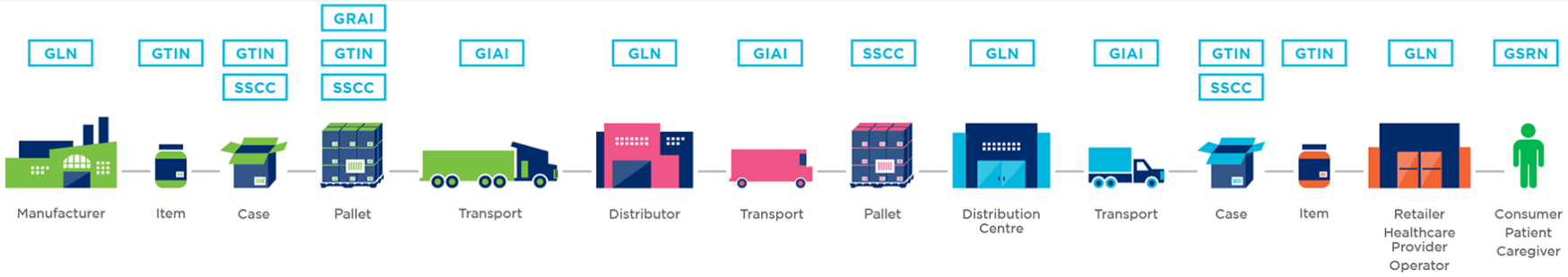
Automatic Identification & Data Capture (AIDC)

GS1: A Global System of Standards

AIDC

Identify: GS1 Standards for Identification

GLN Global Location Number **GTIN** Global Trade Item Number **SSCC** Serial Shipping Container Code **GRAI** Global Returnable Asset Identifier **GIAI** Global Individual Asset Identifier **GSRN** Global Service Relation Number



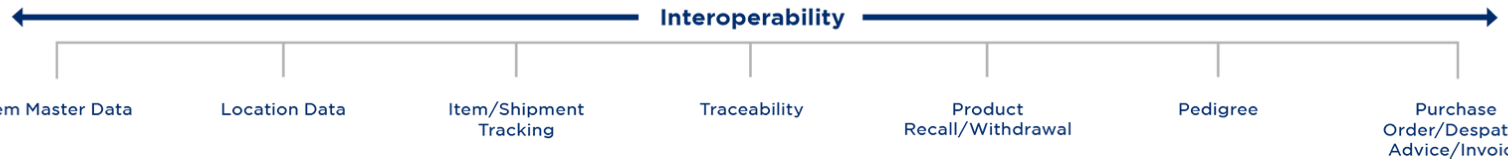
Capture: GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes **GS1 EPC/RFID**

AIDC

Share: GS1 Standards for Data Exchange

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



Automatic Identification & Data Capture (AIDC)

"Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement)."

Wikipedia, 2009

Manual vs. Automation

1 keystroke (input) error in every 300 to 500 keystrokes

versus

1 error in 350,000 on the low end (linear symbology)

…to…

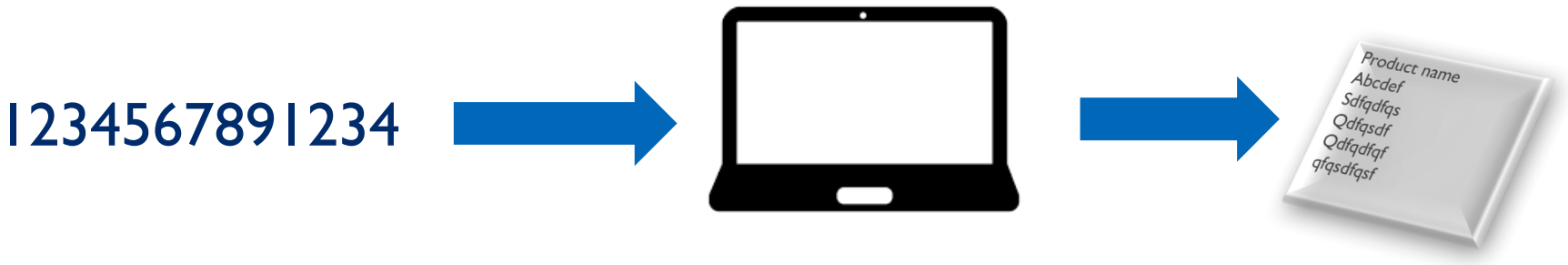
1 error in 10,500,000 on the high end (2D/Matrix symbologies)

The vision of AIDC for healthcare

EVERY item has
ONE set of key identification data carried in
ONE data carrier
able to be scanned by **EVERYONE**
at every key process step…

GS1 Identification Keys

- The foundation of the GS1 system
- Provide access to information held in computer files –
- Information about company/location, package, product, price, shipment, assets etc.



The foundation: GS1 Identification Keys

- Unique
- Non-significant
- International
- Secure
- Foundational

Global Trade Item Number (GTIN)
Item Identifier

Serial Shipping Container Code (SSCC)
Logistics Unit Identifier

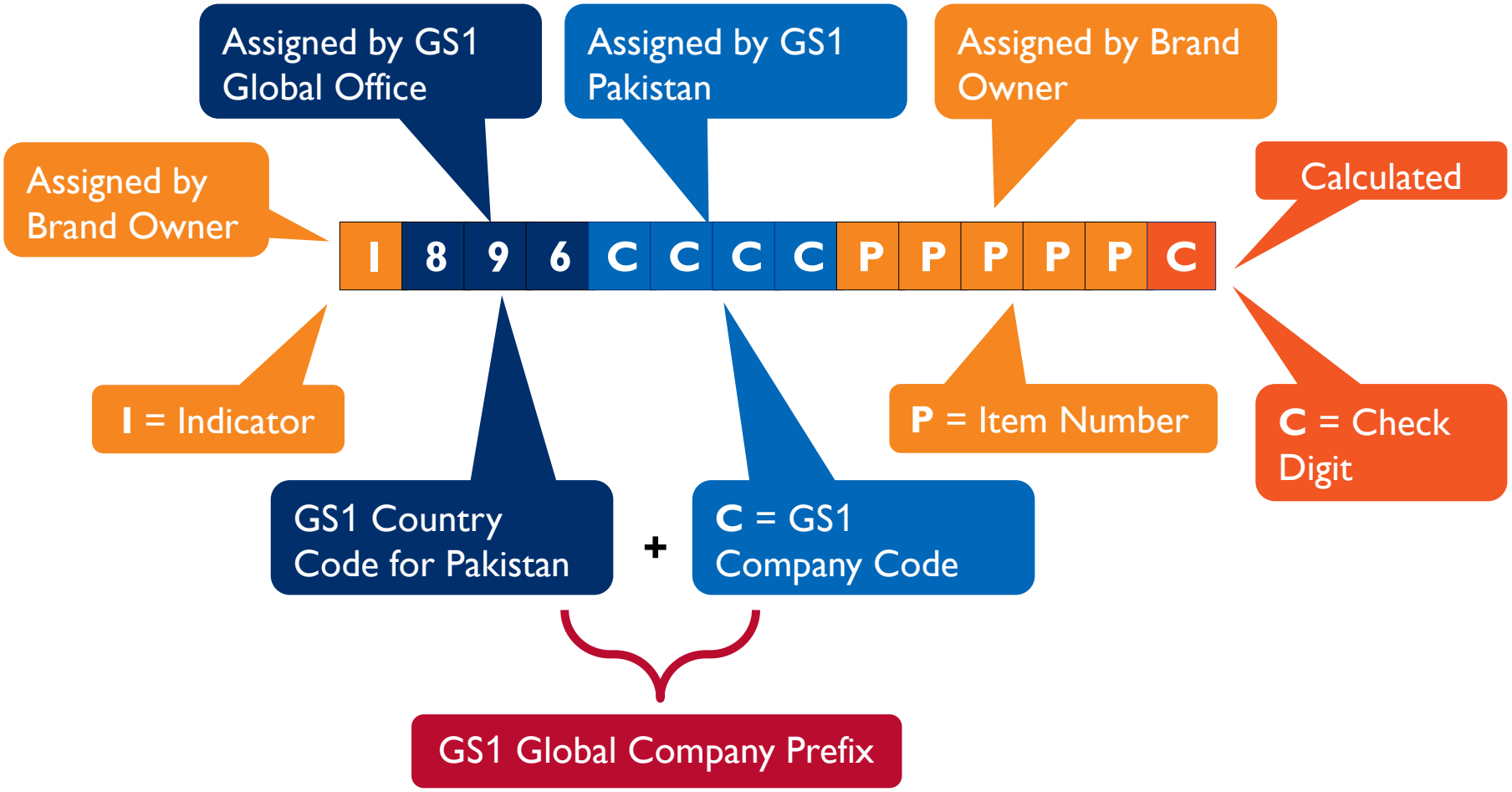
Global Location Number (GLN)
Location Identifier

And there are more …

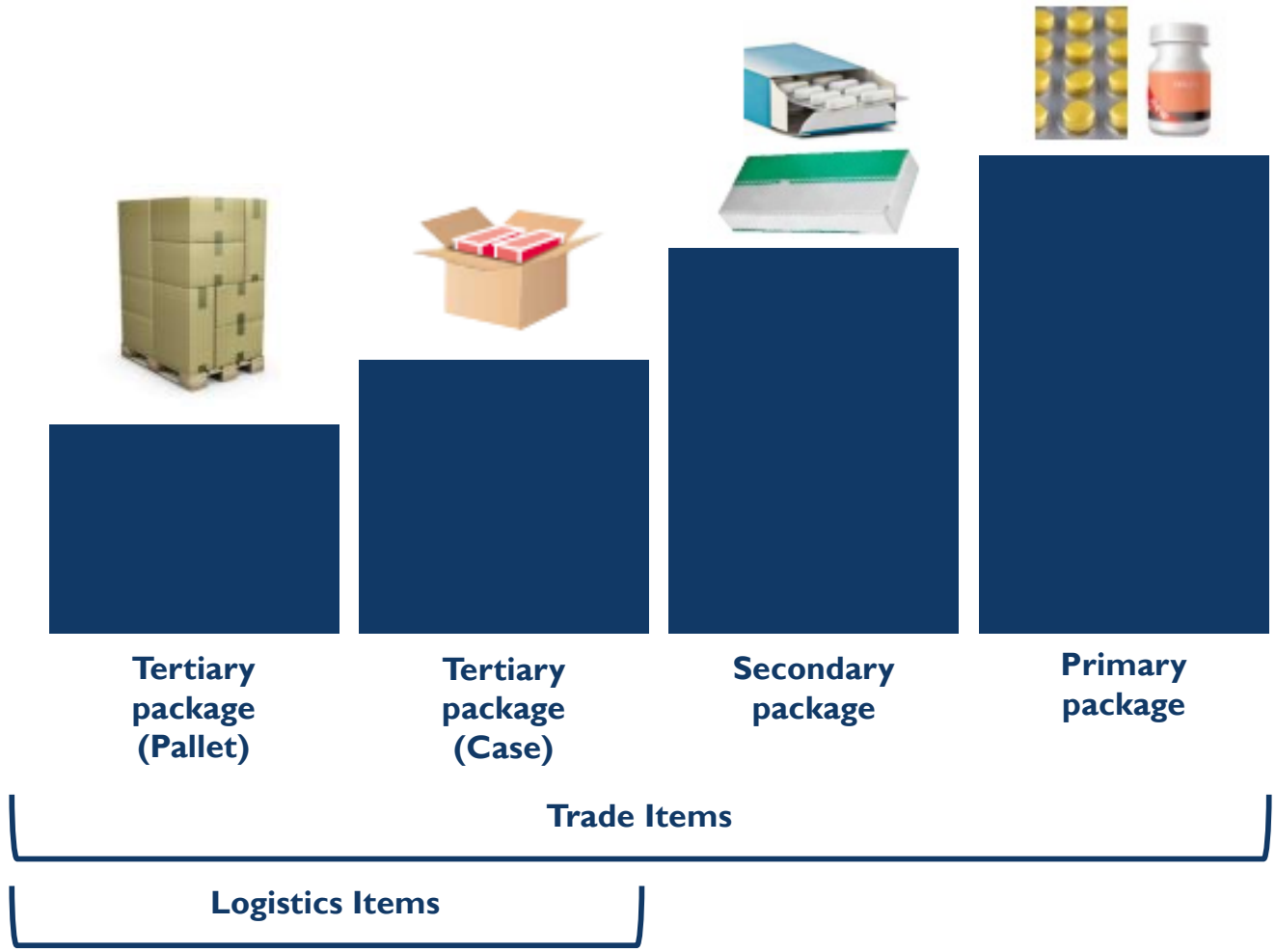
1. Global Trade Item Number (GTIN)

- Used to identify **any item** upon which there is a need to **retrieve pre-defined information** that may be **priced**, **ordered**, or **invoiced** at any point in any supply chain.
- GTIN is an umbrella term for all GS1 "trade item" identification numbers.
- A GTIN may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure, but **GTIN-14 is becoming more common for healthcare**

Anatomy of a GTIN-14… an example

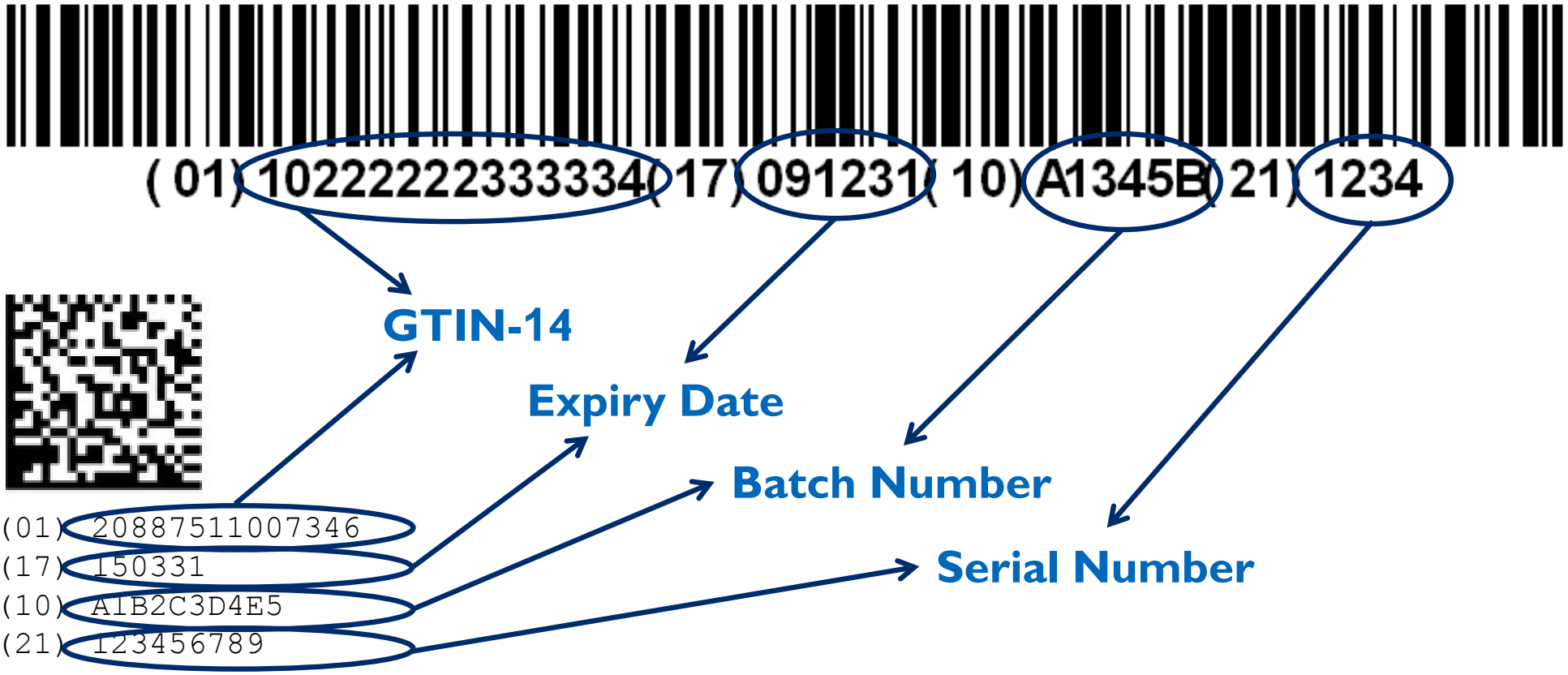


Different packaging levels require different GTINs



Item identification and select other item information needs to be captured in a data carrier

GS1 128-Linear Barcode



GS1 2D DataMatrix Barcode

Additional GS1 Application Identifiers (AI)

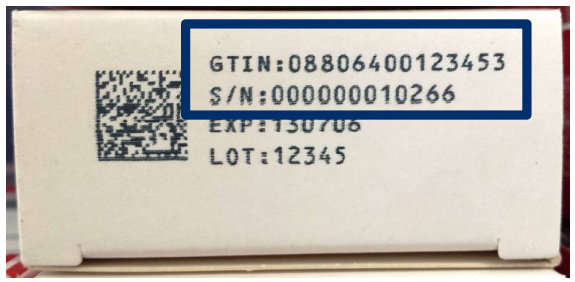
- Enable encoding of additional information besides the product identification into a barcode
- The GS1 General Specification includes 100+ "Application Identifiers" ("Key Attributes" or "AI's") for various use cases and sectors,
- In healthcare, these are the four most commonly used data elements:

01	GTIN
10	Batch / Lot
17	Expiry Date
21	Serial Number

Note: Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI's is *not significant and should not be mandated*.

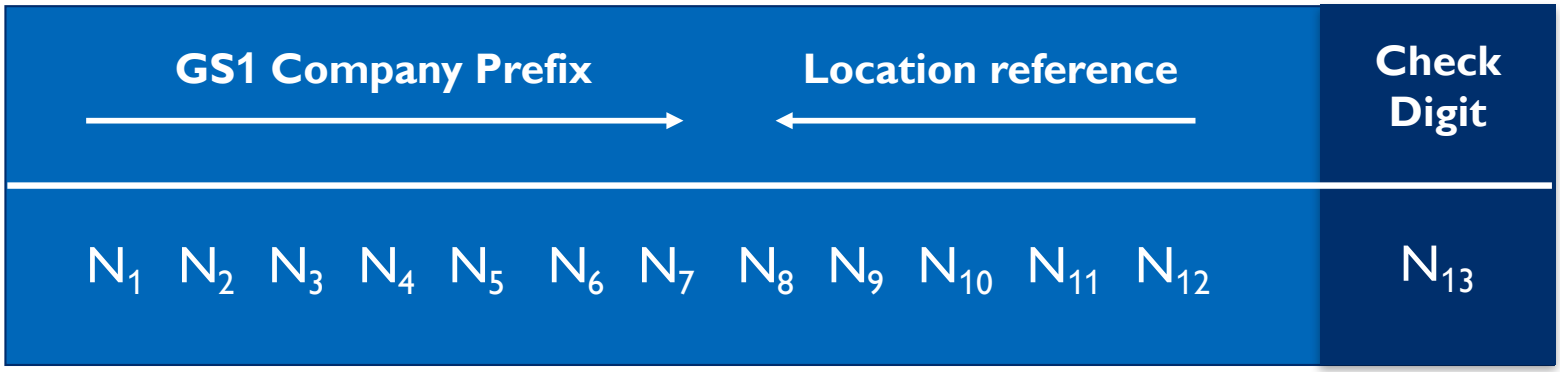
Serialization

- **Serialization is the assignment of unique, traceable numbers to individual items**
- While the GTIN allows you to identify a product as such, serialisation will allow you to identify each single package of this product!
- Generally used from the secondary packaging level
- But – it requires changes of packaging lines and processes (e.g. IT, quality, etc.) – which is costly and complex
- Nevertheless, it is the trend in regulations worldwide as it enables traceability



2. Global Location Number (GLN)

- The GLN is used to identify physical locations and legal entities
- GLNs are used when there is a need to retrieve pre-defined information to improve the efficiency of communication with the supply chain
- GLNs are a prerequisite for data sharing using the GS1 standard
- The GLN is constructed as follows, and can be from the same company prefix as the GTIN:



GLNs in barcodes

- In business operations, GLNs are meaningless if they are not associated with a particular function or purpose.
- The specific Application Identifier indicates the particular function of the location number represented in the bar code symbol, e.g.
  - (AI 410) "Ship to – Deliver to" GS1 Global Location Number
  - (AI 411) "Bill to - Invoice to" GS1 Global Location Number
  - (AI 414) GS1 Global Location Number to identify a physical location
  - (AI 415) GS1 Global Location Number of the invoicing party
- **GLNs are used in regulations on traceability!**
  - Argentina, Turkey, Egypt, etc.

The GLN in use... an example

Company Prefix 0012345

Hospital Headquarters

GLN: 0012345000010

Nursing

GLN: 0012345000065

Pharmacy

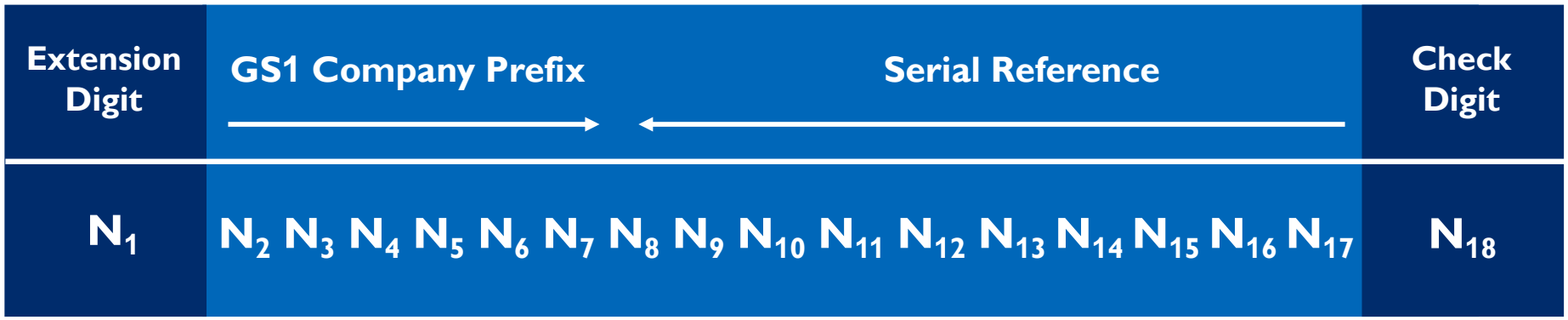
GLN: 0012345000072

Operating Theater

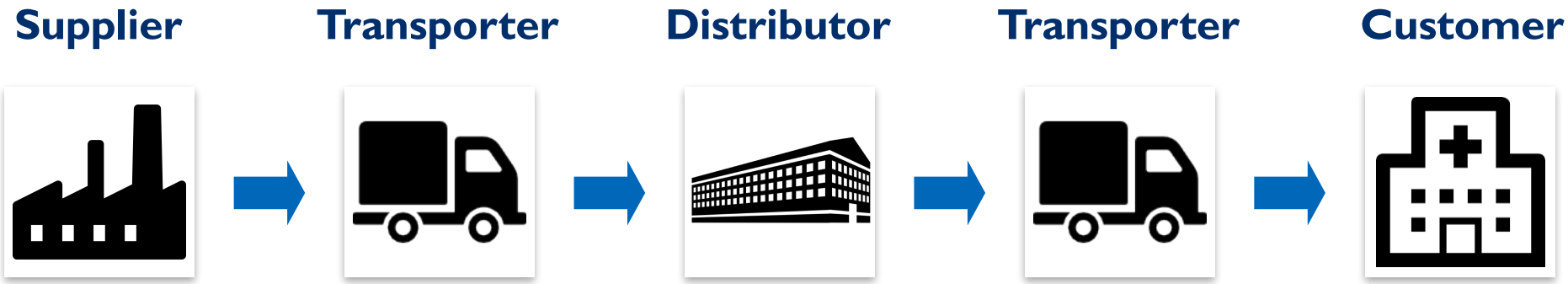
GLN: 0012345000058

3. Serial Shipping Container Code (SSCC)

- The SSCC is a crucial number for traceability
- Uniquely identifies each distributed logistic unit and its contents
- Assigned for the **life time** of the **logistic unit** and is a **mandatory** element of the GS1 Logistic Label
- The SSCC is constructed as follows, and can be from the same company prefix as the GTIN and GLN:



The SSCC in Action



- Applies original SSCC
- Uses SSCC for tracking

- Uses SSCC for internal controls and tracing

- Receives SSCC
- Uses SSCC for internal controls
- Uses SSCC for outbound shipment

- Uses SSCC for internal controls and tracing

- Uses SSCC for tracking
- Receives original SSCC
- Uses SSCC for tracing

- The SSCC enables a logistic unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods-receiving.
- The SSCC provides a unique number for the delivery thus it can be utilized as a look-up number to provide not only detailed information regarding the contents of the load but also as part of an Advanced Shipping Notice (ASN) or Despatch Advice process.

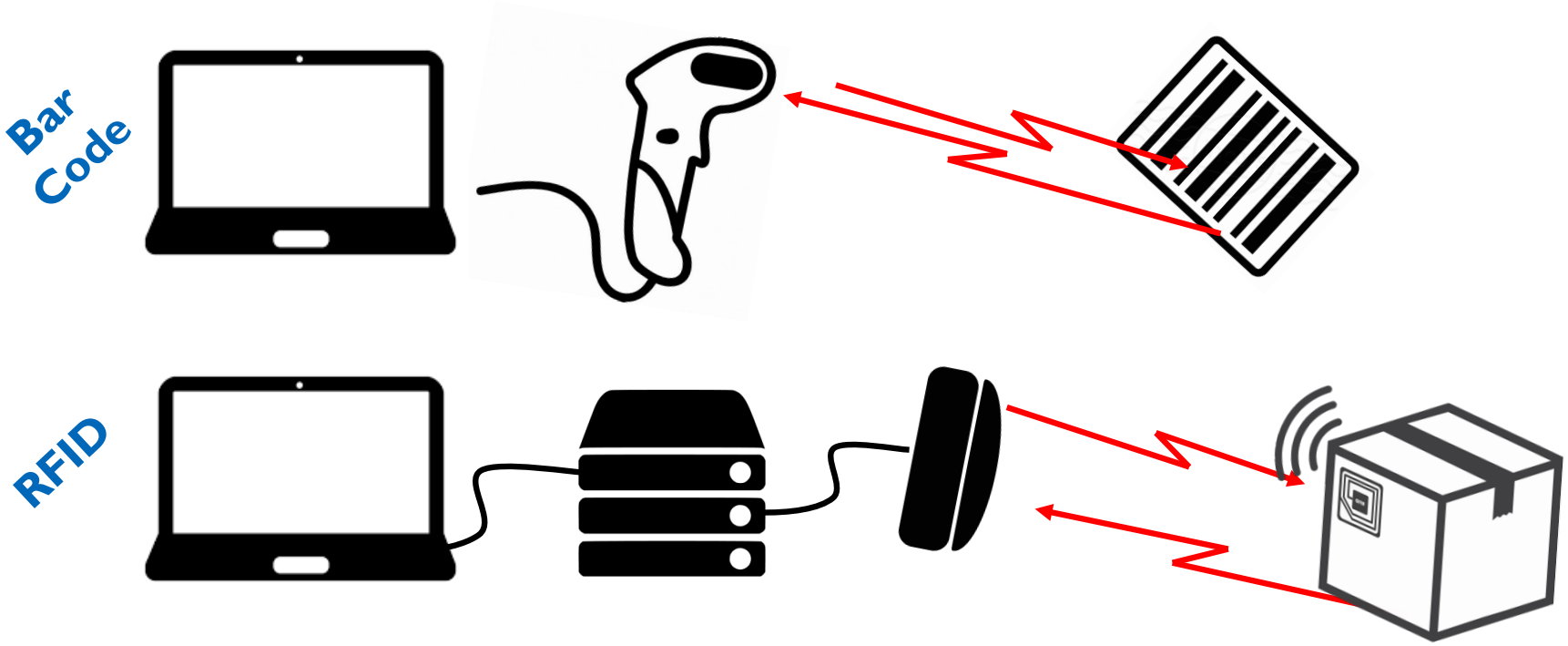
Benefits of SSCC – Shipping & Receiving

Measurable improvements in speed and accuracy!

- More precise and timely information about incoming shipments
- Reduction of time-consuming and error-prone manual intervention
- Reduction of incorrect shipments
- Traceability at all levels along the entire supply chain

GS1 data carriers

GS1's ISO compliant machine-readable **data carriers** for use with the product (via packaging, label or direct part marking (DPM))



NOTE: Though "any" approved machine-readable Data Carrier is applicable, GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers.

GS1 Data Carriers…

…barcode symbologies…

EAN/UPC

GS1 DataBar

GS1-128

GS1 Composite Component

GS1 DataMatrix

GS1 QR Code

ITF-14

GS1 Data Carriers…

…supporting attributes…

EAN/UPC

GS1 DataBar

GS1-128

GS1 Composite Component

GS1 DataMatrix

GS1 QR Code

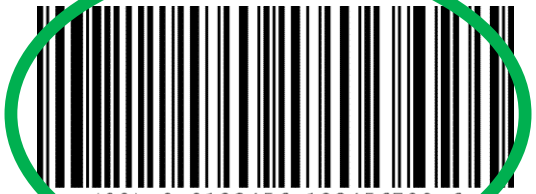
ITF-14

GS1 Data Carriers…

…chosen to support item serialization…

EAN/UPC

GS1 DataBar



GS1-128

GS1 Composite Component

GS1 DataMatrix

GS1 QR Code

ITF-14

Position - GS1 DataMatrix Adoption

GS1 Healthcare Position Paper on GS1 DataMatrix Implementation

GS1 Healthcare Position Statement on GS1 DataMatrix Implementation

To meet the growing demands of increased data needs and facilitate increased patient safety, the healthcare community is in the position to be the leader in GS1 DataMatrix implementation. To demonstrate support of this leadership position, the GS1 Healthcare community has set a goal of 2015 for implementation of GS1 DataMatrix printing on, and scanning of, Regulated Healthcare Trade Items where the current needs are not being met by other GS1 Data Carriers. While not a binding mandate, the community feels strongly in setting a clear direction to further galvanize the industry and encourage action over and above the many active implementations that exist today.

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realized that a global, standardized identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

community, is the most widely used trade item identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as batch/lot numbers, expiry date, etc.) it is uniquely suited to meet the needs of the global healthcare industry.

Pharmaceutical and medical device identification & marking have very specific needs, including:

- Encoding large amounts of variable or dynamic data (lot number, expiration date, serial number, etc.) at high production speeds
- Direct part marking (e.g. marking on surgical instruments, etc.)
- Efficient marking of irregular packaging for many medical products
- Global legal and regulatory requirements that dictate the placement of data in a bar code symbol
- Traceability requirements for both pharmaceuticals and medical devices

Some of these needs are being met, and will continue to be met, through the use of "traditional" linear bar codes, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 DataMatrix as the data carrier (bar code symbol) solution.

GS1 DataMatrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:

- **Allowing the encoding and marking** of a greater amount of data within a smaller space
- **Enabling direct part marking** of trade items where labels may not be practical (small medical / surgical instruments)
- **Providing error detection and correction** capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

As with the implementation of any forward looking technology, there can be challenges that must be recognized. For GS1 DataMatrix, these could include:

- Upgrades to scanner systems: to read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Linear technology based bar code scanners cannot read 2D bar codes, however camera-based bar code scanners can read both linear as well as 2D bar codes and users should be prepared to see both of these types of bar code symbols (see the GS1 Healthcare position statement on 2D camera based scanners)
- Updates to printing systems: to print GS1 DataMatrix, particularly on-line, direct to packaging, within production environments, printing systems may need software / hardware updates or replacement
- Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (lot/batch, expiry, serial number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring that the underlying systems can support the additional data where this is not already implemented

Recognizing all of these needs, as well as the potential challenges of implementation, GS1 Healthcare and its global members strongly support the implementation of 2D capable scanners and the adoption of GS1 DataMatrix. A global implementation will not be accomplished without time and effort. The use of the GS1 DataMatrix can facilitate increased automation of data capture in any country without creating trade barriers that could otherwise potentially impact patient care and safety.

Where GS1 DataMatrix can enhance or solve data capture issues, we need to begin or expand implementations and ensure that the infrastructure is in place as we move to the use of 2D Symbols (like GS1 DataMatrix) through the investment in 2D capable scanners. To bring awareness to the industry of the need to consider these practical challenges and to move forward as quickly as practical, GS1 Healthcare urges that new investments in printing and scanning systems throughout the global healthcare market include compliancy to GS1 DataMatrix.

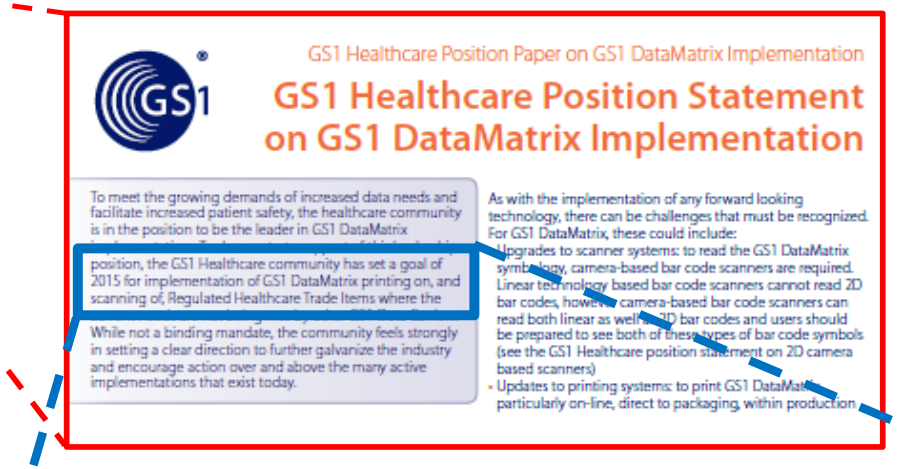
About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.

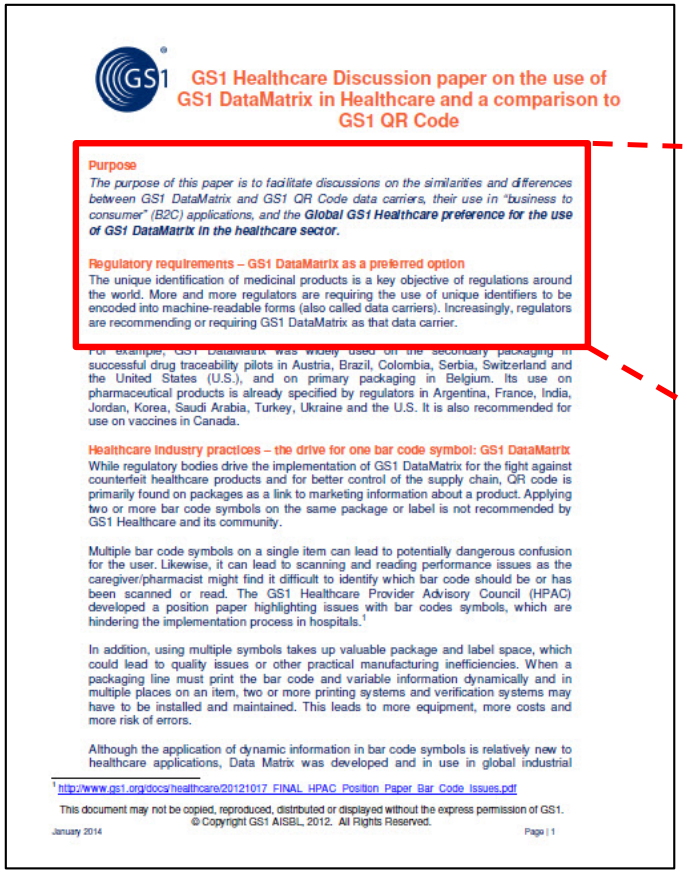
GS1 Healthcare Position Paper on GS1 DataMatrix Implementation - December 2011

Preparing members, solutions providers and end users for the future through global positions…



Get your copy at: http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf

Position - GS1 DataMatrix vs. GS1 QR Code



GS1 Healthcare Discussion paper on the use of GS1 DataMatrix in Healthcare and a comparison to GS1 QR Code

Purpose

The purpose of this paper is to facilitate discussions on the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers, their use in "business to consumer" (B2C) applications, and the ***Global GS1 Healthcare preference for the use of GS1 DataMatrix in the healthcare sector.***

Regulatory requirements – GS1 DataMatrix as a preferred option

The unique identification of medicinal products is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 DataMatrix as that data carrier.

For example, GS1 DataMatrix was widely used on the secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and on primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, France, India, Jordan, Korea, Saudi Arabia, Turkey, Ukraine and the U.S. It is also recommended for use on vaccines in Canada.

Healthcare industry practices – the drive for one bar code symbol: GS1 DataMatrix

While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain, QR code is primarily found on packages as a link to marketing information about a product. Applying two or more bar code symbols on the same package or label is not recommended by GS1 Healthcare and its community.

Multiple bar code symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the caregiver/pharmacist might find it difficult to identify which bar code should be or has been scanned or read. The GS1 Healthcare Provider Advisory Council (HPAC) developed a position paper highlighting issues with bar codes symbols, which are hindering the implementation process in hospitals.[1]

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the bar code and variable information dynamically and in multiple places on an item, two or more printing systems and verification systems may have to be installed and maintained. This leads to more equipment, more costs and more risk of errors.

Although the application of dynamic information in bar code symbols is relatively new to healthcare applications, Data Matrix was developed and in use in global industrial

[1] http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

Reinforcing the GS1 Global Healthcare direction for **ONE** 2D Matrix data carrier… **GS1 DataMatrix**…

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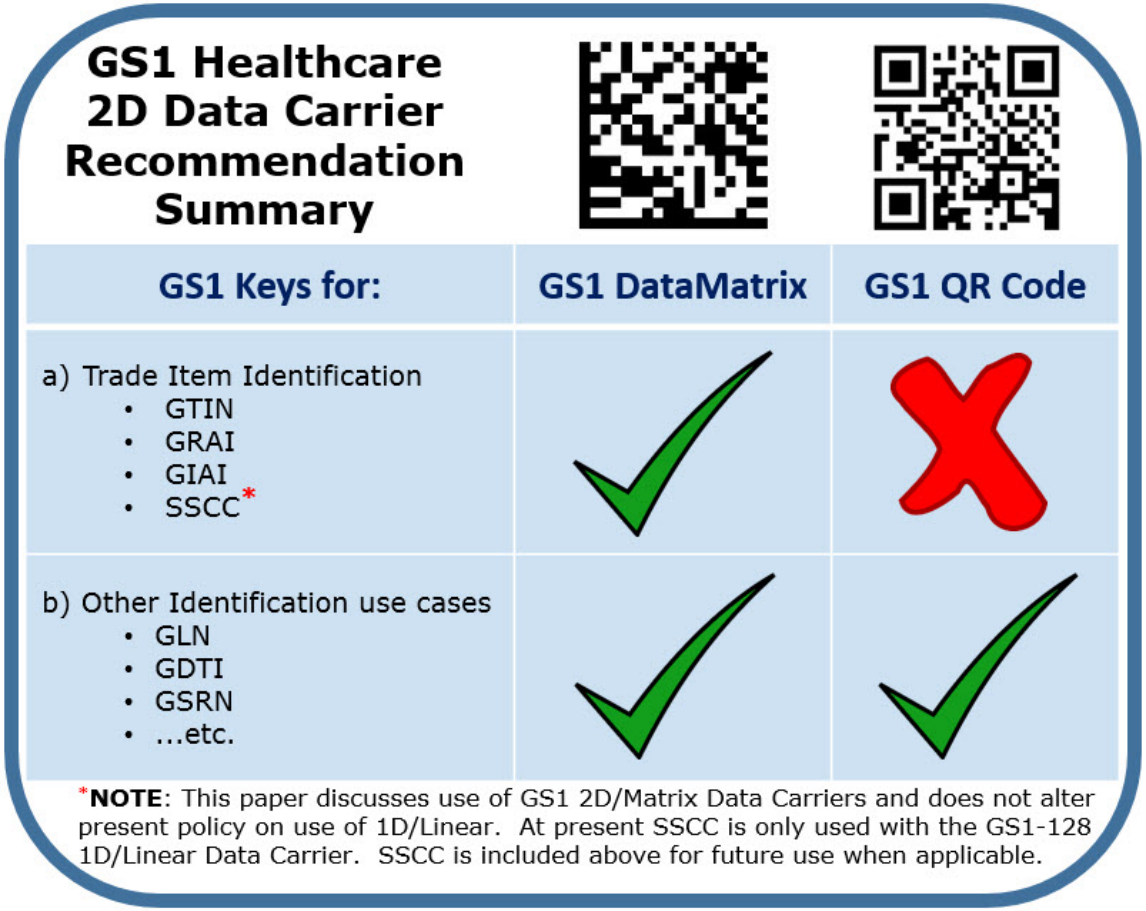
Get your copy at: http://www.gs1.org/sites/default/files/docs/healthcare/GS1%20QR%20DM%20discussion%20paper_20140113_FINAL.pdf

Position - GS1 DataMatrix vs. GS1 QR Code



GS1 Healthcare 2D Data Carrier Recommendation Summary

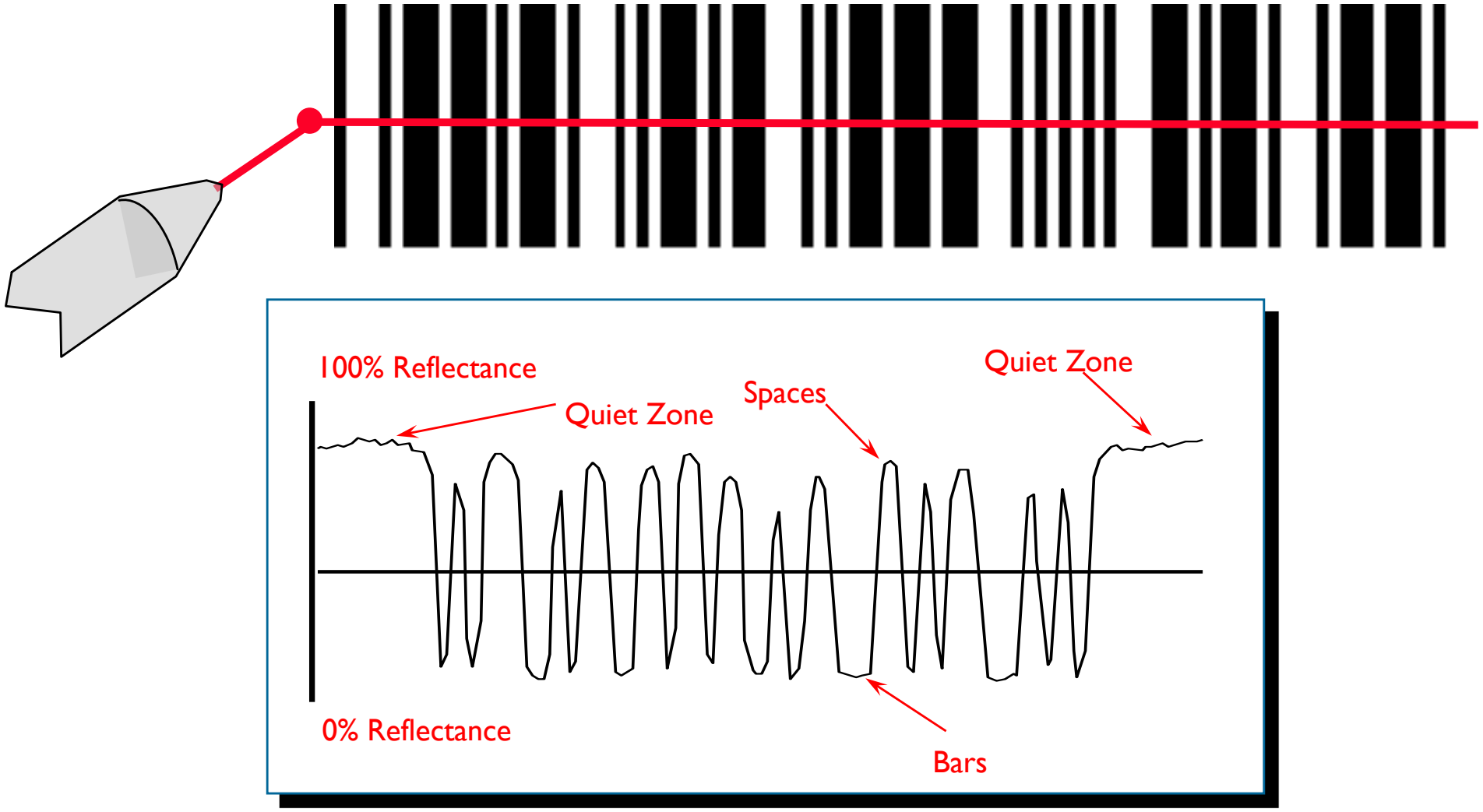
GS1 Keys for:	GS1 DataMatrix	GS1 QR Code
a) Trade Item Identification • GTIN • GRAI • GIAI • SSCC*	✓	✗
b) Other Identification use cases • GLN • GDTI • GSRN • ...etc.	✓	✓

*__NOTE__: This paper discusses use of GS1 2D/Matrix Data Carriers and does not alter present policy on use of 1D/Linear. At present SSCC is only used with the GS1-128 1D/Linear Data Carrier. SSCC is included above for future use when applicable.

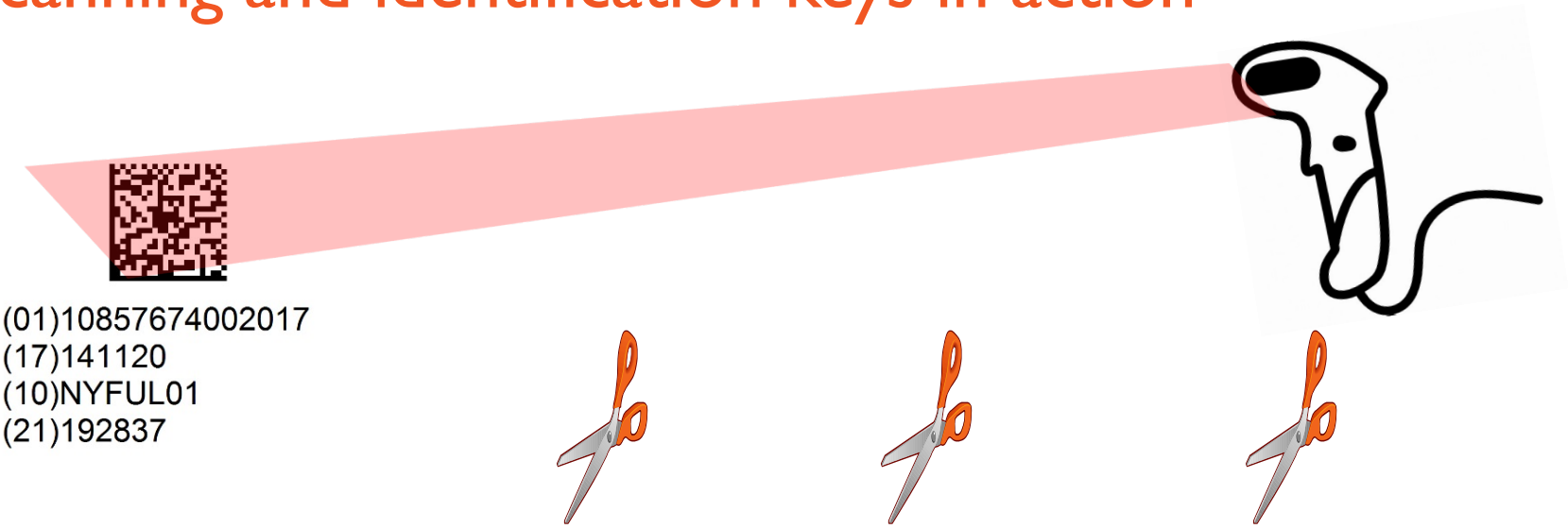
GS1 data carriers for healthcare

GS1-128 & GS1 DataBar	GS1 DataMatrix	EPC/RFID
		
<u>Preferred</u> option if: ✓ Package size allows	**<u>Preferred</u> option** if: ✓ Large amounts of data in a small space ✓ Variable information at high production rates ✓ Direct part marking	**<u>Additional</u> option** if: ✓ No line of sight ✓ Large amounts of data

So, how does this work?



Scanning and identification keys in action



(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837

?

0110857674002017171411201 0NYFUL0121192837

0110857674002017 **17**141120 **10**NYFUL01 **21**192837

10857674002017 20 Nov 2014 NYFUL01 192837

ERP Entries

GTIN:

EXPIRATION:

BATCH/LOT:

SERIAL:

Barcode scanners for healthcare

Camera-based barcode scanners are required in healthcare because they can read linear and 2D barcodes

GS1 Healthcare

Position Statement

GS1 Healthcare recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare

Because of the increased capabilities of camera-based bar code scanners, GS1 Healthcare (GS1 global Healthcare user group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 Healthcare promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, …) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct part marking (e.g. surgical instruments and implants)
- unscannable bar codes ~~do~~ not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:

The two examples contain identical data

GS1 DataMatrix

Mobile phones

Original Paper

Feasibility and Limitations of Vaccine Two-Dimensional Barcoding Using Mobile Devices

Cameron Bell[1], BEng; Julien Guerinet[1], BEng; Katherine M Atkinson[1,2], BSc; Kumanan Wilson[1,3], MD, MSc, FRCP(C)
[1]Ottawa Hospital Research Institute, Clinical Epidemiology Program, Ottawa, ON, Canada
[2]Karolinska Institutet, Department of Public Health Sciences, Stockholm, Sweden
[3]University of Ottawa, Departments of Medicine, Epidemiology and Community Medicine, Ottawa, ON, Canada

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Abstract

Background: Two-dimensional (2D) barcoding has the potential to enhance documentation of vaccine encounters at the point of care. However, this is currently limited to environments equipped with dedicated barcode scanners and compatible record systems. Mobile devices may present a cost-effective alternative to leverage 2D vaccine vial barcodes and improve vaccine product-specific information residing in digital health records.

Objective: Mobile devices have the potential to capture product-specific information from 2D vaccine vial barcodes. We sought to examine the feasibility, performance, and potential limitations of scanning 2D barcodes on vaccine vials using 4 different mobile phones.

Methods: A unique barcode scanning app was developed for Android and iOS operating systems. The impact of 4 variables on the scan success rate, data accuracy, and time to scan were examined: barcode size, curvature, fading, and ambient lighting conditions. Two experimenters performed 4 trials 10 times each, amounting to a total of 2160 barcode scan attempts.

Results: Of the 1832 successful scans performed in this evaluation, zero produced incorrect data. Five-millimeter barcodes were the slowest to scan, although only by 0.5 seconds on average. Barcodes with up to 50% fading had a 100% success rate, but success rate deteriorated beyond 60% fading. Curved barcodes took longer to scan compared with flat, but success rate deterioration was only observed at a vial diameter of 10 mm. Light conditions did not affect success rate or scan time between 500 lux and 20 lux. Conditions below 20 lux impeded the device's ability to scan successfully. Variability in scan time was observed across devices in all trials performed.

Conclusions: 2D vaccine barcoding is possible using mobile devices and is successful under the majority of conditions examined. Manufacturers utilizing 2D barcodes should take into consideration the impact of factors that limit scan success rates. Future studies should evaluate the effect of mobile barcoding on workflow and vaccine administrator acceptance.

(J Med Internet Res 2016;18(6):e143) doi:10.2196/jmir.5591

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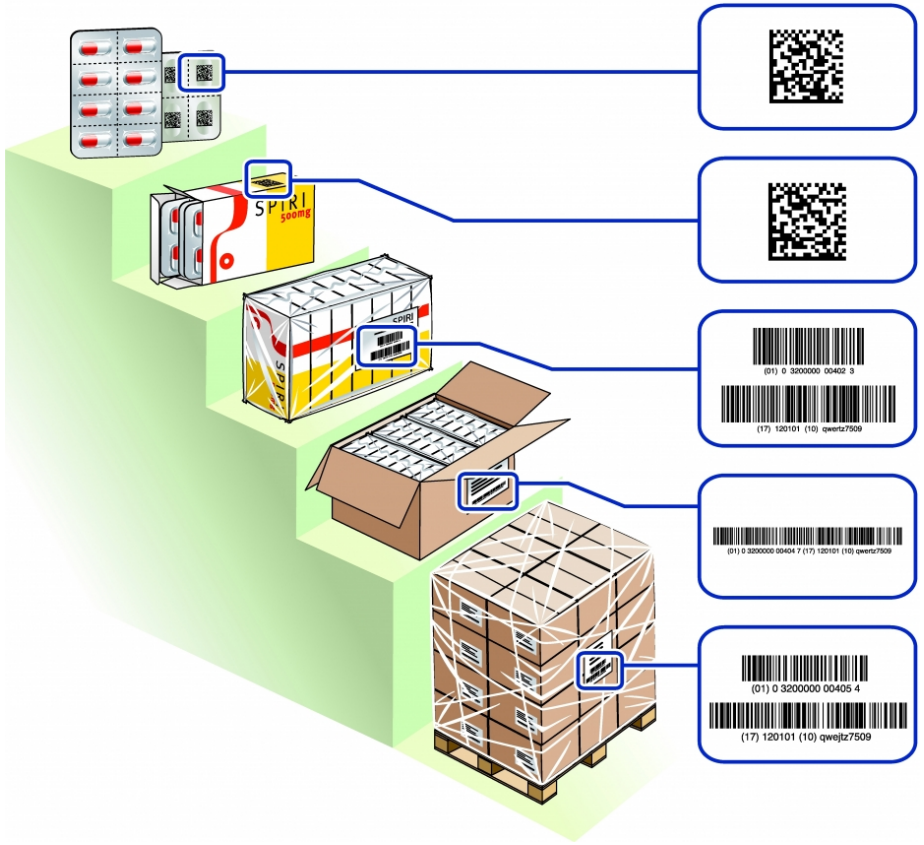
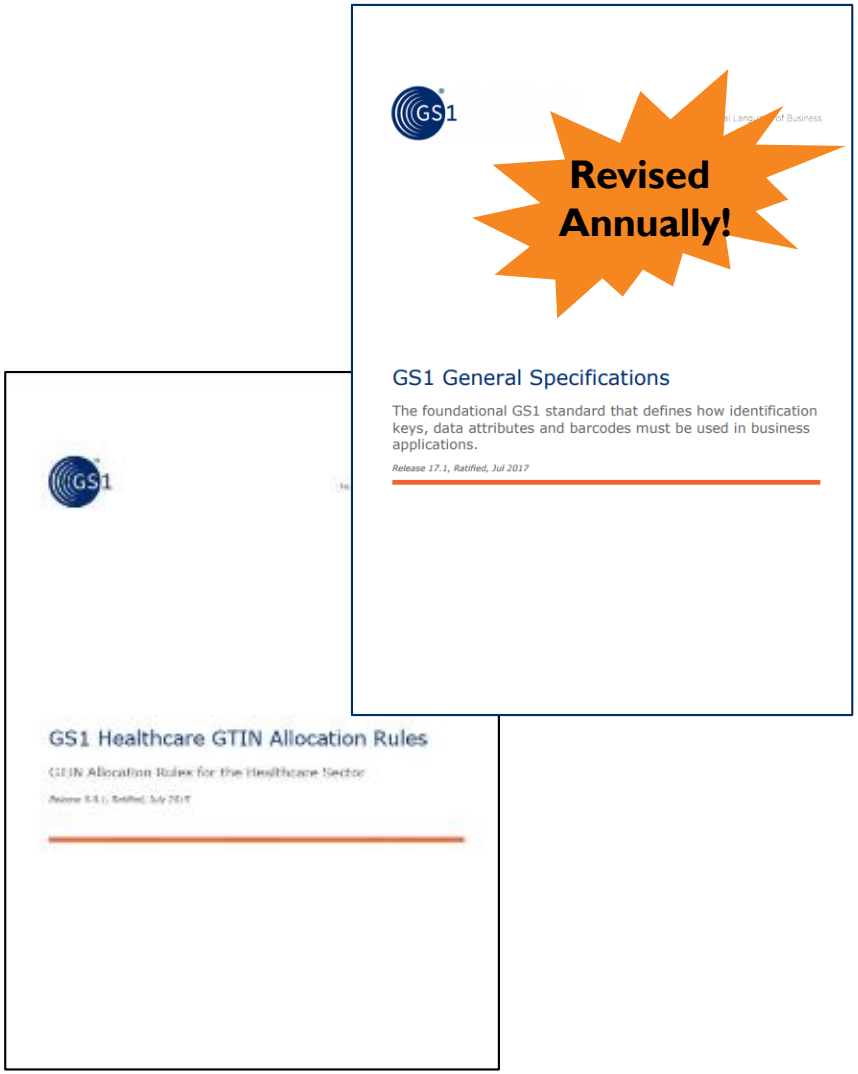
Journal of Medical Internet Research, vol.18,2016

Ideally, there are identifiers and data carriers at all packaging levels



NOTE: Data carriers shown are for illustration purposes only! Refer to local regulations an/or the GS1 General Specification for more details.

GS1 system of standards

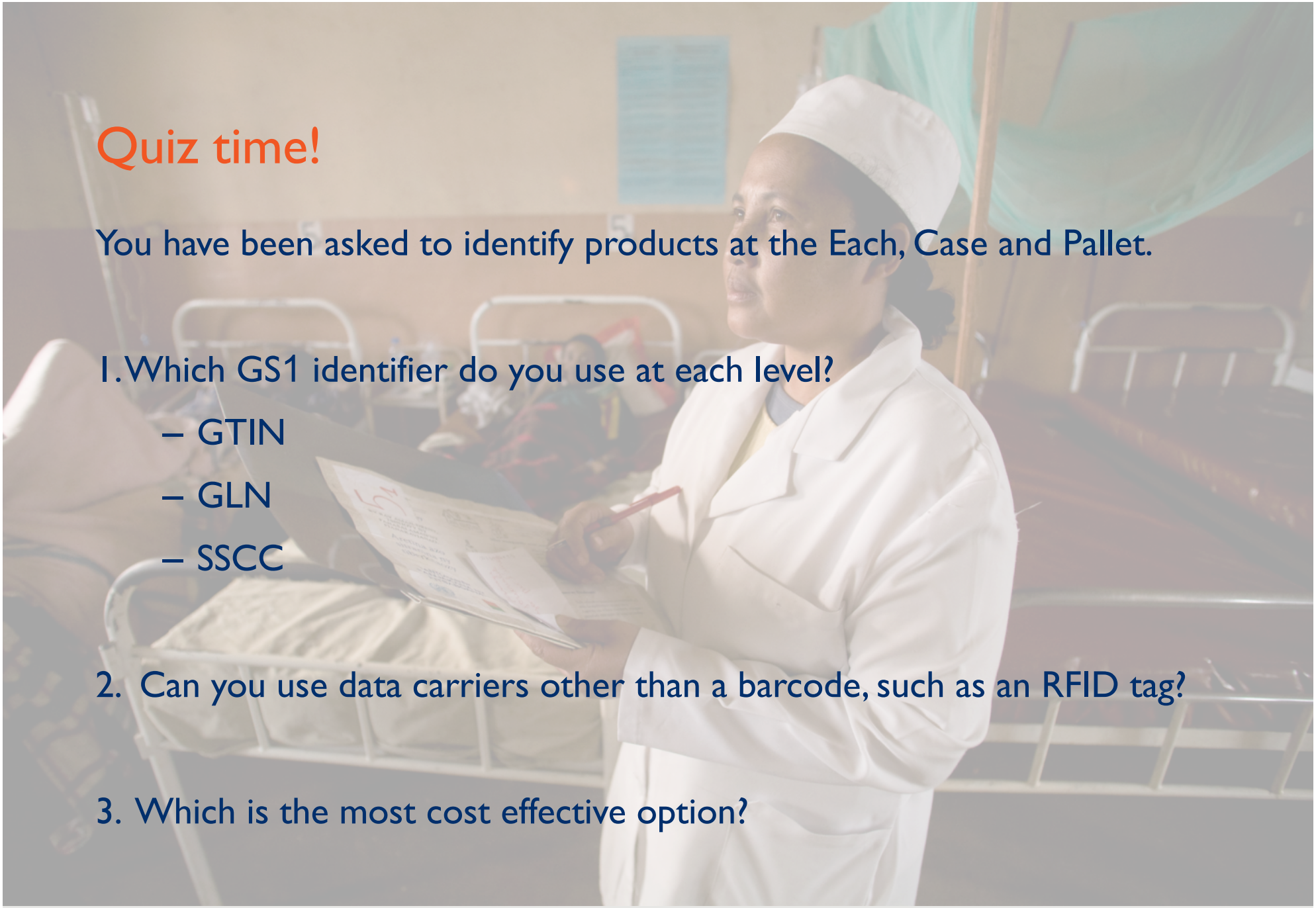


GS1 General Specifications – the ONE global standard for AIDC in Healthcare

- The core standards document of the "GS1 System"… describes how GS1 keys & data carriers should be used - Available online at: http://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications

GS1 Healthcare GTIN Allocation Rules – GTIN assignment in Healthcare

- A guide to GS1 ID Key assignment… the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at: http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf



Quiz time!

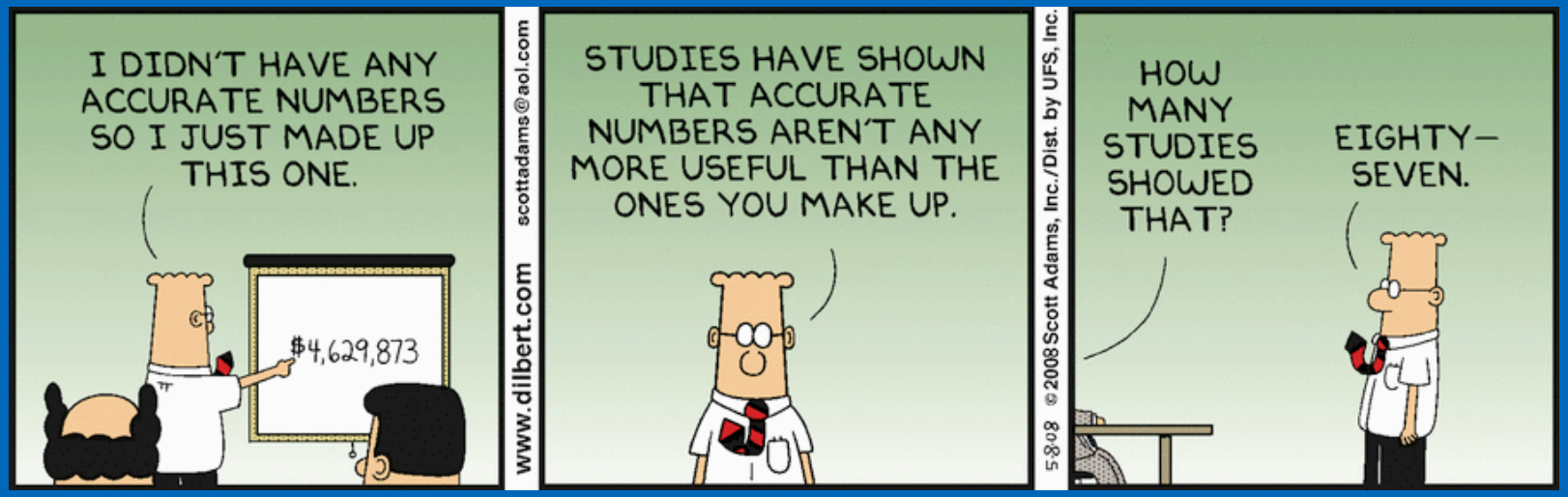
You have been asked to identify products at the Each, Case and Pallet.

1. Which GS1 identifier do you use at each level?
   - GTIN
   - GLN
   - SSCC

2. Can you use data carriers other than a barcode, such as an RFID tag?

3. Which is the most cost effective option?

Master Data Management (MDM) and Master Data Exchange



There are three kinds of data that is shared in healthcare supply chains

Master Data

- GTINs and GLNs are the keys used to access master data across multiple systems, applications or processes
- Examples: shelf-life, dimensions, weights, quantity
- *GS1 Standard*: Global Data Synchronization Network™ (GDSN®)

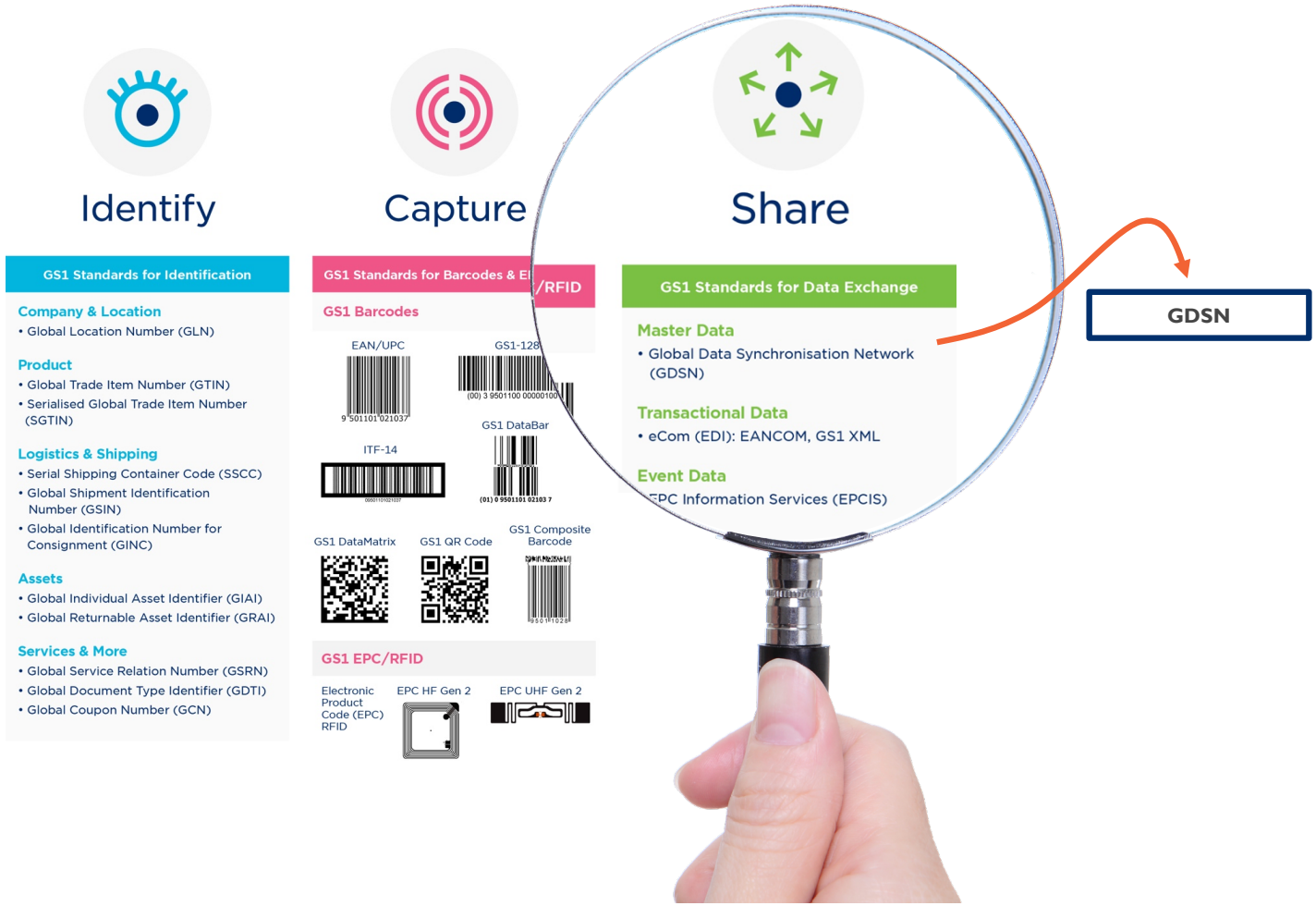
Transactional Data

- Information about production, purchasing, selling, and other transactions that occur through the supply chain
- Examples: units sold, stock on hand, stock on order, forecasted units
- *GS1 Standard*: GS1 XML, EANCOM, EDI

Event Data

- Information about the physical movement and status of products as they move through the supply chain
- Examples: commissioning, shipping, receiving, decommissioning
- *GS1 Standard*: EPCIS, CBV

GS1 Master Data standards



The Master Data problem

Every company has a database filled with master data about the products they make, sell, or buy

But when one company changes any bit of information in their database or adds a new item, another database becomes outdated!

Alignment of master data is the basis for trade and traceability!

What happened to "Master Data"

- Systems have evolved in "silos" over the last 40 years
- The link between "process" and data was broken (*remains so in many cases*)
- Numerous efforts to "unify" data and process, or views of data – one use at a time
- **So what?** Business success still happened anyway…
- **Only when costs increase, profits fall, (*or a patient is negatively affected)* does the real impact of bad data become known!**

1970s

1990s

2000s

Original source: Gartner

Data Errors in Healthcare
US Department of Defense Study

% of Total Data Error	Manufacturer	Distributor	GPO	HC Provider
Missing Middle Levels of Packaging	15-20%	1-4%	20-25%	15-25%
Hard "Packaging Quantity" Errors	1%	1%	2%	2-5%
Unit of Measure Confusion/Misuse	2-6%	1-3%	2-5%	Unknown
Missing Packaging—not Middle Level	3-8%	3-8%	3-7%	5%
Manufacturer Name Problems	NA	2-5%	1-4%	30%
Obsolete Products	1-4%	2-5%	1-8%	5-15%
Missing Product Brand Names	2-5%	5-10%	5-10%	20-25%
Incomplete Item Descriptions	5-15%	3-12%	5-15%	10-20%
Wrong Customer Unit Prices	Unknown	1-2%	NA	1-2%
Customer Paid More Than Lowest Contract Price	NA	Unknown	NA	3-6%

Source: https://www.gs1.org/docs/healthcare/events/291105/KG_HUG_301105.pdf

No standardized product identification

Different products, same number

Projects previously used proprietary identification numbers that resulted in duplicity across health areas

- **Product ID 102033**
  - Bed Net, Polyester, Deltamethrin, 100 Denier (180(L) x 190(W) x 170(H) cm), Rectangular, Light Blue
  - Lopinavir/Ritonavir 200/50mg [Aluvia], tablets, 120 Tabs
- **Product ID 102043**
  - Condom, Male, 49mm lubricated, non-colored, non-scented [Top], latex, piece
  - Stavudine 20mg [Zerit], capsules, 60 capsules
- **Product ID 102062**
  - Test, Rapid Diagnostic Malaria, Ag HRP2/pLDH Single Pack POCT [First Response Malaria] kit, 30 tests
  - Amoxicillin 250mg, capsules, 1000 Caps

No standardized legal entity or location identification

Multiple ways to list a manufacturer

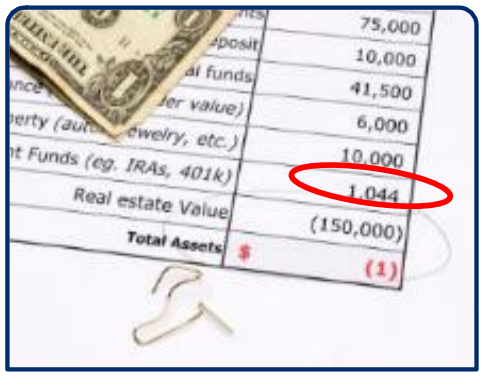
Manually logged entity information is prone to errors and results in duplicity, making it difficult to discern which entity is the correct trading partner

- Abbott
- Abbott GmbH + Co.KG
- Abbott Laboratories
- Abbott Molecular
- Abbott,
- ABBVIE
- AbbVie Deutschland GmbH + Co KG
- F. Hoffmann
- Hoffmann - La Roche
- ROCHE
- Roche
- Roche Diagnostics
- Roche Diagnostics international Ltd
- Roche Molecular Systems Inc.-US
- Roche Molecular Systems Inc, US
- Roche Products (Pty) Ltd-Diagnostics Division
- Fischer Scientific
- Fischer Technical
- Fisher BioReagents
- Fisher Healthcare
- Fisher Scientific
- Fisherbrand
- Fisherbrand HistoPrep Chemicals
- Thermo Fisher Scientific
- Thermo Scientific
- ThermoFisher
- ThermoFisher Scientific
- VWR
- VWR Brand
- VWR Chemicals
- VWR Chemicals France
- VWR INTERN
- VWR International
- VWR INTERNATIONAL LLC

The cost of data errors

Catalog Disparities

Incorrect Item Data: 30%
Costs: US$60-$80/error to correct
Time Lost: 25 minutes/SKU/year



Invoice Errors

60% invoices with errors, of which 43% have deduction costs
To Correct: US$40-$400 to reconcile

Lost Business

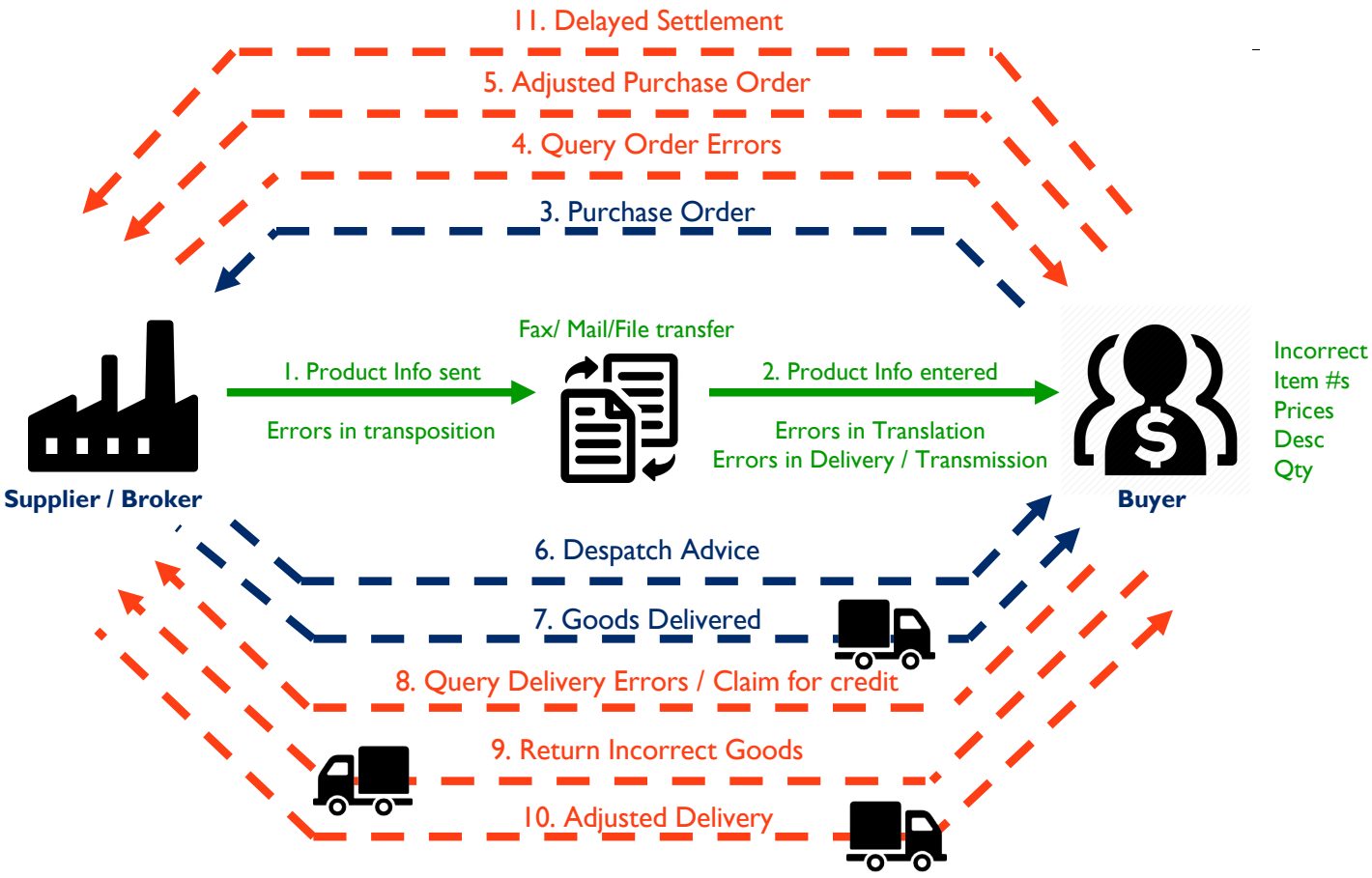
Product Roll-in: About 4 weeks
Lost Sales: 3.5% due to inaccurate data

- Source: Supply Chain Management Review - Synchronization: a cure for bad data.(INNOVATIONS: New ways of thinking about supply chain management)
- Link to GDSN cases studies: http://www.gs1.org/standards/gdsn/case-studies

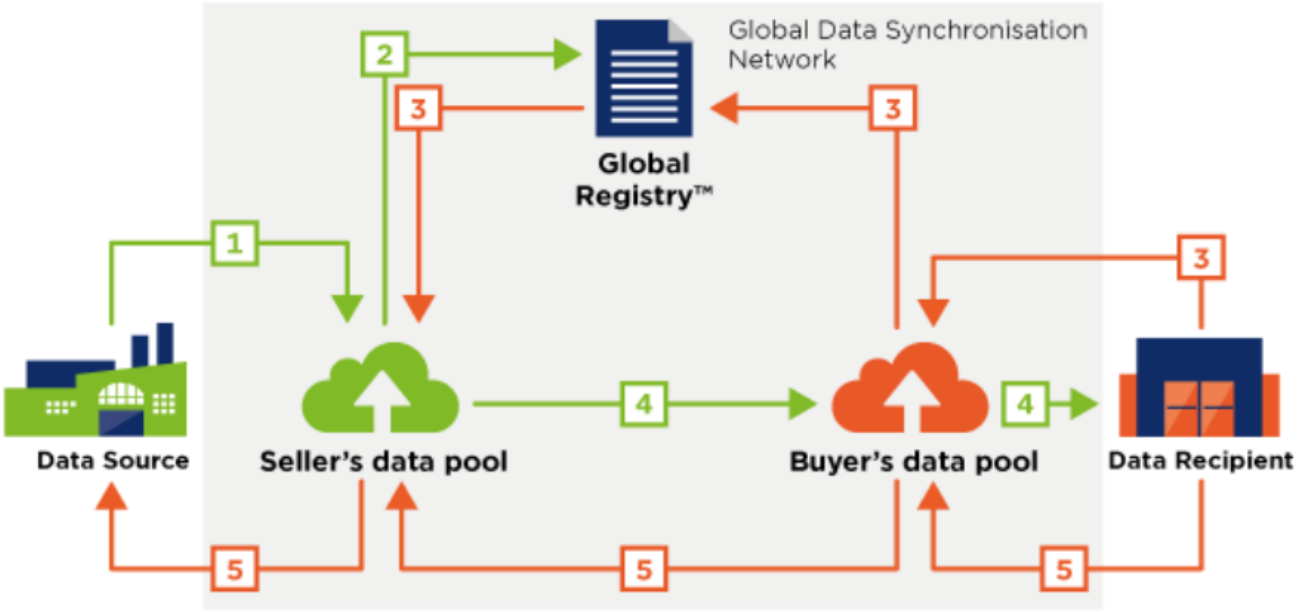
The Australian data crunch report puts a cost on the problem!

Source: https://www.gs1au.org/resources/publications/

Order-to-cash before data synchronization



How data exchange works in the GDSN

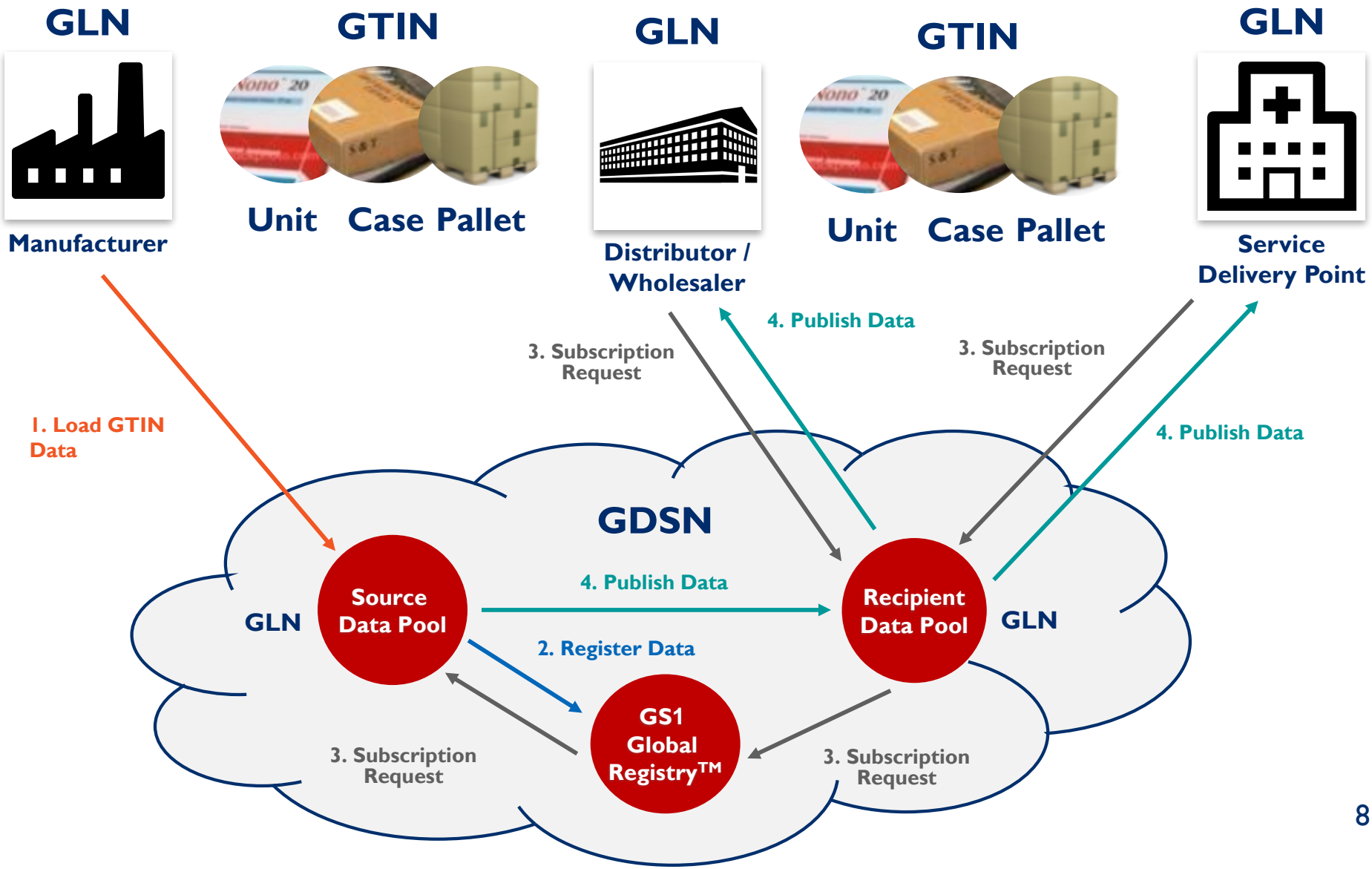


1. Loading of company data
2. Registering of company data
3. Subscription to seller's data pool
4. Publishing of company data
5. Confirmation of receipt of company

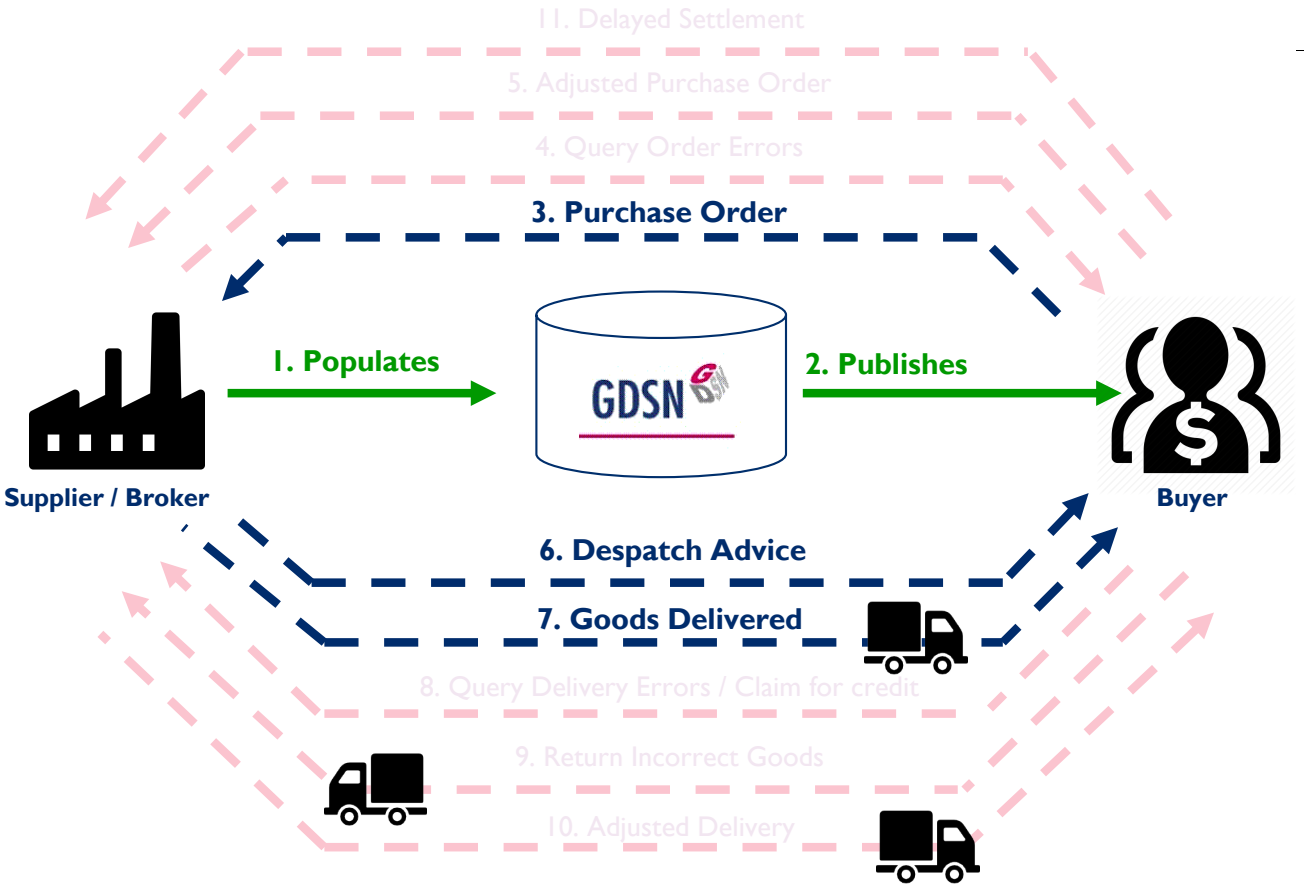
- 39 certified GDSN Data Pools
- 2.1+ million healthcare products
- 3,500+ suppliers
- Published to 96 Target Markets

GDSN Information: http://www.gs1.org/gdsn

The GDSN in action



Order-to-cash after data synchronisation



GDSN by the numbers

- Overall, more than 24 million GTINs and 44,000 GLNs
- In healthcare –

Total GTINs	**2,103,245**
Device GTINs	1,578,835
Pharma GTINs	67,437
All other GTINs	456,973
Total GLNs	**3,811**
Total Target Markets	**96**

Quiz time!

- What is the purpose of the GDSN?
- What are two examples of data challenges that Master Data Management can address?
- What does GDSN stand for?


TIME
FOR
A
BREAK

GHSC-PSM Implementation of Global Standards

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

The journey to today

USAID FROM THE AMERICAN PEOPLE

USAID & UNFPA to collaborate to address interoperability and data visibility challenges for RH

GS1 Workshop at USAID

Ethiopia & Pakistan pilots started jointly between USAID and UNFPA

USAID joins VPPAG

Collaboration for standards adoption introduced at ISG and led by USAID, UNFPA, GAVI

Hosts E2E / standards adoption workshop with 5 countries

Pilots conclude

Present on pilots at GS1 Global Healthcare Conference – Budapest

USAID / UNFPA found RH GTAG

USAID & Pakistan DRAP present at GS1 Global Healthcare Conference - Dubai

USAID & UNFPA sponsor 10 delegates from Ethiopia FMHACA and PFSA to attend

Participate in Ethiopia National Consultative Workshop

Attend GS1 Global Healthcare Conference - Beijing

Attend GS1 Global Healthcare Conference - Berlin

Publish RH GTAG Reco

Issue TDM to GHSC-PSM to implement GS1

Launch USAID / GF / SA NDoH harmonizaton effort

Attend GS1 Global Healthcare Conference - Chicago

2014 2015 2016 2017

GHSC-PSM

GHSC-PSM is launched

Join RH GTAG

Attend GS1 Global Healthcare Conference - Dubai

Attend GS1 Global Healthcare Conference - Beijing

Hire consultants for readiness assessments and recommendations

Launch GDSN RFP

Develop requirements and implementation road maps

Present at Supplier Summit

Announce Procurement Requirement

Develop 2-year work plan

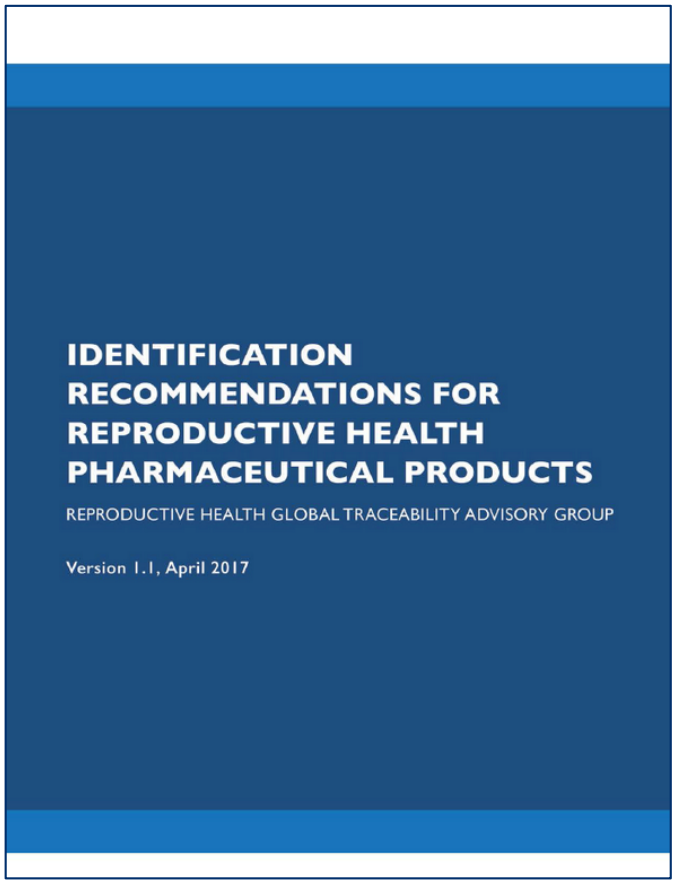
Launch Work Stream

Launch GDSN Contract

Issue Country Work Plan Guidance

Attend GS1 Global Healthcare Conference - Chicago

Reproductive Health Global Traceability Advisory Group (RH GTAG)



A forum for subject matter experts from industry and the public sector to discuss and provide recommendations for the adoption and implementation of global standards for RH product identification, data capture, and data exchange in the supply chain.

Industry Advisors

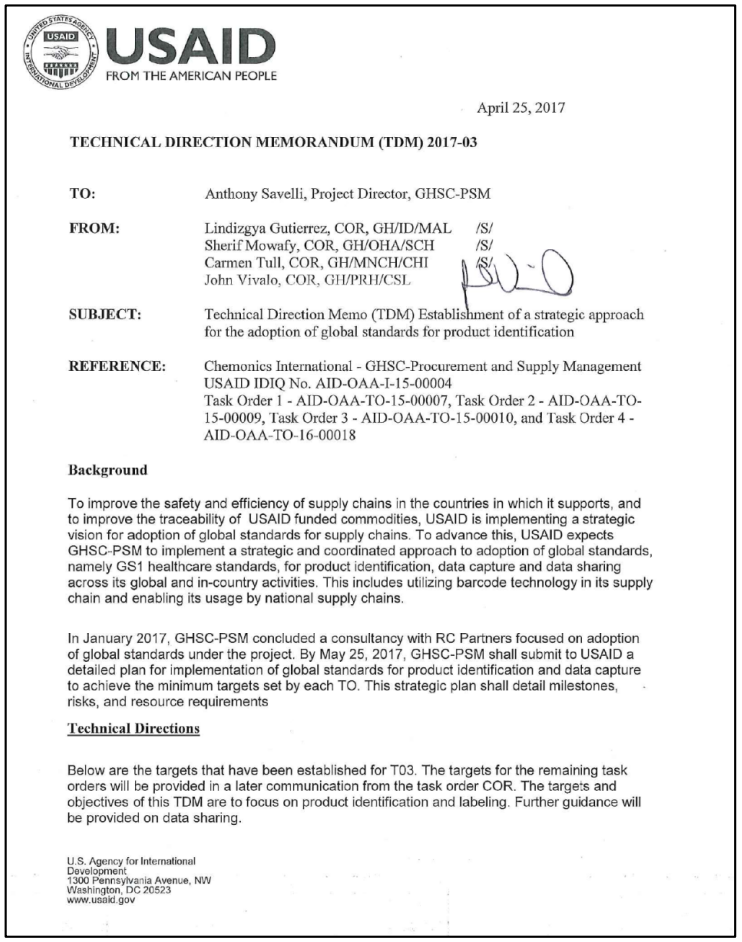
Pfizer, Bayer, Merck, Indus, Pregna International Ltd, Ansell, The Female Health Company, Mylan

Facilitators

UNFPA, USAID, GS1, Reproductive Health Supplies Coalition

Identification Recommendations for Reproductive Health Pharmaceutical Products

USAID Technical Direction Memorandum



USAID
FROM THE AMERICAN PEOPLE

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

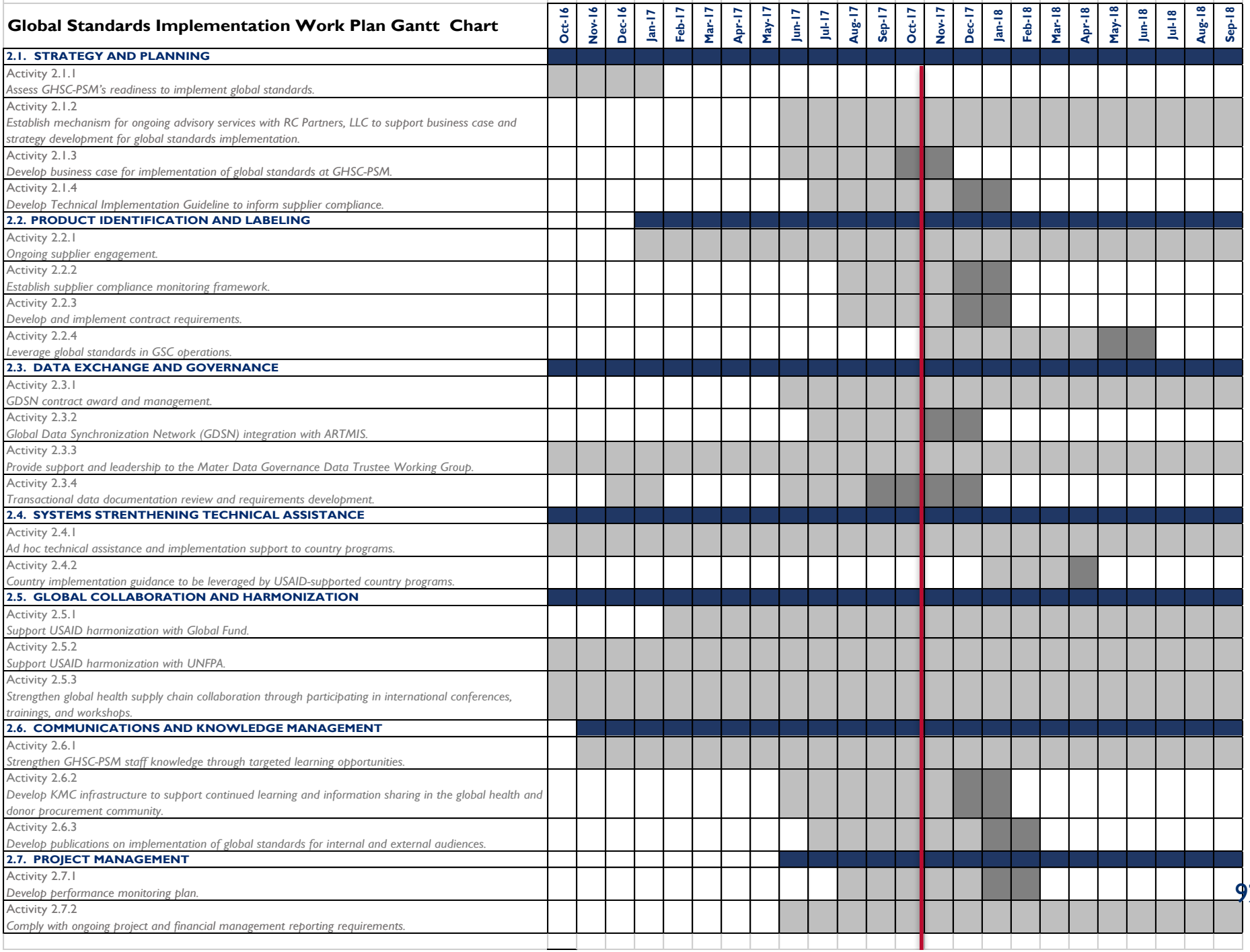
Below are the targets that have been established for T03. The targets for the remaining task orders will be provided in a later communication from the task order COR. The targets and objectives of this TDM are to focus on product identification and labeling. Further guidance will be provided on data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

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

Based on the RH GTAG recommendation, in April 2017, USAID issued a Technical Direction Memorandum to the GHSC-PSM Project for establishment of a strategic approach for the adoption global standards for product identification, data capture and data sharing.

Who else is on board?

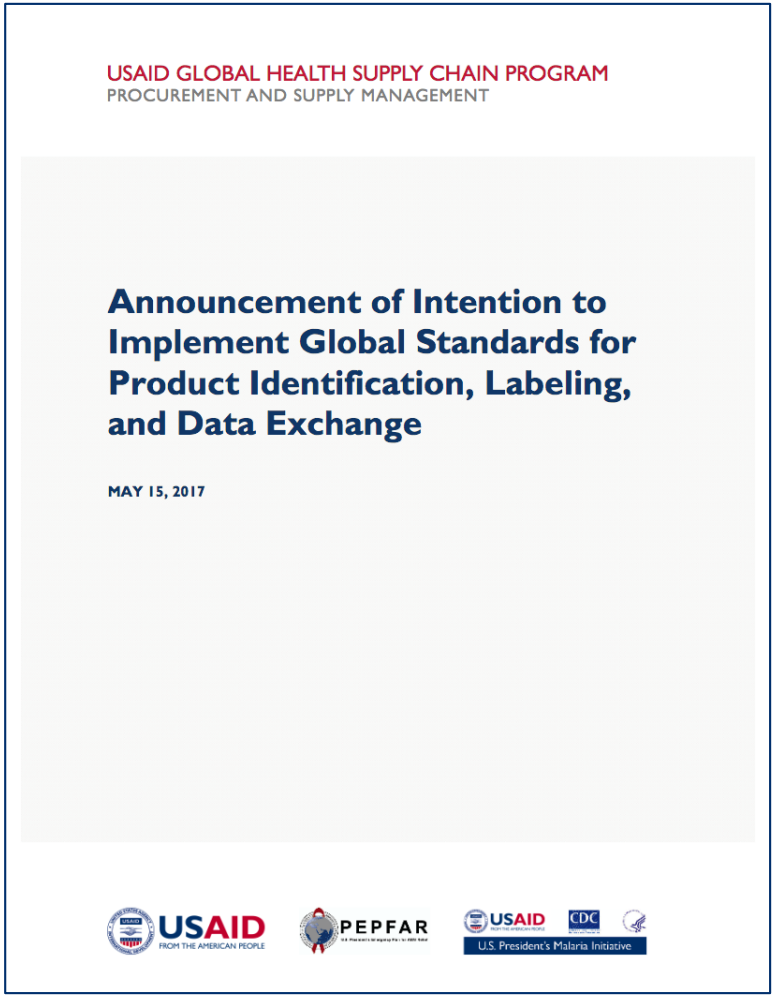
- South Africa National Department of Health (NDoH)
- UNFPA
- Global Fund
- Bill & Melinda Gates Foundation
- Reproductive Health Supplies Coalition
- The Global Steering Committee for Quality Assurance of Health Products
- Interagency Supply Chain Group (ISG)


Global Standards Implementation Work Plan Gantt Chart
Oct-16
Nov-16
Dec-16
Jan-17
Feb-17
Mar-17
Apr-17
May-17
Jun-17
Jul-17
Aug-17
Sep-17
Oct-17
Nov-17
Dec-17
Jan-18
Feb-18
Mar-18
Apr-18
May-18
Jun-18
Jul-18
Aug-18
Sep-18
2.1. STRATEGY AND PLANNING
Activity 2.1.1
Assess GHSC-PSM's readiness to implement global standards.
Activity 2.1.2
Establish mechanism for ongoing advisory services with RC Partners, LLC to support business case and strategy development for global standards implementation.
Activity 2.1.3
Develop business case for implementation of global standards at GHSC-PSM.
Activity 2.1.4
Develop Technical Implementation Guideline to inform supplier compliance.
2.2. PRODUCT IDENTIFICATION AND LABELING
Activity 2.2.1
Ongoing supplier engagement.
Activity 2.2.2
Establish supplier compliance monitoring framework.
Activity 2.2.3
Develop and implement contract requirements.
Activity 2.2.4
Leverage global standards in GSC operations.
2.3. DATA EXCHANGE AND GOVERNANCE
Activity 2.3.1
GDSN contract award and management.
Activity 2.3.2
Global Data Synchronization Network (GDSN) integration with ARTMIS.
Activity 2.3.3
Provide support and leadership to the Mater Data Governance Data Trustee Working Group.
Activity 2.3.4
Transactional data documentation review and requirements development.
2.4. SYSTEMS STRENTHENING TECHNICAL ASSISTANCE
Activity 2.4.1
Ad hoc technical assistance and implementation support to country programs.
Activity 2.4.2
Country implementation guidance to be leveraged by USAID-supported country programs.
2.5. GLOBAL COLLABORATION AND HARMONIZATION
Activity 2.5.1
Support USAID harmonization with Global Fund.
Activity 2.5.2
Support USAID harmonization with UNFPA.
Activity 2.5.3
Strengthen global health supply chain collaboration through participating in international conferences, trainings, and workshops.
2.6. COMMUNICATIONS AND KNOWLEDGE MANAGEMENT
Activity 2.6.1
Strengthen GHSC-PSM staff knowledge through targeted learning opportunities.
Activity 2.6.2
Develop KMC infrastructure to support continued learning and information sharing in the global health and donor procurement community.
Activity 2.6.3
Develop publications on implementation of global standards for internal and external audiences.
2.7. PROJECT MANAGEMENT
Activity 2.7.1
Develop performance monitoring plan.
Activity 2.7.2
Comply with ongoing project and financial management reporting requirements.

GHSC-PSM Announcement of Contract Requirements

In response to the TDM, GHSC-PSM developed a two year work plan and strategic vision (FY17 – FY18) to drive implementation across the organization.

In May 2017, GHSC-PSM issued an announcement of our requirement to suppliers stating the new requirement and implementation timeline.

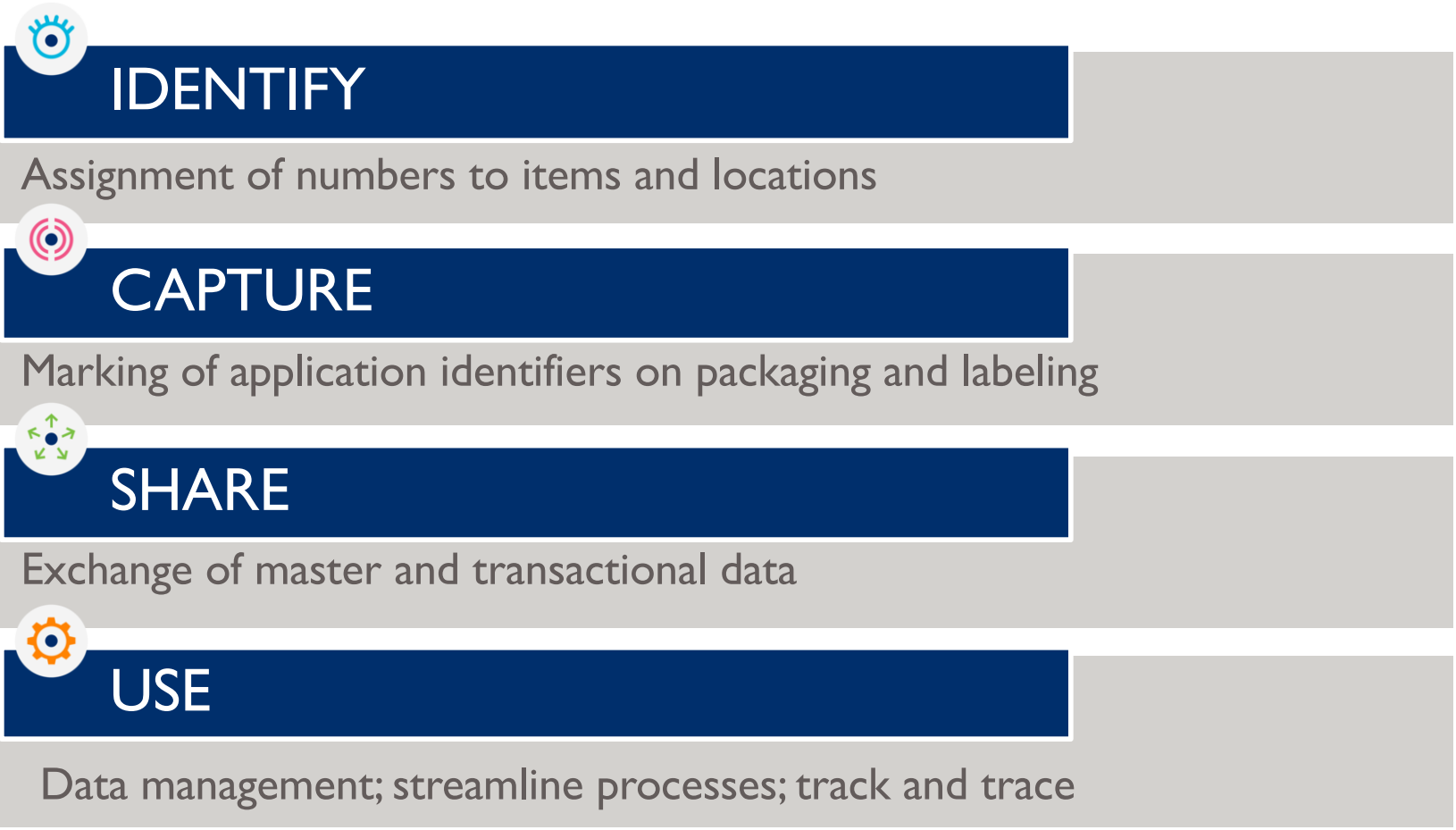


Announcement of Intention to Implement Global Standards for Product Identification, Labeling, and Data Exchange

General Principles

- Adopt global standards to promote efficiency, reliability, and effectiveness
- Clearly identify vision, goals, and objectives to motivate requirements
- Requirements should capture what is necessary to secure the supply chain
- Requirements should be phased in over time to allow for transition
- Leverage successful practices and systems from other markets
- Harmonize with other key stakeholders in the community to:
  - ✓ Minimize the risk and investment required by suppliers
  - ✓ Maximize benefits to country supply chains and patients
- Establish benchmark metrics and KPIs to ensure accountability and measure progress

There are four elements to our strategy



What does it apply to?

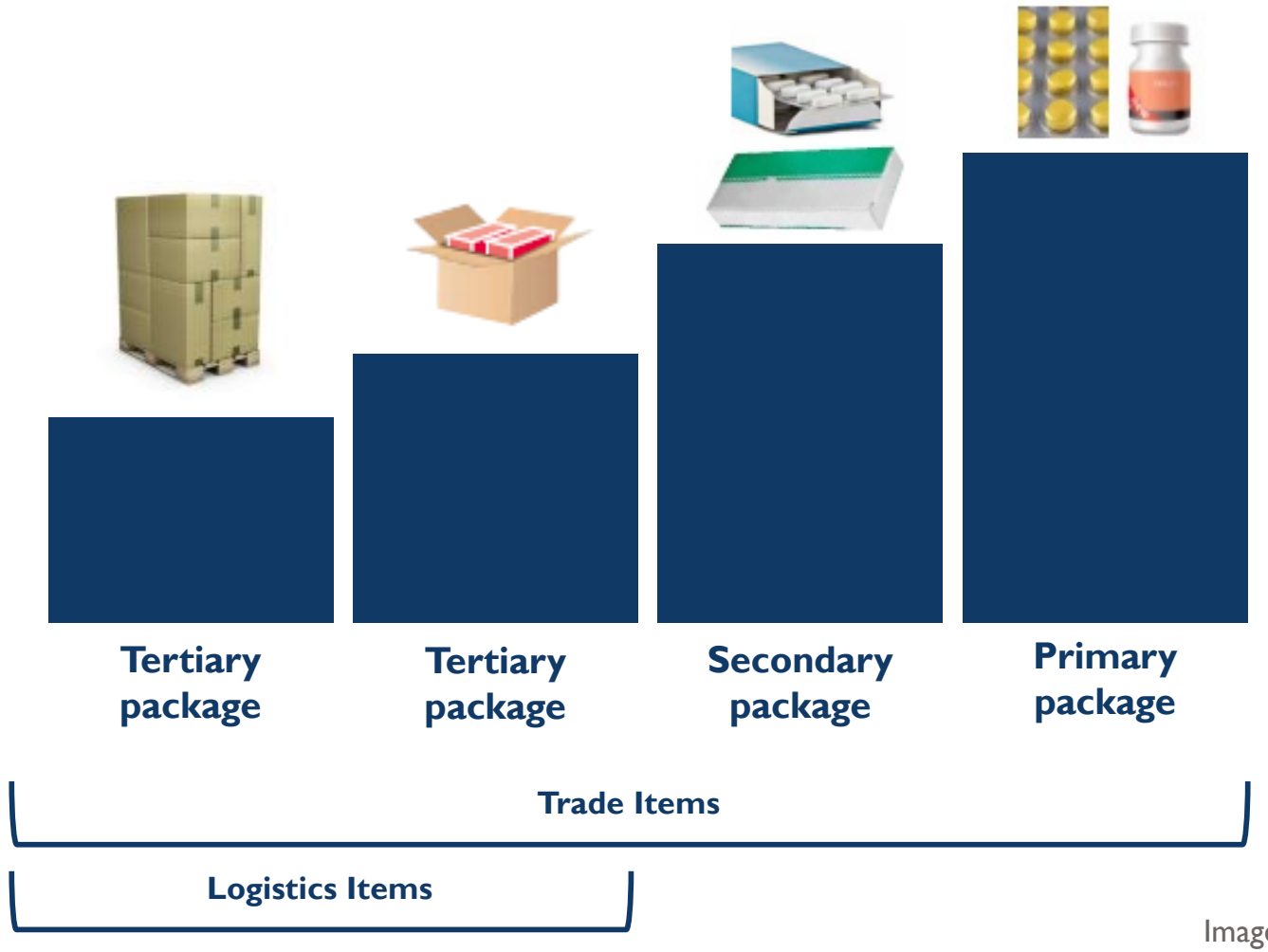
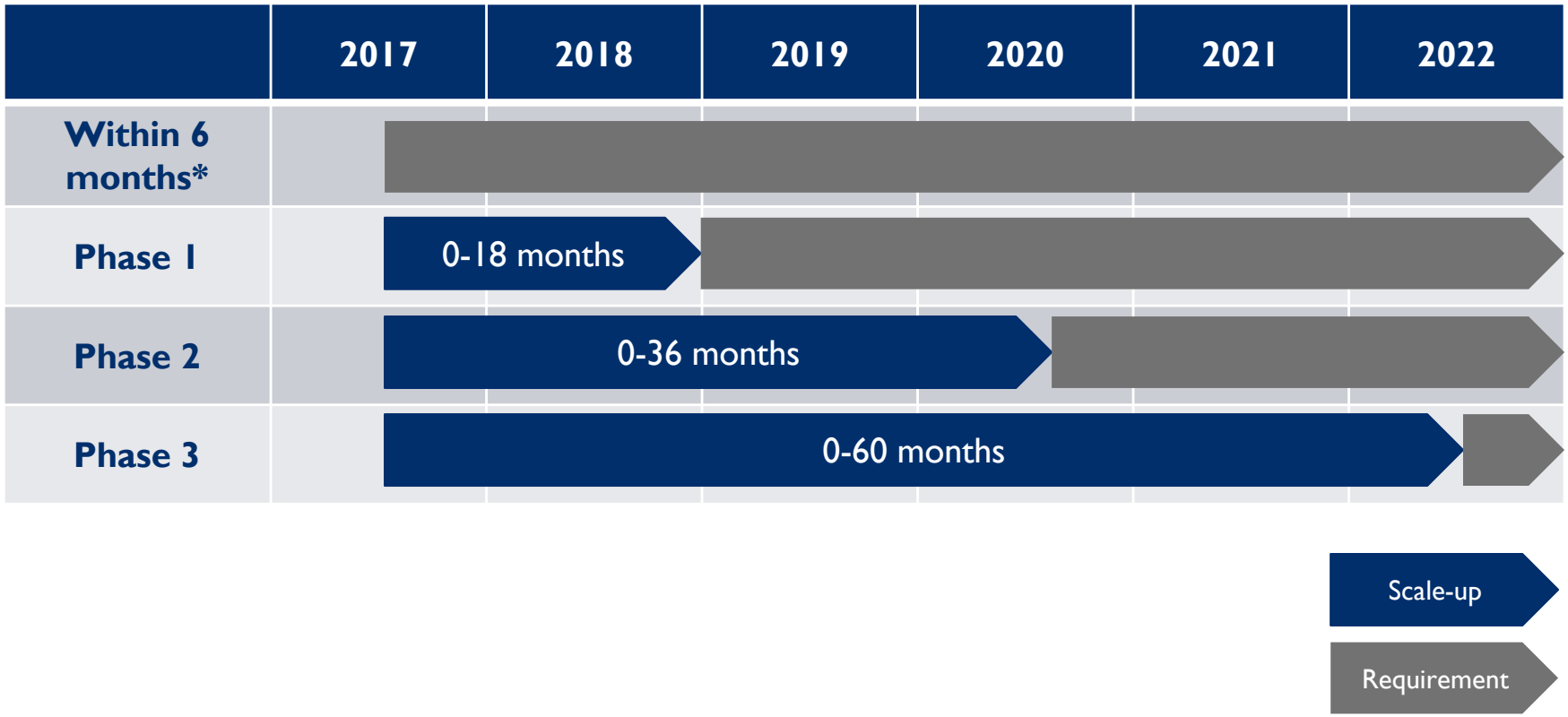


Image source: GS1 Global

Implementation will roll out in four phases



*Within 6 months of initial contract being signed

IDENTIFY

To identify, organizations need to register with GS1 to obtain a GS1 Company Prefix and assign numbers to items and locations.

	Within 6 months	Dec 2018
Secondary Packaging Multipack and/or Single Pack Carton (Trade Item)	✓ (01) Global Trade Item Number (GTIN) ✓ Other attributes as requested	
Tertiary Packaging Case/Carton (Trade Item)	✓ (01) GTIN ✓ Other attributes as requested	
Tertiary Packaging Pallet (Trade Item)	✓ (01) GTIN ✓ Other attributes as requested	
Location		✓ Global Location Number (GLN) Sold-from ✓ GLN Ship-from

GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811

CAPTURE

To capture, organizations need to apply relevant automatic identifier and data capture (AIDC) technology to packaging that includes required application identifiers and human readable interpretation (HRI)

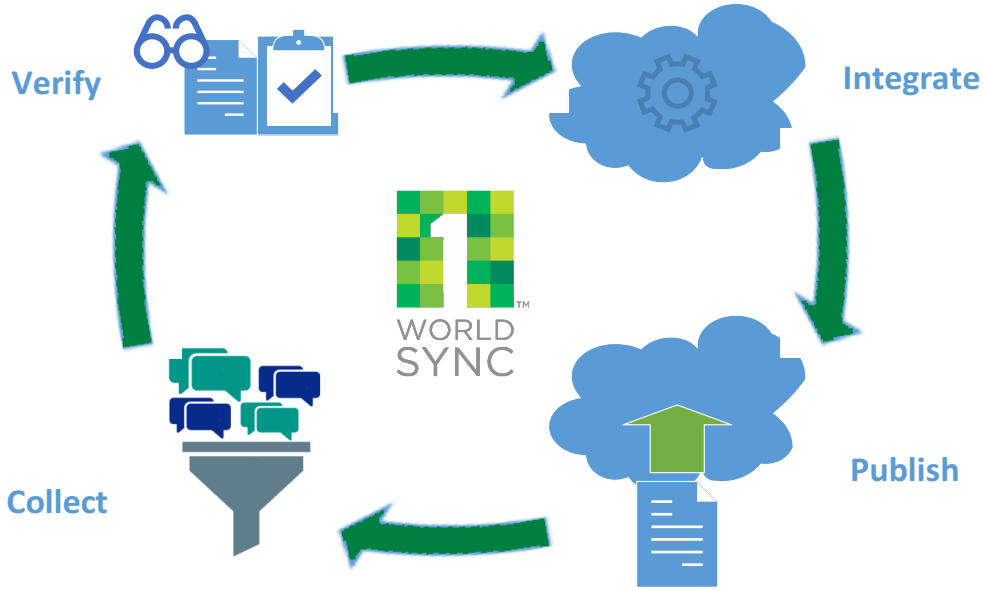
	AIDC	Dec 2018	Jun 2020	Jun 2022
Secondary Packaging Multipack/Single Pack Carton (Trade Item)			✓ (01) GTIN ✓ (10) Batch / Lot ✓ (17) Expiry	✓ +(21) Serial Number (pharma only)
Tertiary Packaging Case/Carton (Trade Item)		✓ (01) GTIN ✓ (10) Batch / Lot ✓ (17) Expiry		✓ +(21) Serial Number (pharma only)
Tertiary Packaging Pallet (Trade Item)		✓ (01) GTIN ✓ (10) Batch / Lot ✓ (17) Expiry		✓ +(21) Serial Number (pharma only)
Tertiary Packaging Case/Carton (Logistics Item)				✓ (00) Serial Shipping Container Code (SSCC)
Tertiary Packaging Pallet (Logistics Item)				✓ (00) SSCC

SHARE

To share, organizations need to register with GHSC-PSM's Supplier Portal for transactional data and the Global Data Synchronization Network (GSDN) for master data.

	Within 6 months	Dec 2018	Jun 2022
Master Data Products	✓ (01) GTIN ✓ Additional attributes		
Master Data Location		✓ GLN Sold-From ✓ GLN Ship-From	
Transactional Data Purchase Order (PO)	✓ (01) GTIN ✓ (37) Quantity	✓ +GLN Sold-from ✓ +GLN Ship-from ✓ +GLN Bill-to / Sold-to	✓ +GLN Ship-to
Transactional Data Advanced Shipping Notice (ASN)	✓ (01) GTIN ✓ (10) Batch / Lot ✓ (17) Expiry ✓ (37) Quantity	✓ +GLN Sold-from ✓ +GLN Ship-from ✓ +GLN Bill-to / Sold-to	✓ +SSCC ✓ +GLN Ship-to
Transactional Data Packing Slip	✓ (01) GTIN ✓ (37) Quantity	✓ +GLN Sold-from ✓ +GLN Ship-from ✓ +GLN Bill-to / Sold-to	✓ +GLN Ship-to
Transactional Data Invoice	✓ (01) GTIN ✓ (37) Quantity	✓ +GLN Sold-from ✓ +GLN Ship-from ✓ +GLN Bill-to / Sold-to	✓ +GLN Ship-to

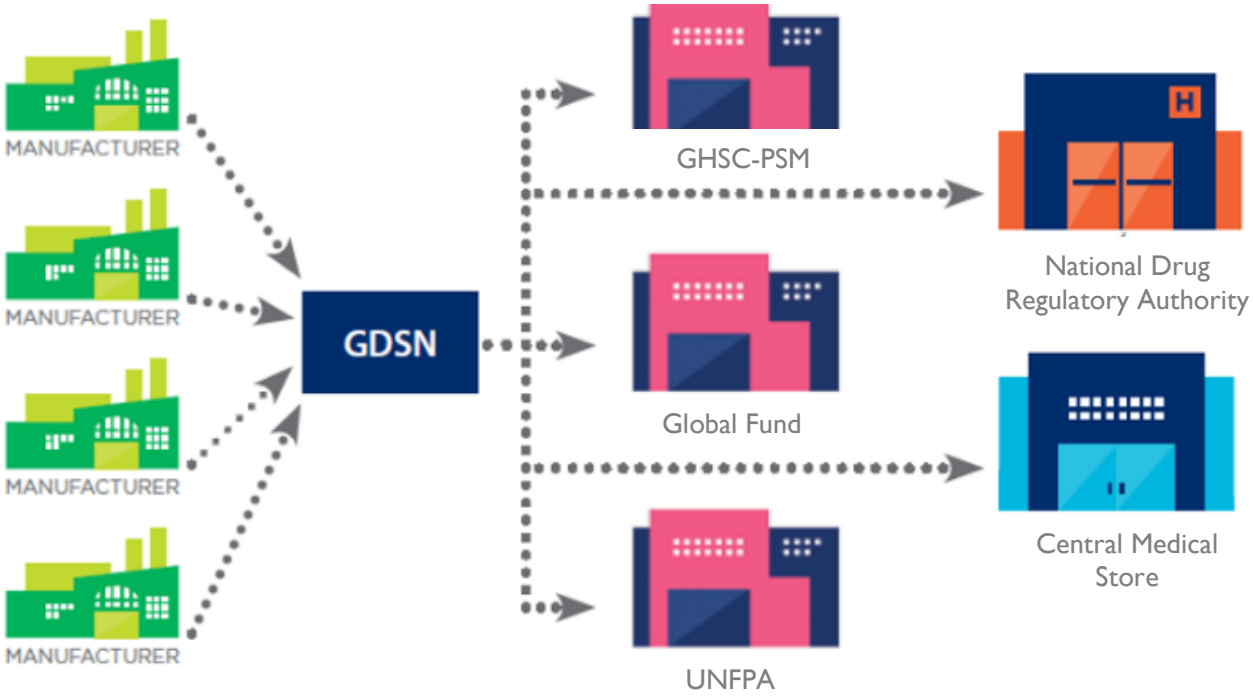
GHSC-PSM is using 1WorldSync as our GDSN data pool



1. Supplier registers with GS1 and obtains a company prefix
2. Supplier assigns GTINs to its products
3. Supplier registers with a GDSN data pool provider
4. Supplier provides product attributes based on GHSC-PSM's Attribute Guide through their GDSN Data Pool

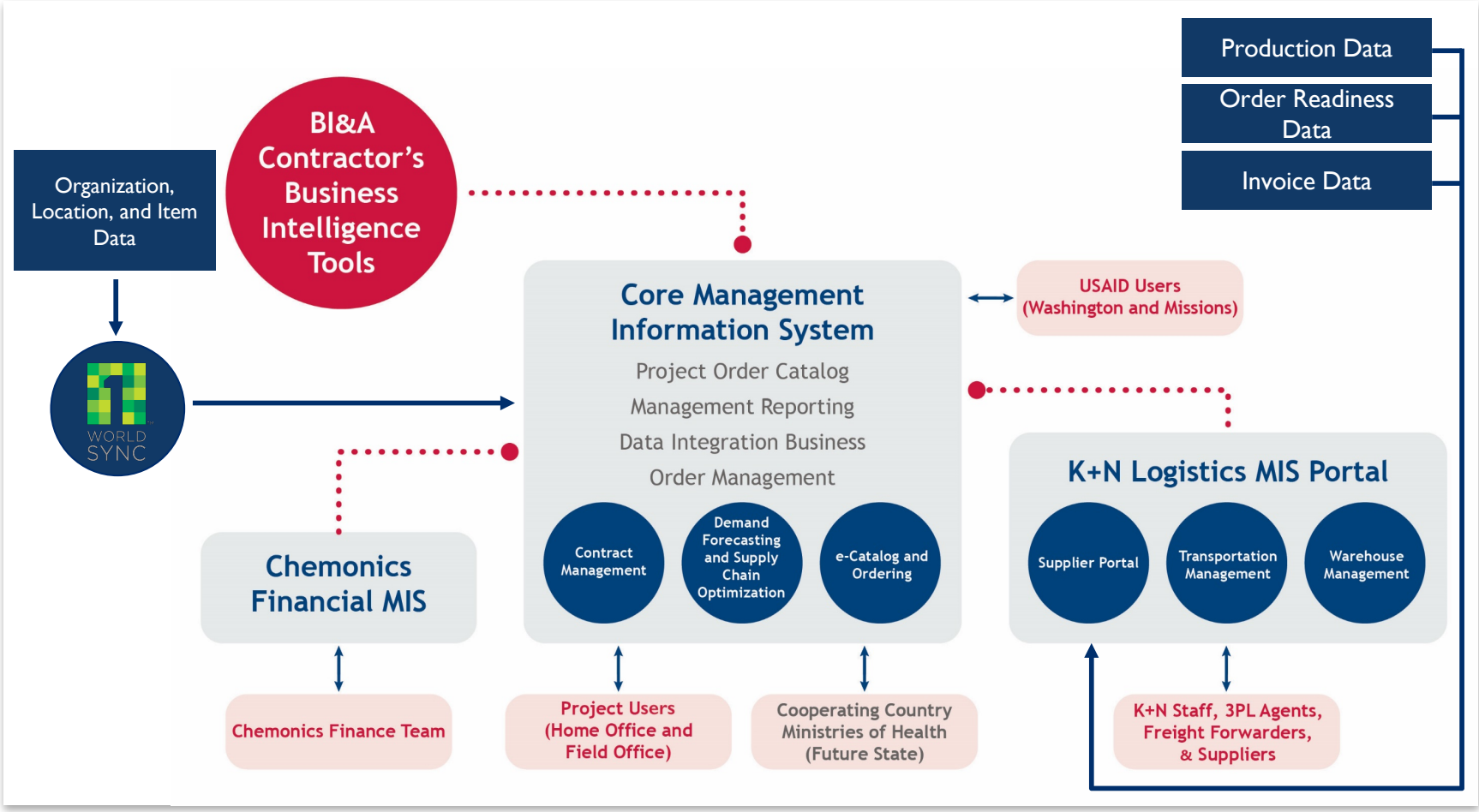
The GDSN opportunity for global health

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.

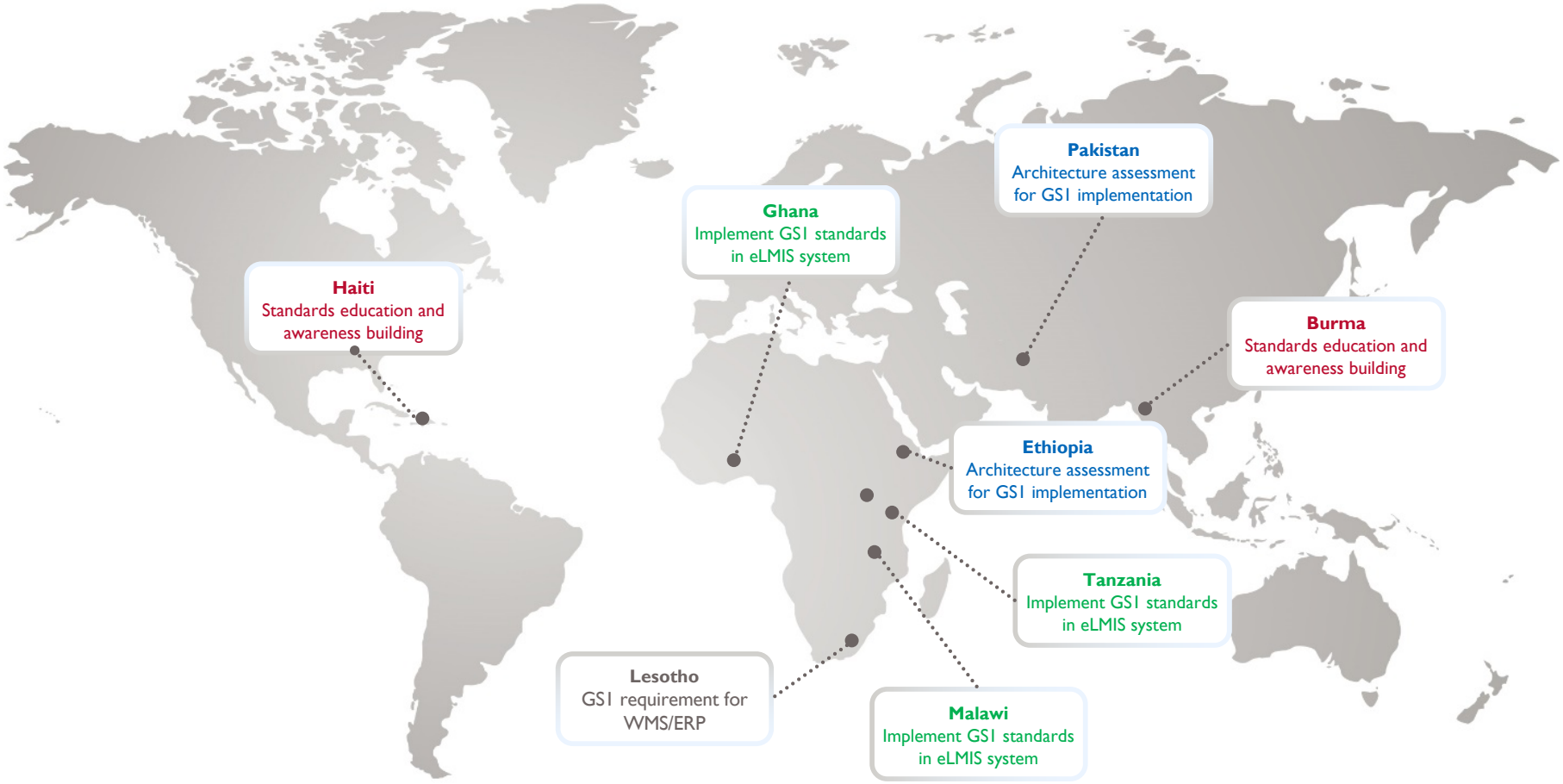
GDSN data will feed into ARTMIS and form the basis of the GHSC-PSM product catalog



Opportunities for GHSC-PSM with GDSN

- 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

GHSC is supporting standards implementation in several countries



GHSC-PSM has developed preliminary technical guidance for country programs

USAID Global Health Supply Chain Program
Procurement and Supply Management

GS1 Global Standards
Work Planning for Country Programs

The purpose of this document is to provide GHSC-PSM country program offices with a guideline on key considerations for your FY18 work plans and budgets around global standards implementation activities.

WHAT IS GS1?

GS1 is a non-profit, international standards organization with offices both globally and locally through more than 119 member organizations. GS1 has developed a global system of standards to ensure visibility through the supply chain in the areas of product and location **identification**, data **capture**, and master, transactional, and event **data exchange**.

USAID Global Health Supply Chain Program

The USAID Global Health Supply Chain Program includes nine projects aimed at strengthening health supply chain systems. The Procurement and Supply Management project provides procurement and logistics services, strengthens supply chain systems, and promotes global collaboration.

For Questions about GS1 Global Standards

Kaitlyn Roche
Manager for Global Standards
kroche@ghsc-psm.org

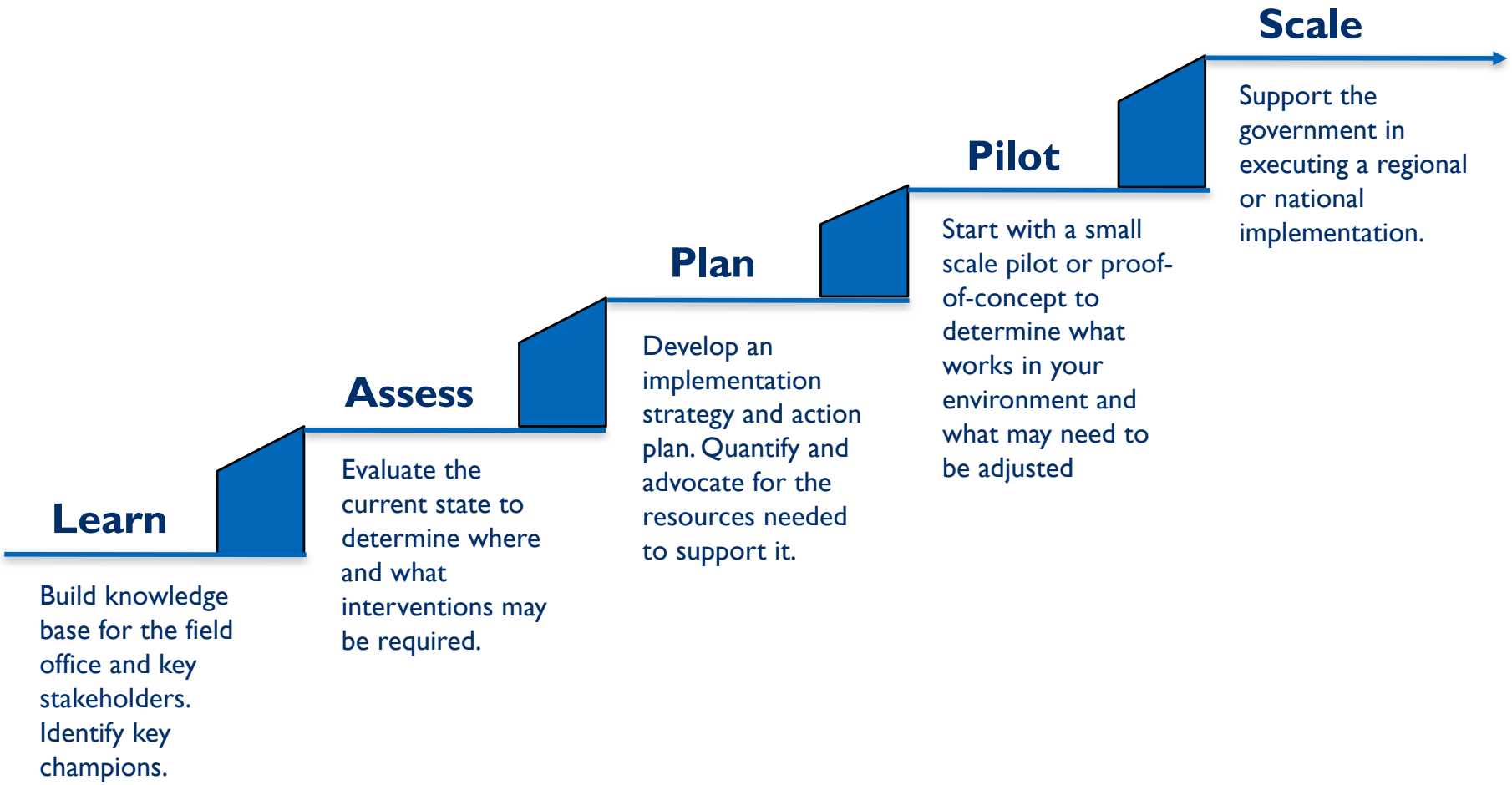
Global Standards Strategic Task Force
globalstandards@ghsc-psm.org

USAID FROM THE AMERICAN PEOPLE · PEPFAR · USAID U.S. President's Malaria Initiative · CDC

Version 1.0

PHASE	Activities to Consider
Learn	• Identify a global standards champion within your GHSC-PSM field office • Attend GS1 Global Healthcare Conferences including October 2017 in Chicago, US and April 2018 in Bogota, Colombia • Attend GHSC-PSM (to be developed) and industry webinars on global standards, authentication, and track and trace • Develop a Global Standards Working Group or other forum for building knowledge and socializing ideas • Develop a vision and high-level action plan to achieve it
Assess	• Work with regulatory agencies to review existing regulatory and procurement requirements to determine gaps around product identification and labeling • Engage your country's supplier base to understand current GS1 capabilities • Review your country's Master Data Management approach and governance structures and develop recommendations for standardization • Review supply chain processes (e.g. procurement, warehousing and distribution) and transactional documentation to identify where global standards may bring efficiencies • Undertake a systems architecture assessment to determine whether current systems are able to support the GS1 standard • Identify key priority areas where your country may want to focus future interventions (i.e. product authentication, track and trace)
Plan	• Generate demand for global standards through holding workshops and trainings for key stakeholders including the National Drug Regulatory Authority, Ministry of Health, and other implementing partners • Develop an implementation road map for regulation, procurement, MIS, and/or warehousing & distribution, taking into account a phased approach and realistic timelines • Establish national benchmarks and key performance indicators • Design a pilot or proof-of-concept with key stakeholders • Develop an application to support implementation
Pilot	• Execute one or more targeted pilots and document successes, lessons learned, and areas for improvement • Develop a plan to take the proof-of-concept to scale • Determine future capacity building requirements and develop a plan for training and education
Scale	• Support regulation and/or national requirements development • Integrate standards into supply chain processes and procedures • Lead trainings for supply chain and public health human resources

Proposed approach



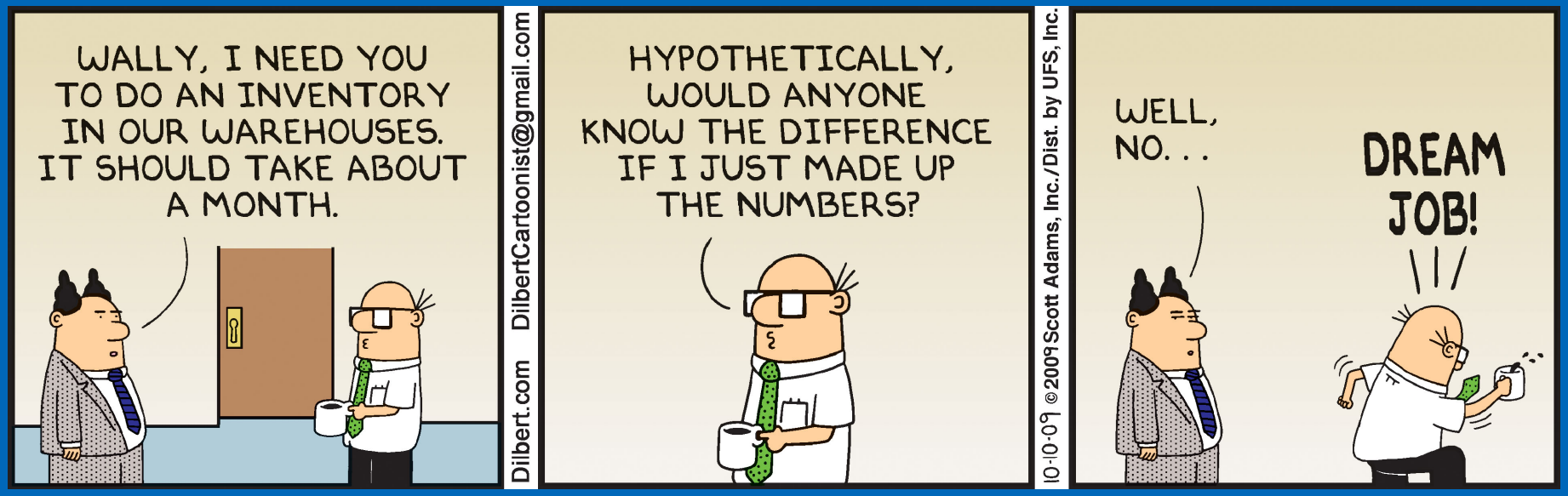
What's next?

- **Q4 CY 2017**
  - Publish the business case for standards at GHSC-PSM
  - Formal requirement language for supplier contracts
  - Technical implementation guideline
- **Q1/Q2 CY 2018**
  - GDSN campaign launch
  - Country implementation guideline
  - Review of D/R processes and documentation
  - Training, knowledge management, communications dissemination
  - Implementation roadmap for small, regional, or local manufacturers

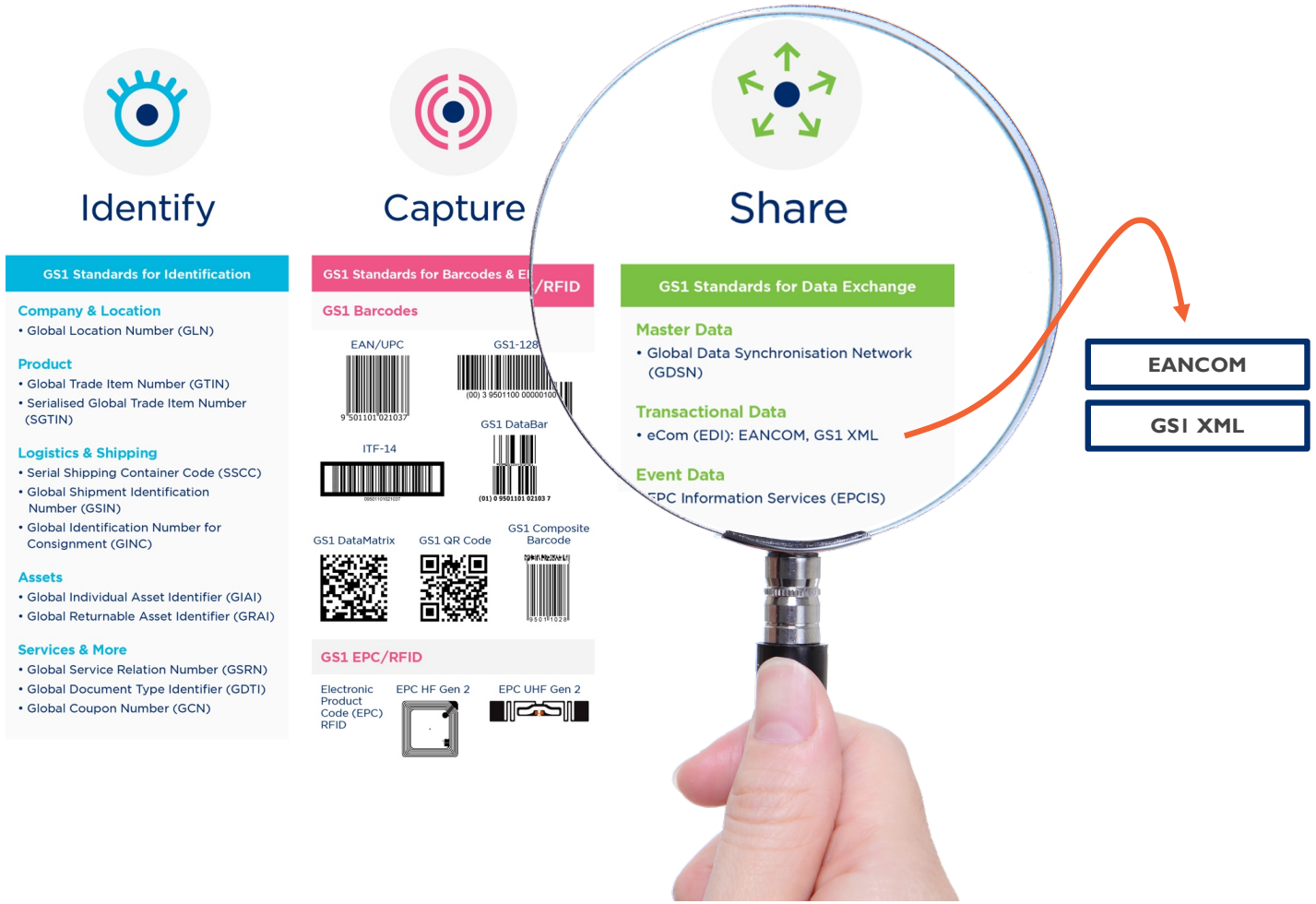
Quiz time!

- What is GHSC-PSM's first requirements deadline?
- Who is GHSC-PSM's GDSN data pool provider?
- What other global health partners are also implementing GS1 standards?
- Which countries have activities that incorporate GS1 standards?

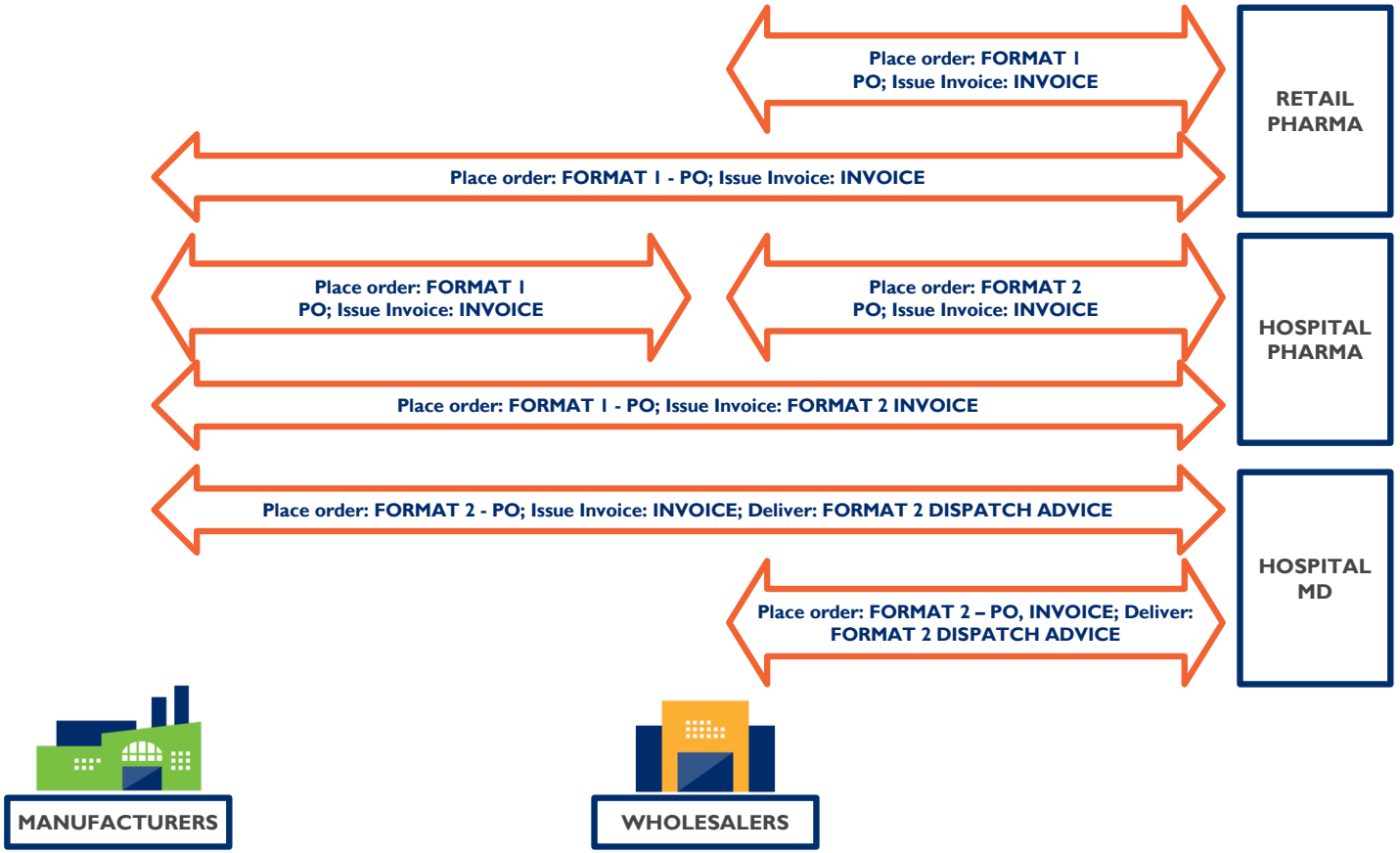
Electronic Data Interchange (EDI) in Healthcare



GS1 EDI standards



EDI in healthcare



EDI implementation drivers

1. HELPING TO ENSURE QUALITY OF CARE
2. MEETING REGULATORY OR TRADING PARTNER REQUIREMENTS
3. FACILITATING PRODUCT TRACEABILITY
4. INCREASING EFFICIENCY, ACCURACY, REDUCING COST
5. ENABLING NEW BUSINESS PROCESSES

Design principles for GS1 EDI

- **Master Data alignment**
  - ✓ Foundational info must be agreed & shared pre-EDI
  - ✓ Use of GS1 globally unique identifiers – GS1 Keys
  - ✓ Only coded information (machine readable)

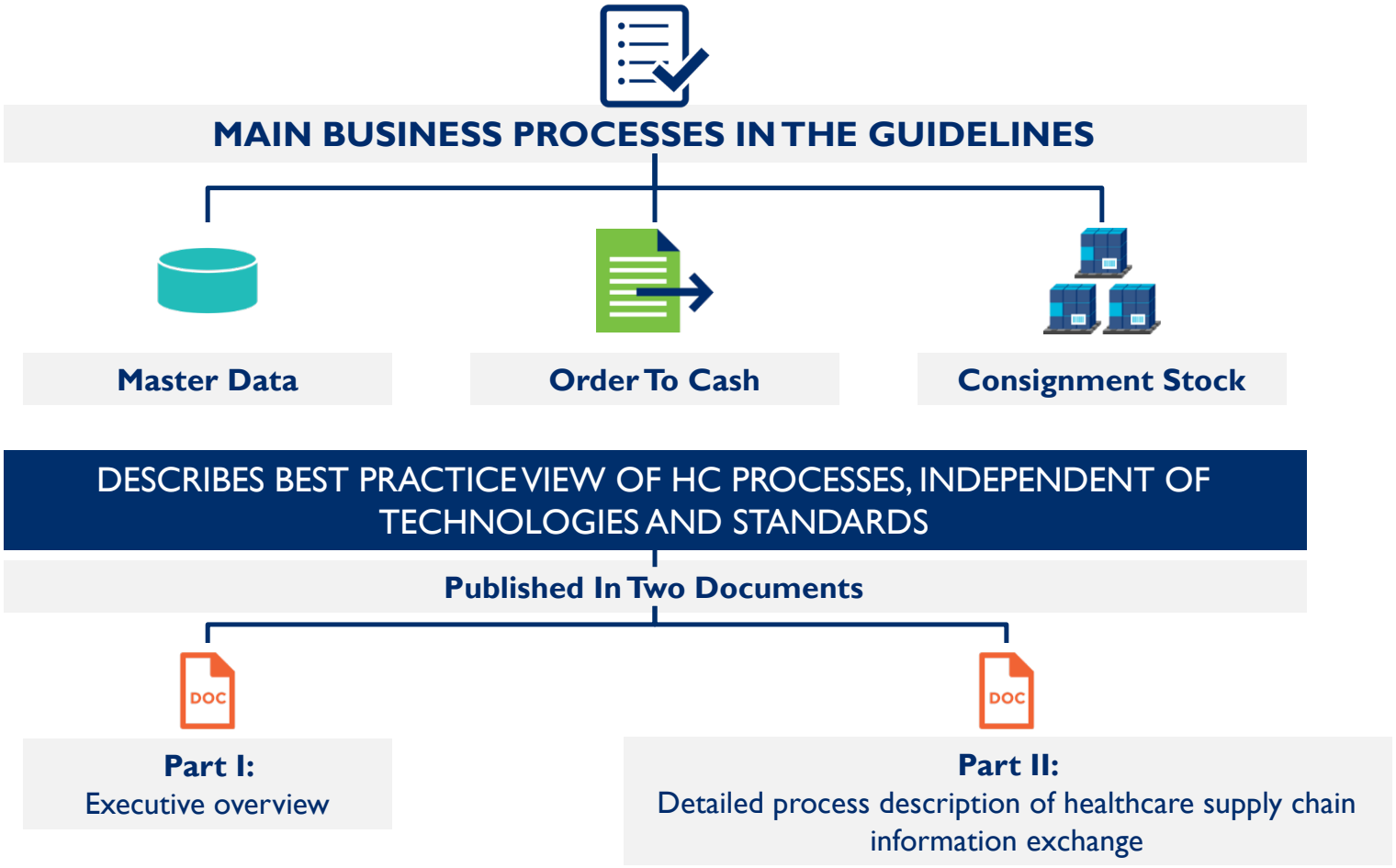
- **Guidelines**
  - ✓ Global guideline comprises core processes and data
  - ✓ Local guidelines add local requirements (e.g., regulatory)

Global guideline for EDI

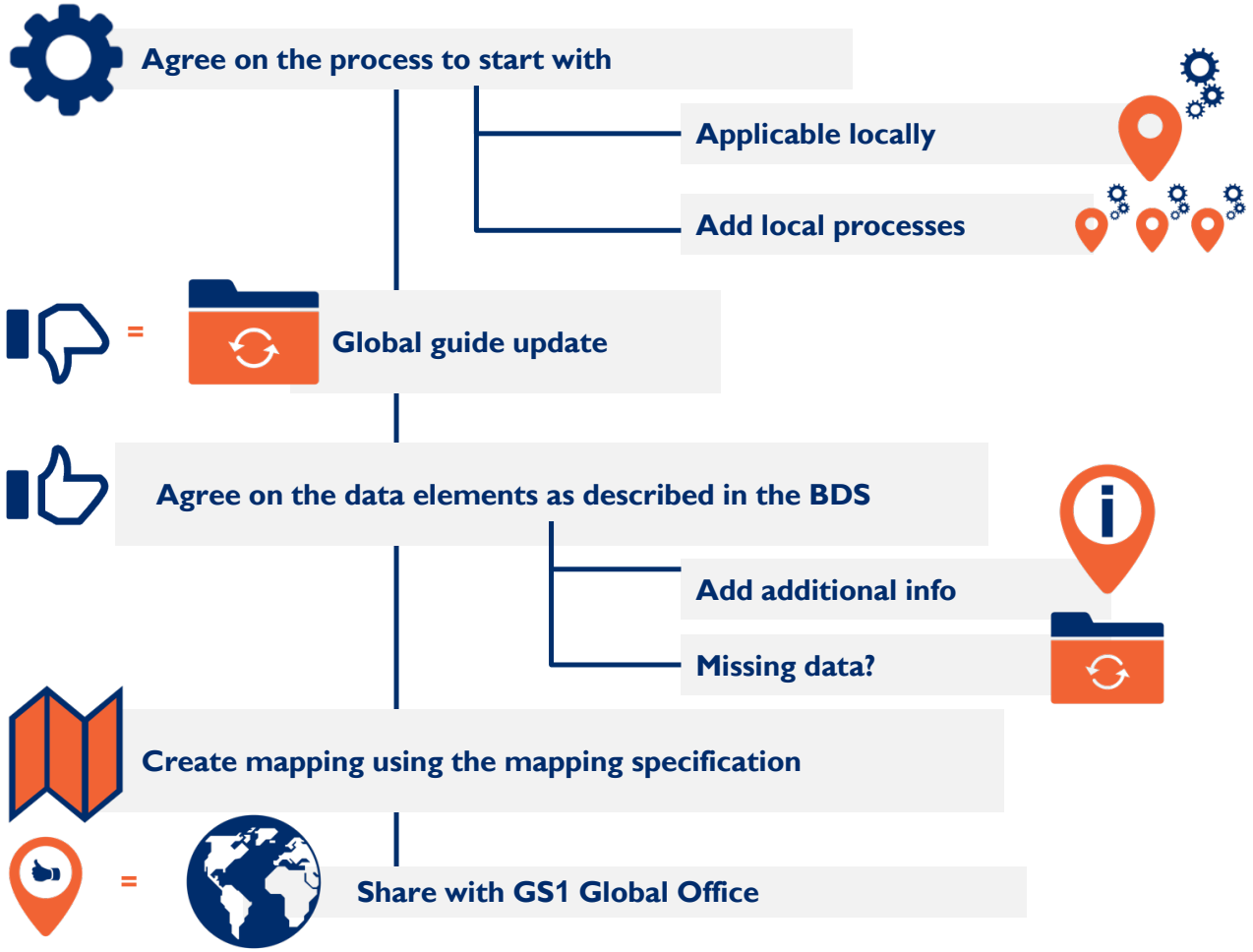
- Business contents and technical information is separated

1. HEALTHCARE BUSINESS PROCESS MODEL
2. BDS - BUSINESS DOCUMENT SPECIFICATION
3. BDS SUMMARY
4. MS EANCOM – MAPPING SPECIFICATION
5. MS XML– MAPPING SPECIFICATION

Healthcare business process model



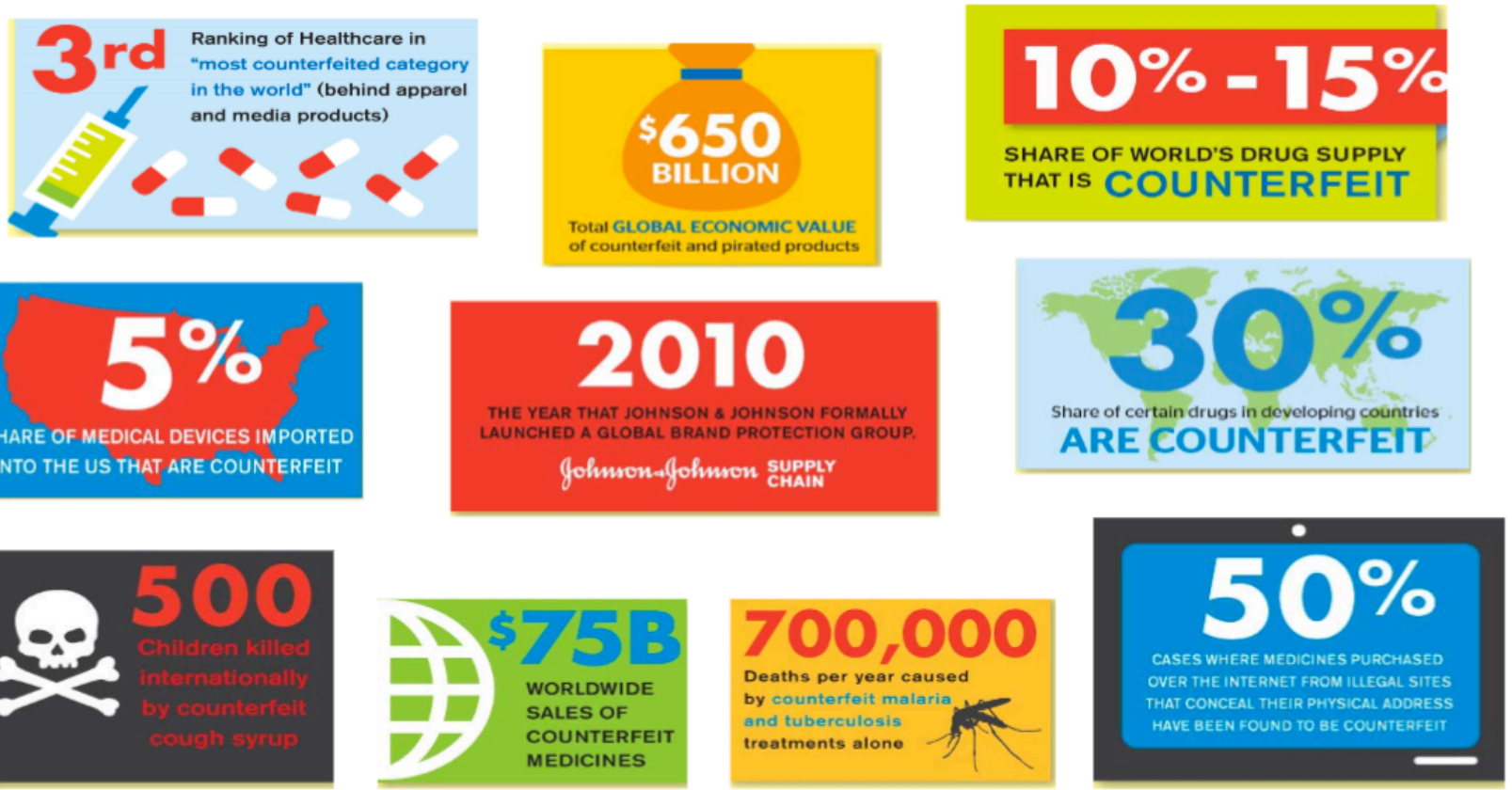
How to use the global guideline when creating local guidelines



Event-based Traceability in Healthcare

Why serialization and track and trace?

Counterfeit and diverted products are a global problem… but especially in Africa!



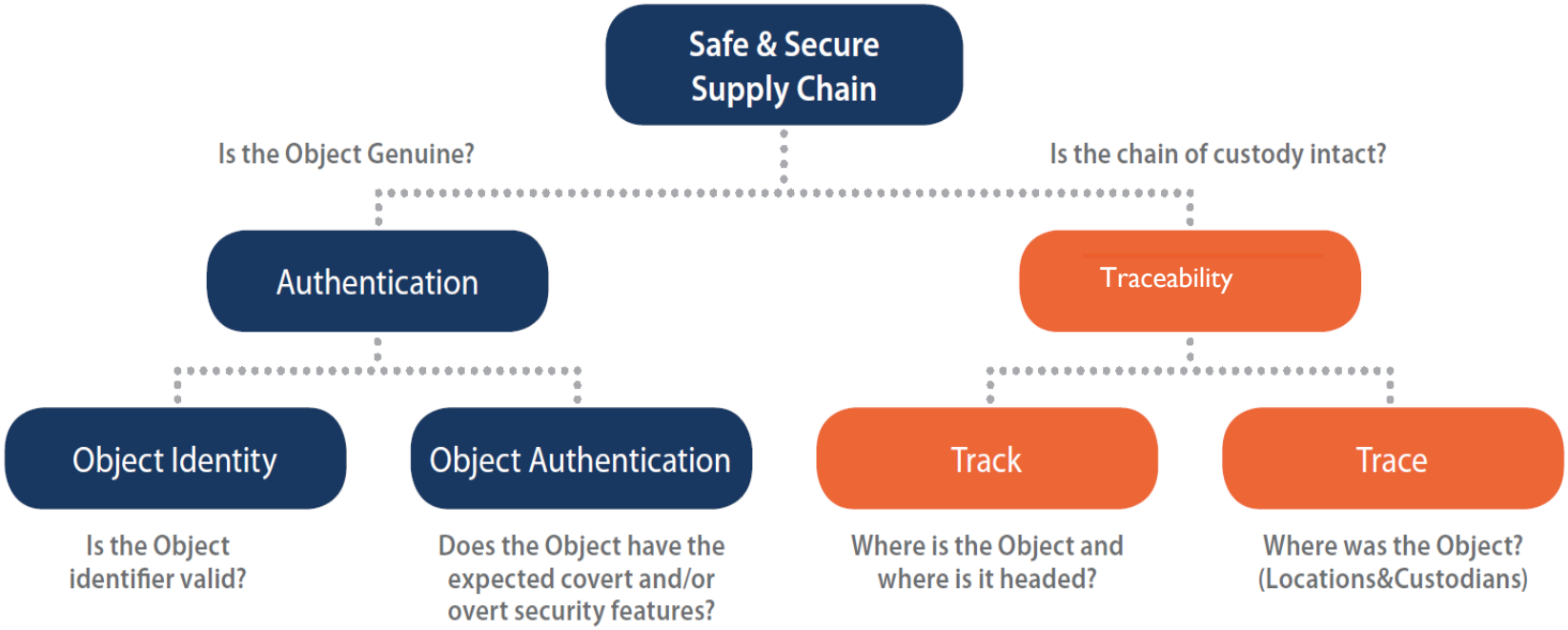
Credit: Chris Reed, Johnson & Johnson

Traceability/Visibility

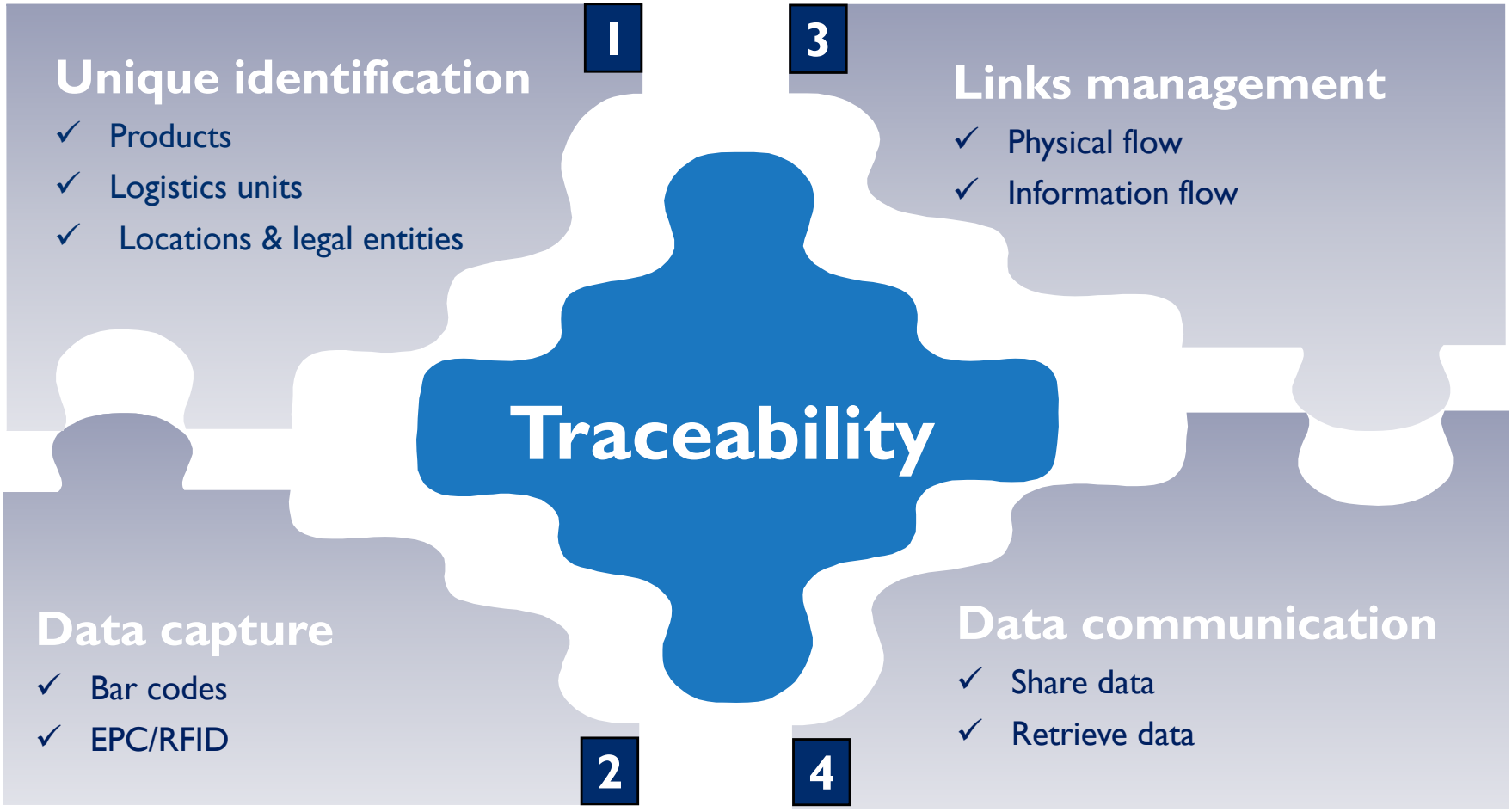
- Where is the product now?
- Where has it been? Who owned it?
- When has it been shipped/delivered/received?

Different Approaches

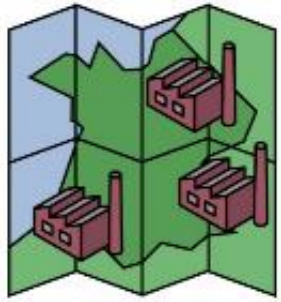
- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced from where it has been?



Building Blocks for Traceability



Enables Supply Chain Visibility



- **Tracking**

  Where are the pharmaceuticals I shipped?

- **Tracing**

  Where did this batch of pharmaceuticals come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**

  Which parties had custody of these pharmaceuticals?

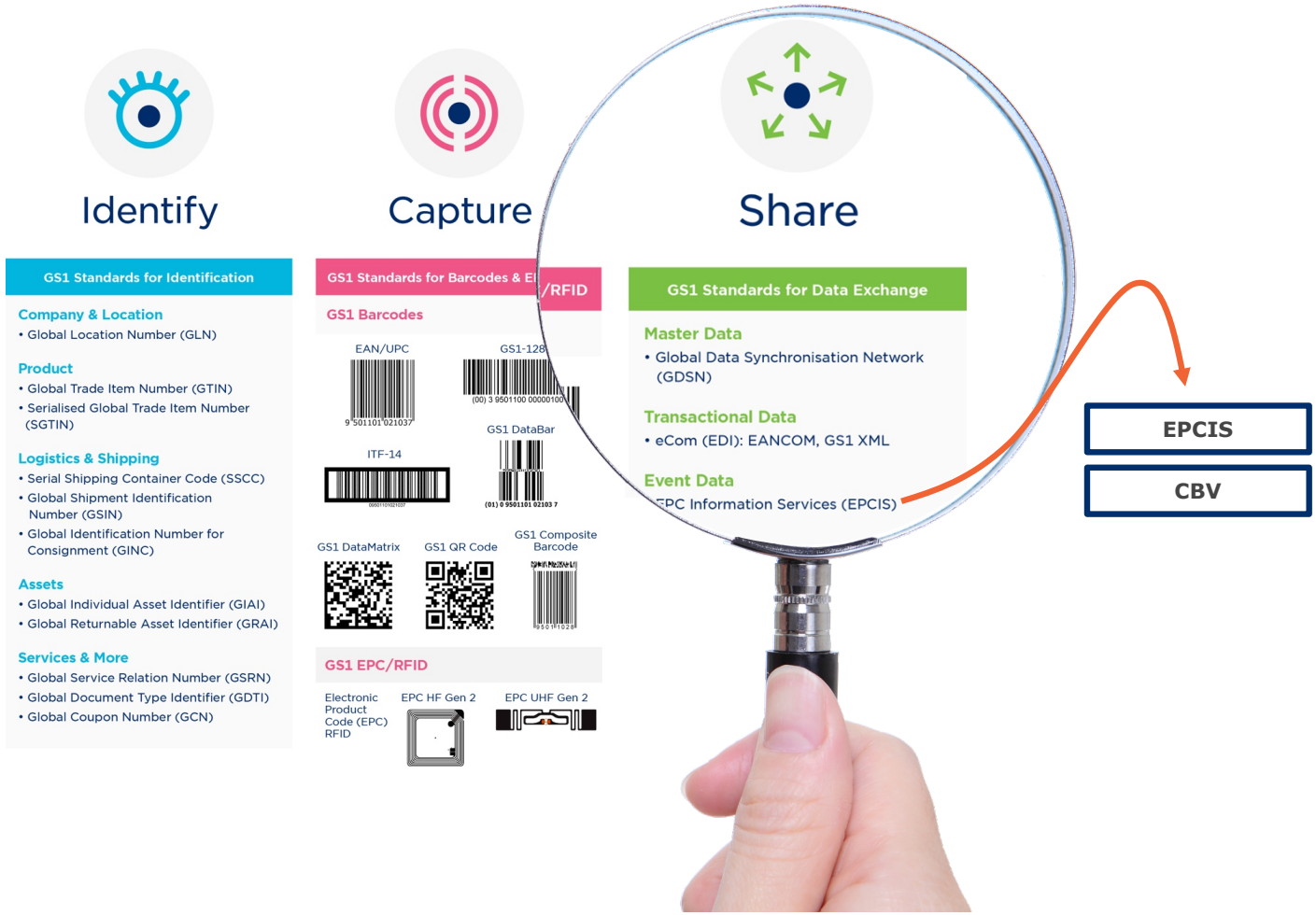
- **Recall**

  Where were meds produced on 14 April shipped to?

- **Asset Management**

  Where are all of the hospital's balloon pumps?

EPCIS: a GS1 "Share" standard



What is EPCIS?

- A GS1 standard that enables trading partners to share information about events – physical movement and status of products through the supply chain
- It does not replace an ERP, WMS or Track and Trace system; it is a complimentary layer that offers interoperability between disparate systems.
- EPCIS is intended to be used in conjunction with the GS1 Core Business Vocabulary (CBV) standard. The CBV provides definitions of data values that may be used to populate the data structures defined in the EPCIS standard.
- The use of the standardized vocabulary provided by the CBV standard is critical to interoperability and critical to provide for querying of data by reducing the variation in how different businesses express common intent.

EPCIS is an open GS1 and ISO standard

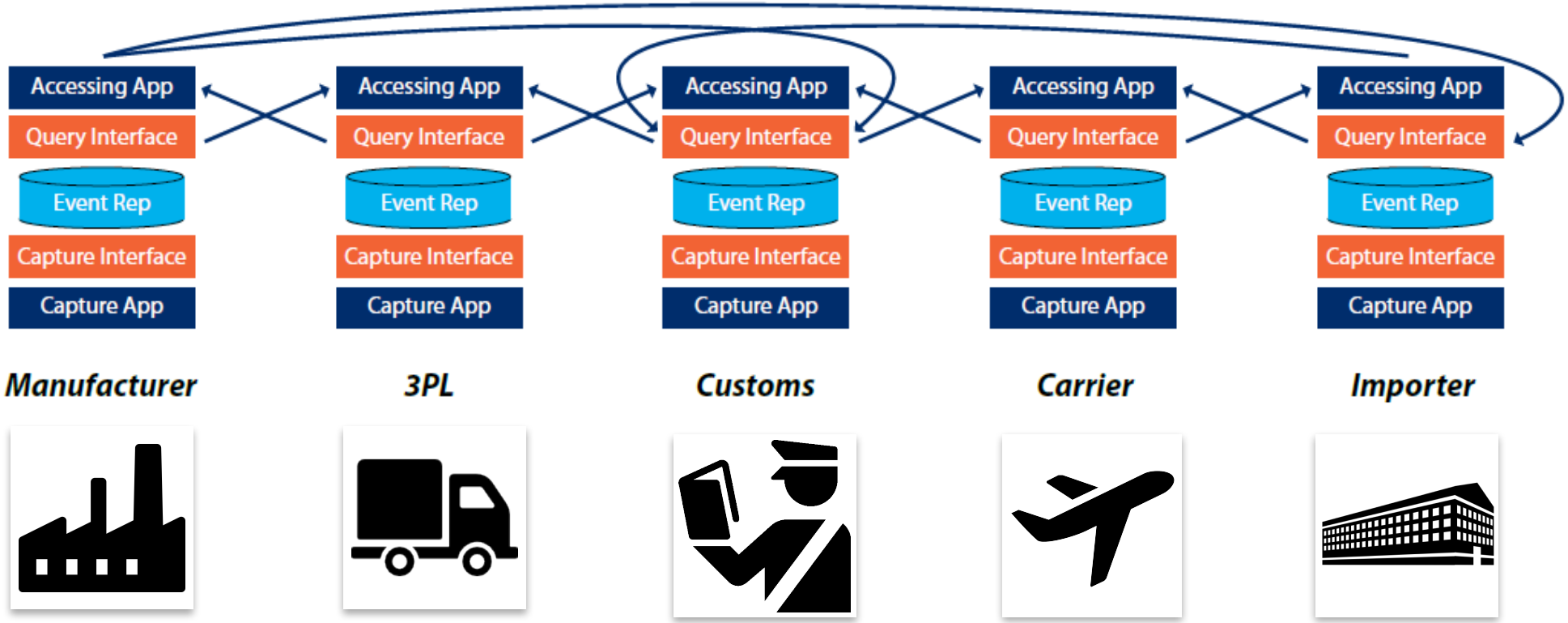
- Defines framework data model & interfaces for sharing data
- Enables services and solutions for supply chain visibility
- Data-carrier-neutral: works with Barcodes and/or RFID
- Approved as ISO/IEC 19987
- EPCIS is an open standard, not a product or service for sale
- US FDA draft guidance points to EPCIS as a way to **interoperably** exchange pharmaceutical traceability data
- GS1 Keys identify the "What" & "Where" of visibility events…

Sharing information on events

- **WHAT** objects are the subject of event?
  - *Individual objects (SGTIN) or groupings (GTIN + Lot/batch)*
- **WHEN** did this event take place?
  - *Date, time, time zone*
- **WHERE** did this event take place?
  - *GLN of physical location and object's subsequent whereabouts*
- **WHY** did this event take place?
  - *Business step, Disposition, Source/Destination info*

All captured in an EPCIS repository!

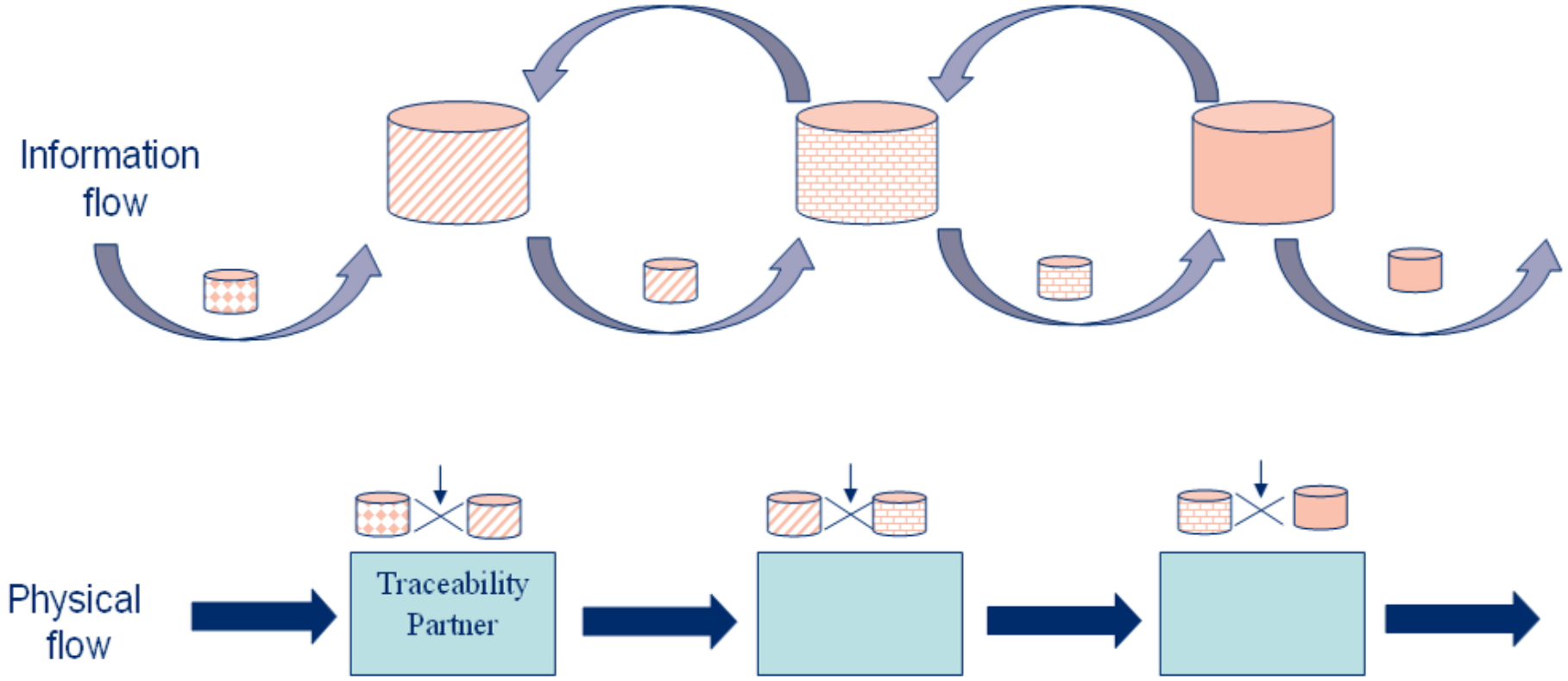
EPCIS end-to-end data visibility



EPCIS enables tracking and tracing AND easy sharing of event data in real-time among trading partners up and downstream

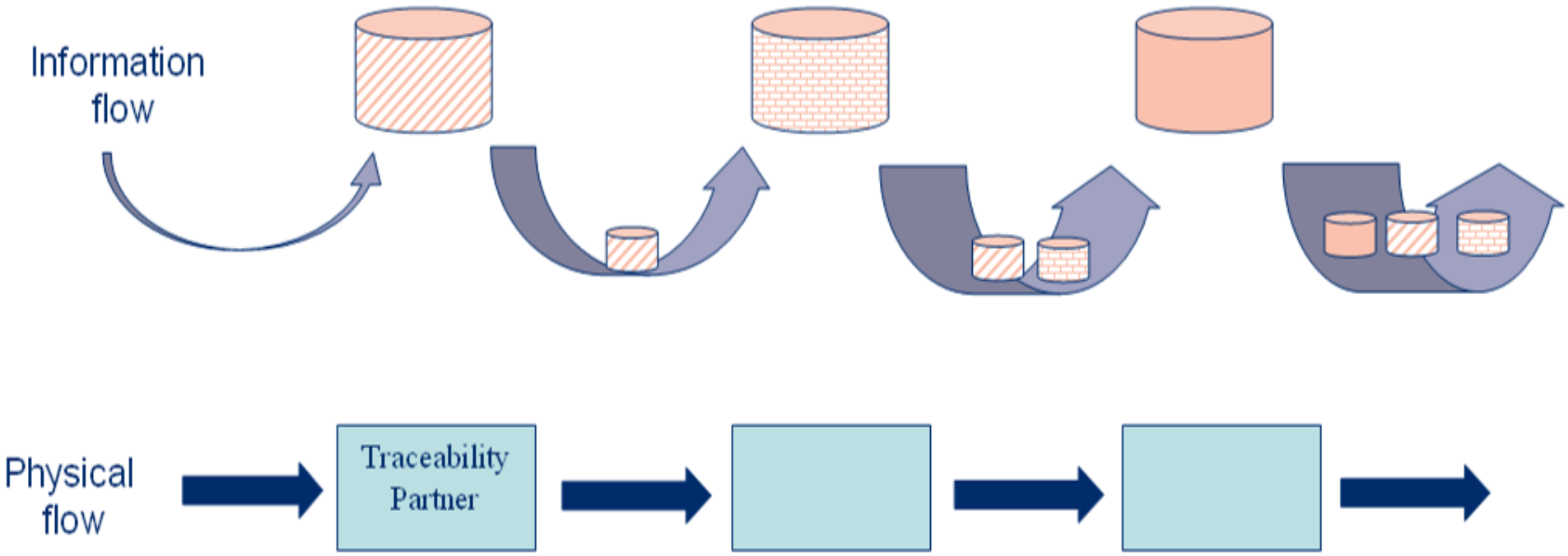
1. One Up, One Down

- Point-to-point information sharing for day-to-day operations
- Data sent upon request to previous actor on ad hoc basis



2. Cumulative Tracking*

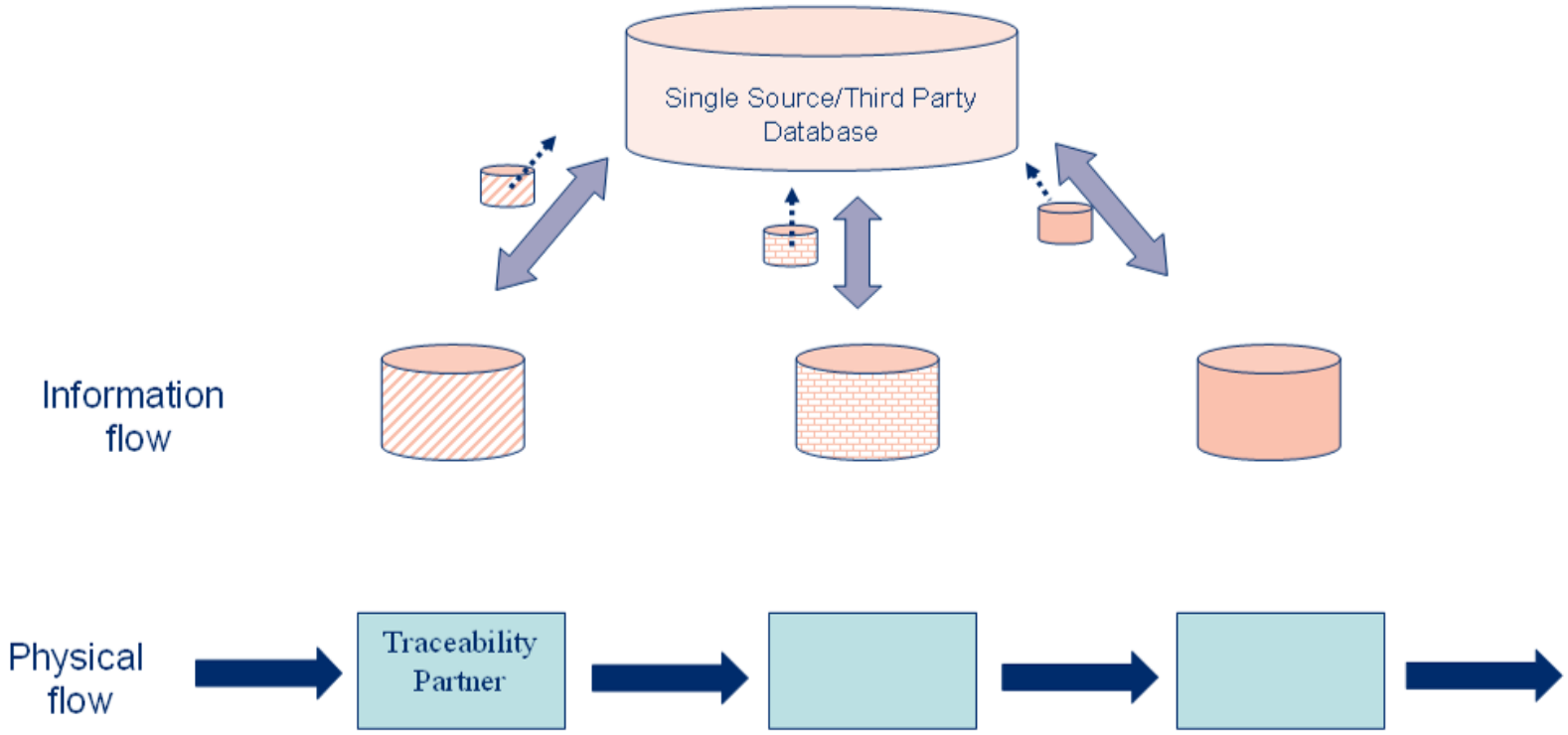
Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.



*Also known as former California ePedigree

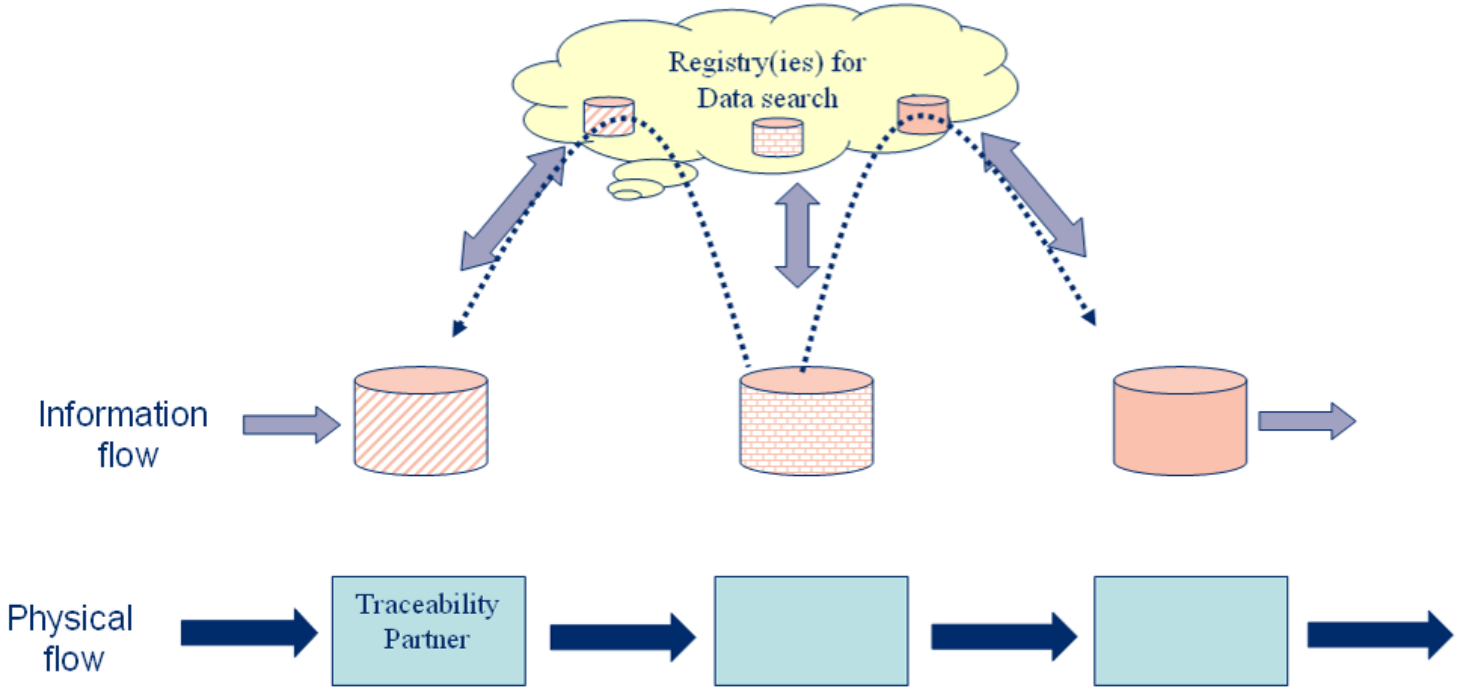
3. Central Database

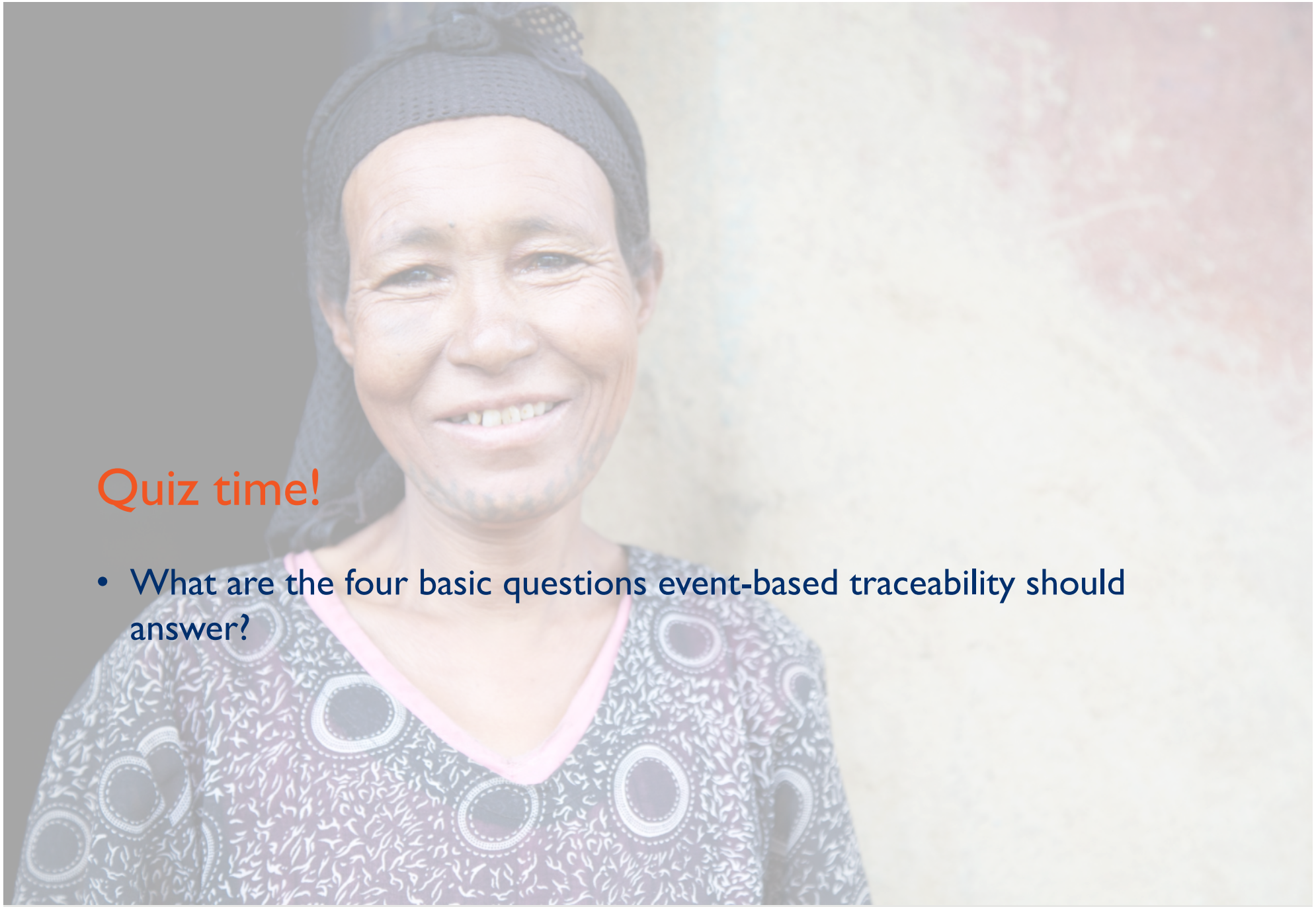
The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a Third Party/regulatory body.



4. Distributed Model

- Traceability identification keys available in a registry to enable traceability data search
- information can be stored anywhere as the registry provides the link and data search mechanism.





Quiz time!

- What are the four basic questions event-based traceability should answer?

Global regulatory environment

GS1 Healthcare aims for harmonization of regulatory requirements across the world

- A global standardized system is needed for "unique" identification numbers to ensure world-wide supply chain compatibility.
- **THE RESULT**

  Prevent counterfeit drugs entering the market, gain efficiency, have the right product in the right place at the right time, more effective recalls, and ultimately, improve patient safety

Data elements on which regulatory bodies agree

Data Matrix – Coding proposal derived from GS1 standards

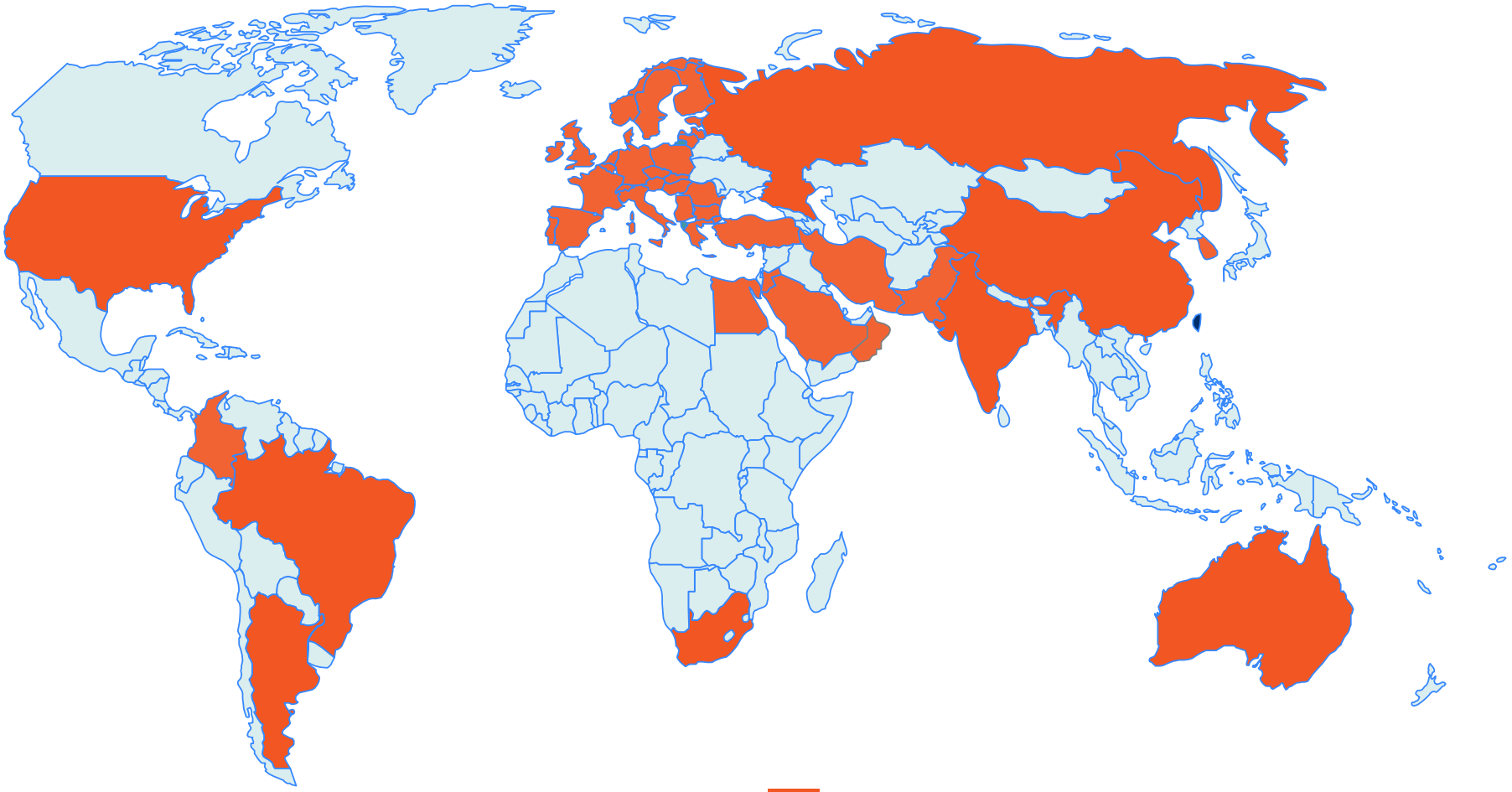
- Manufacturer Product Code (GTIN or NTIN): 14 digits
- Unique Serial Number (randomized): up to 20 alpha-numeric characters
- Expiry Date: 6 digits (YYMMDD)
- Batch Number: up to 20 alpha-numeric characters

Example:

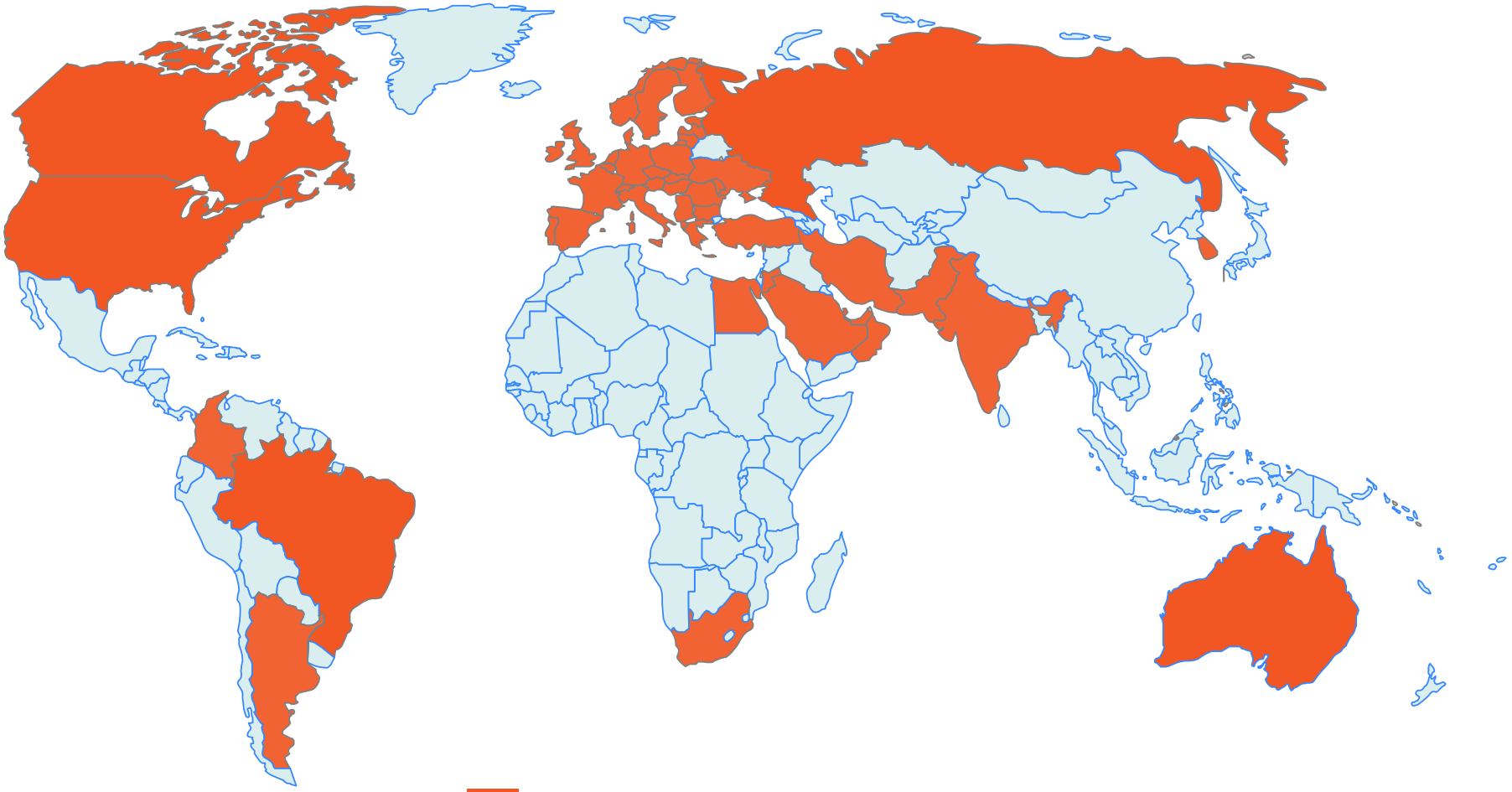
GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811

Specifications provided in EFPIA's: "European Pack Coding Guidelines"

Serialisation of pharmaceuticals



GS1 DataMatrix on pharmaceuticals



Country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots

United States

Drug Supply Chain Security Act (DSCSA)

Scope: Pharmaceuticals (prescription drugs)

Purpose: Traceability, combat counterfeit

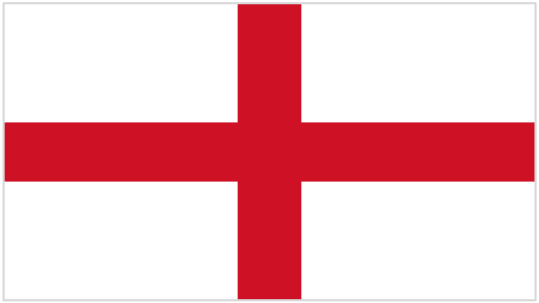
Requirements:

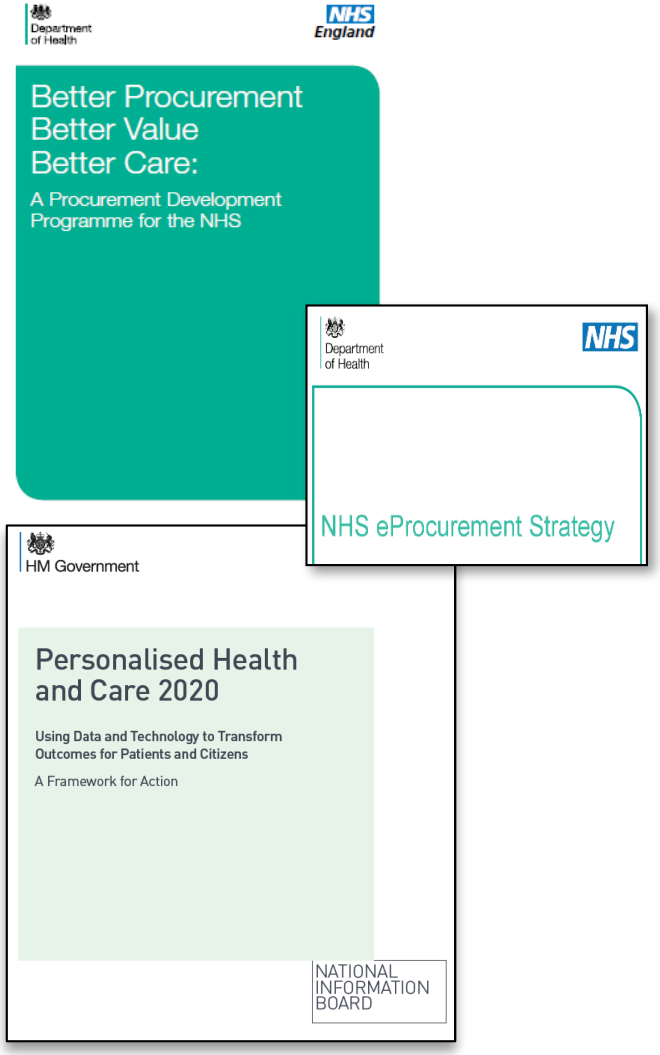
- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines
  - First phase lot based (2015) – delayed to 1 March 2016 for dispensers
  - Serialisation (SNI) after four years (Nov. 2017)
  - Full track & trace after 10 years (2023)

Traceability Model: First lot based traceability, full track & trace in 10 years

Open point(s)/upcoming dev: US FDA points to **EPCIS** as one of possible way for exchange of traceability data in their draft guidance, industry alignment

England
National Health Service





Objectives:

- Deliver efficiency and productivity gains
- Improve data, information and transparency
- Re-think clinical engagement in procurement
- Improve trust capabilities in procurement

Actions:

- **Mandate through contracts GS1 standards GTIN, GLN and GDSN**
- **Create a single NHS GS1 data pool**
- Define standards for eProcurement
- Establish standards for datasets/classification
- Put implementation support in place

Medicines traceability - where else?

China
CFDA suspended the drug monitoring system in February 2016; public consultation on new system.

India
Central traceability portal (DAVA) now established. All packaging levels for export – primary excluded for the moment. Next steps: regulation for domestic market.

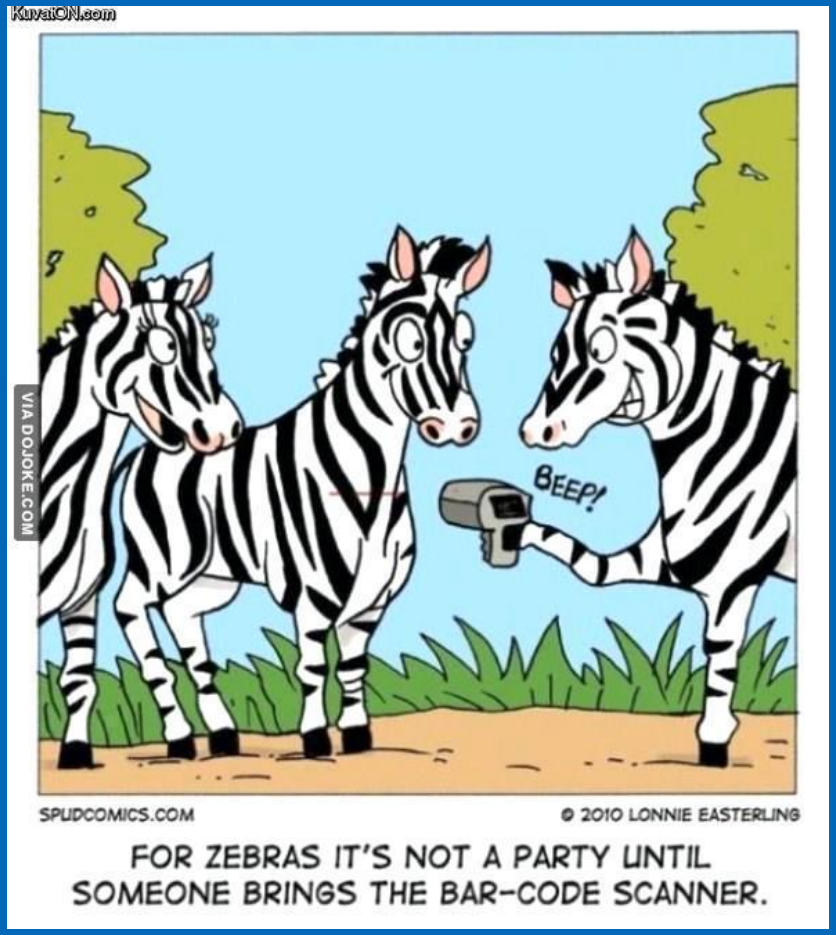
South Korea
A central traceability portal – secondary packaging level with aggregation – reporting of serialization still voluntary

Argentina
ANMAT successfully established traceability with central database, deployed on a category by category basis

Brazil
ANVISA track and trace 2020 – regulation released RDC 157 / 2017 has been released on 11 May 2017, applicable to a pilot and will be reviewed afterwards

Russia
No clear information on the requirements for barcoding in the Russian DRAFT regulation establishing the national system of drug traceability. Serialization pilot project by global manufacturers using GS1 standards.

Global health developments



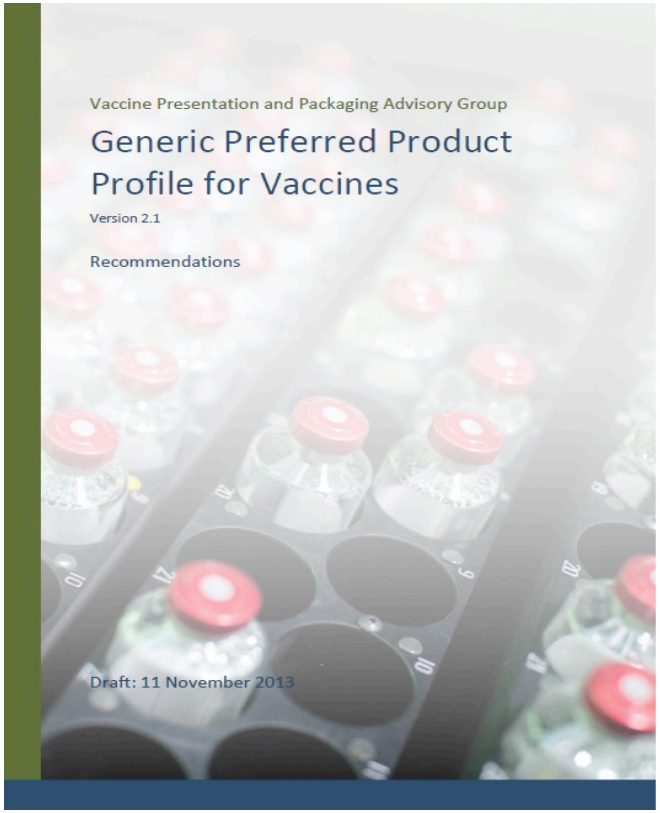
Supply chain in developing countries

Often the supply chain is broken

- Drugs are expired or not stored correctly
- Products are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled

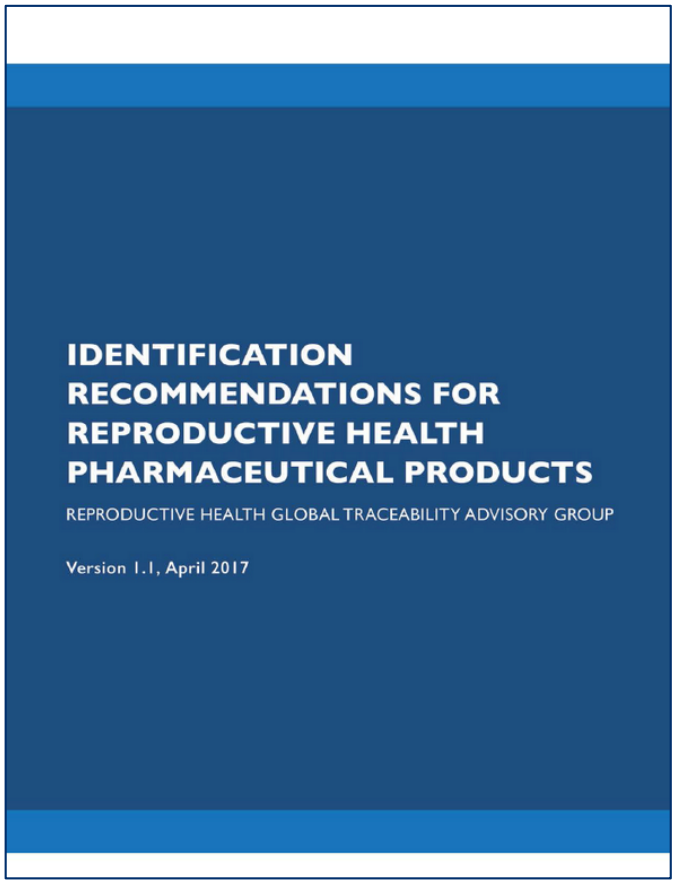
Vaccine Presentative and Packaging Advisory Group (VPPAG)

- A group coordinated by the World Health Organization with the purpose to align around global standards for vaccine identification and labeling
- 2015 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes with GS1 standards (GTIN, lot number, and expiry date) on all packaging levels used by manufacturers, with the exception of primary packaging



LINK: *Generic Preferred Product Profile for Vaccines*

Reproductive Health Global Traceability Advisory Group (RH GTAG)



A forum for subject matter experts from industry and the public sector to discuss and provide recommendations for the adoption and implementation of global standards for RH product identification, data capture, and data exchange in the supply chain.

Industry Advisors

Pfizer, Bayer, MERCK, Indus, PREGNA, Ansell, The Female Health Company, Mylan

Facilitators

UNFPA, USAID, GS1, Reproductive Health SUPPLIES COALITION

LINK: *Identification Recommendations for Reproductive Health Pharmaceutical Products*

ISG position paper on global data standards

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chicualacuala District hospital in Mapai, Mozambique, in July 2016. ©UNICEF/Rich.

The ISG has committed to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

Countries where GS1 standards implementation is receiving support from ISG partners:

Ethiopia: Support to National Drug Regulatory Authority for the development of policy and regulation for GS1 standards adoption, designing and implementing a national level track and trace system.

Pakistan: Support to Drug Regulatory Authority for the development of policy and regulation for GS1 standards adoption.

Myanmar, Haiti, Tanzania, Zambia: GS1 standards education and awareness building.

Lesotho, Uganda: GS1 standards required for WMSERP.

South Africa: Implementation of GS1 standards.

Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labeling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

Ethiopia's journey toward traceability

for patient safety and efficiency in the healthcare supply chain

Traceability pilot

During the course of a year, the Traceability Working Group is testing verification and traceability capabilities in Ethiopia's pharmaceutical supply chain in four pilots: (1) the ability for an end user to verify the authenticity of a product; (2) verify if a product entered the country legally; (3) do a product recall to the facility level and (4) do a product recall down to the patient level.

Patient safety

Global standards in healthcare help support the five patient rights: right patient, right drug or device, right time, right dose and right route. Supply chain visibility with improved traceability and transparency will help fight counterfeit medication. Finally, the use of global standards will improve the recall process by linking the medical product to the patient.

Roadmap

A roadmap for the implementation of traceability from manufacturer until the patient will be developed. The document discusses policy recommendations, time lines, roles and responsibilities.

Awareness

Implementation is impossible without all stakeholders in the supply chain fully understanding and endorsing the use of standards. Awareness creation is therefore very important. Stakeholders will be informed and trained on the importance of standards through workshops, (social) media and one-on-one meetings.

Efficiency

Greater visibility, traceability and transparency through the use of global standards will improve efficiency in the healthcare supply chain. The implementation of standards enables organizations to develop effective information systems for electronic record management and will eliminate waste and inefficiencies in the supply chain.

Assessment

An assessment will help us understand the current landscape in terms of stakeholders awareness level, gaps in legislation, and existing technological platforms that will be needed for the implementation of global standards. The result of the assessment will be used as input for a roadmap for Ethiopia to implement the global standards in the healthcare sector.

Information revolution

This is one of the four transformation agendas of the Ethiopian Ministry of Health. The ministry and its specialized agencies have embarked on initiatives critical to build information systems fit to the purpose of ensuring patient safety and efficiency. Implementation of global standards is one such fundamental undertakings.

GS1 standards

GS1 standards ensure globally unique identification and enable cross-border compatibility of supply chain solutions. This means all stakeholders can efficiently and effectively comply with various local and global requirements, and achieve interoperability and compatibility within their organization, between organizations and across borders.

100 million inhabitants, one of the oldest nations in the world, over 82 languages, more than 79 ethnicities and home to Lucy, a human fossil believed to have existed over 3 million years ago.

Twenty percent of the pharmaceuticals are locally manufactured. This number is expected to grow significantly in the coming years. The public sector has approximately 340 hospitals, 3,500 health centers and 16,000 health posts.

Important stakeholders including the government, manufacturers, and healthcare providers are supporters of the initiative to develop a roadmap for the implementation of global standards.

Tanzania Pilot

"Improves my work by reducing time used to count the stock during receiving or dispatching of vaccines."

"Reduces the emergency trips which is usually caused by inadequate vaccine record keeping."

"The improvement of quality of data could be significant when assessing movement of stock (time) from higher levels to low levels."

Overview

- Proving the benefits of bar coding for vaccines has been launched in region of Arusha with one vaccine from Pfizer
- Project led by PATH and supported by GAVI

Initial Findings

- Labor savings foreseen across various business processes:
  - Tracking stock movement, counting, expiry date management, and ordering (50-60%)
  - Demand planning, data cleansing and synchronization (2-5%)
  - Reverse logistics associated with the location, identification, return and receipt of recalled health commodities (2-4%)

Source: Presentation Brian Taliesin, PATH at GS1 Healthcare Conference in Dubai, April 2016

Further reading: LINK

Nicaragua Pilot

Overview

- Main objective was to evaluate the benefit of barcode scanning on vaccine tracking and visibility
- Pfizer vaccine with GTIN, lot number and expiry date in 2D DataMatrix
- On three different levels – from central store to regional to local
- MoH wants to extend to ALL vaccines

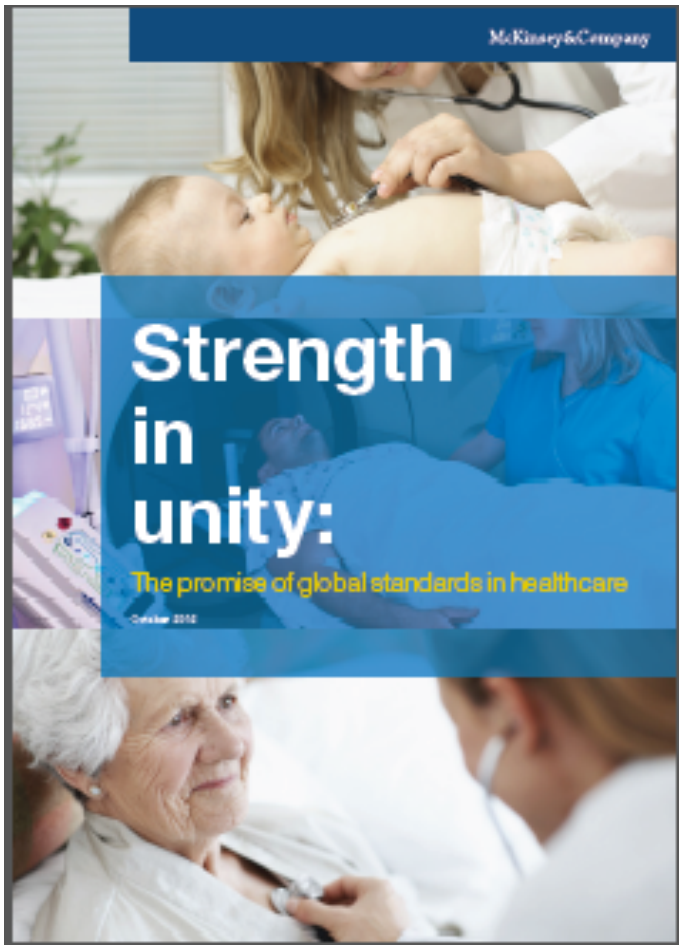
Results

- Adjustments reduces to 1:233 transactions
- 68% reduction in time needed for 1 transaction
- 100% stock visibility at all levels of the system
- Improved security with central data repository

Source: Presentation Rehana Wolfe, Pfizer at GS1 Healthcare Conference in Berlin, April 2017

Further reading: LINK

McKinsey quantifies supply chain issues in healthcare



McKinsey report "Strength in unity: The promise of global standards in healthcare"

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:
http://www.gs1.org/healthcare/mckinsey

Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

- "Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities"
- "Rolling out such standards-based systems globally could prevent tens of billions of dollars' worth of counterfeit drugs from entering the legitimate supply chain"
- [We] "estimate that healthcare cost could be reduced by $40 billion-$100 billion globally" from the implementation of global standards
- "Adopting a single set of global standards will cost significantly less than two" (between 10-25% less cost to stakeholders)

SOURCE: McKinsey report, "Strength in unity: The promise of global standards in healthcare", October 2012

Ultimately, it's all about…

Credit: Maggie Hallahan

Photo credit: Wendy Tactuk, courtesy of CapacityPlus and IntraHealth International

PATIENT SAFETY!


Thank you
Asante
អរគុណ
Shukran
شكرا لك
Zikomo
謝謝您
Meda w'ase
ขอบคุณ
Cảm ơn bạn
Merci
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Obrigado
Gracias
آپ کا شکریہ
Grazie
Danke
Ngiyabonga
Daalụ
Mange tak

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Solution Providers
Special Projects

Sophie Molle
Manager Healthcare

This training is based on materials prepared by GS1.

GS1 is a not-for-profit organization that develops and maintains global standards for business communication.

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

Acronyms

Acronym	Definition	Acronym	Definition
AI	GS1 application identifier	ISG	Interagency Supply Chain Group
AIDC	automatic identification and data capture	MDM	master data management
ARTMIS	GHSC-PSM automated requisition tracking management information system	MOH	Ministry of Health
ASN	advanced shipping notice	PSM	Procurement and Supply Management Project
DRAP	Drug Regulatory Authority Pakistan	RMNCH	Reproductive, maternal, newborn and child health
EDI	electronic data interchange	RH GTAG	Reproductive Health Global Traceability Advisory Group
eLMIS	electronic logistics management information system	SSCC	serial shipping container code
EPCIS	electronic product code information services	UNFPA	United Nations Population Fund
GDSN	global data synchronization network	UNICEF	United Nations Children's Fund
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria	USAID	United States Agency for International Development
GHSC	Global Health Supply Chain Program	VPPAG	Vaccine Presentation & Packaging Advisory Group
GLN	global location number	WMS	warehouse management system
GTIN	global trade item number		
HRI	human readable interpretation		