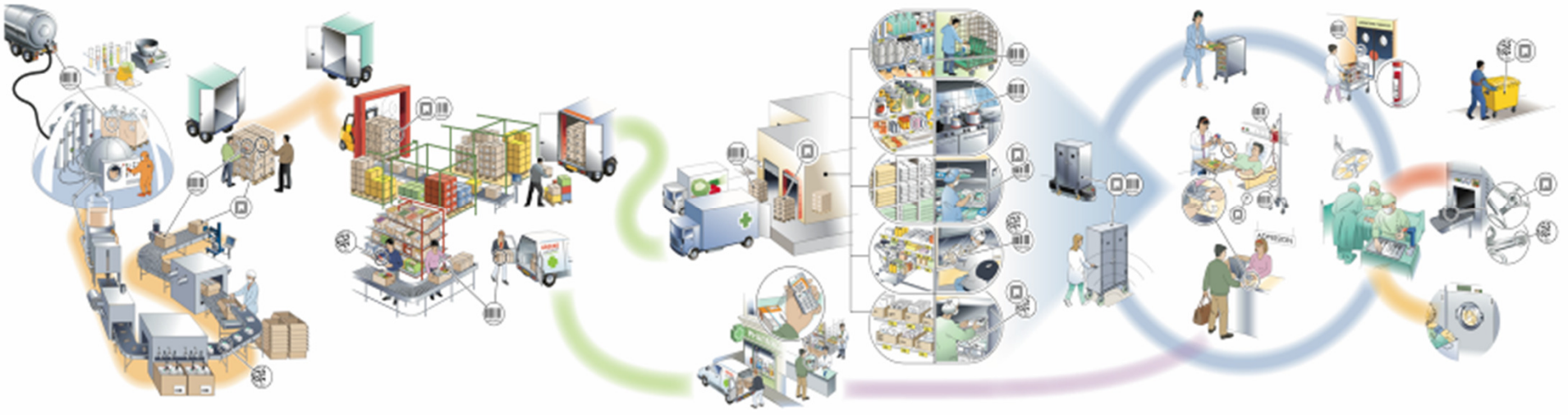
GS1 Healthcare Introduction Session

Copenhagen, 21 October 2014

GS1 Healthcare – a 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**.

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

What will be covered

- Automatic Identification & Data Capture – ***Chuck Biss***
- Data synchronisation / GDSN – ***Pete Alvarez (Anouk Chavel)***
- eCom – ***Hans Lunenborg***
- Traceability – ***Janice Kite***

GS1 Enabling AIDC Solutions in Healthcare

Chuck Biss
Senior Director, AIDC Healthcare
GS1 Global Office

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

GS1 AIDC Application Standards

GOAL - Define the **data** to carry using specific **data carriers** for every healthcare **product** at every **packaging level**

VISION - **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…

AIDC for Healthcare…Why?

- **To improve patient safety**
  - Achieve the “5 Patient Rights” / “8 Patient Rights”
  - Reduce errors
  - Ensure needed information is readily available to the healthcare practitioner
- **To increase efficiency in supply chain and treatment chain**

GS1 System "building blocks"…

…Identify, Capture & Share

"Identify" Unique Identification

- ✓ Product, Logistic Unit, Location & Legal Entity ID (static data)
- ✓ Product Attributes (dynamic data)

AIDC

"Capture" Machine Readable Data Carriers

- ✓ 1D/2D Bar Codes
- ✓ EPC/RFID Tags

"Identify, Capture & Share" enables…

TRACEABILITY

Pete will cover next…

Janice will cover later…

…for Med Device & Pharma

Scope: Data & Data Carriers

Data – a few examples:

- ✓ Global Trade Item Number (GTIN)
- ✓ Expiry Date
- ✓ Batch / Lot
- ✓ Serial Number

Data Carriers – a few examples:

GS1-128 & GS1 DataBar

(01)07612345678900(17)100503
(10)AC3453G3

GS1 DataMatrix

EPC / RFID

Scope: All healthcare products

Pharma / Vaccine / Nutritional

Medical devices

Retail

Non-retail

Scope: All packaging levels

Pallet (Tertiary*) | **Case / Shipper (Tertiary*)** | **Secondary package** | **Primary package** | **Single Unit package**

NOTE: * - Potentially a new defintion that is needed…

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

Scope: Data based on information needs

AIDC ID & Marking needs

Highest

Enhanced

Minimum

Pacemakers, hip replacements, …

Catheters, needles, …

Cotton balls, bandages, patient exam gloves, …

Foundation of the GS1 System…

GS1 Identification Keys

Provide access to information held in computer files – Information about company/location, package, product, price, etc.

1234567891234

GS1 Identification Keys

Item identifier = **GTIN**

Global Trade Item Number

Logistics unit identifier = **SSCC**

Serial Shipping Container Code

Location identifier = **GLN**

Global Location Number

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

And there are more …

The need to capture the trade item ID … and beyond…

GS1 Keys prevail… but some users need more detailed information about that specific unit

GS1 Application Identifers…

GS1 Gen Spec includes 100+ “Application Identifiers” or “Key Attributes”

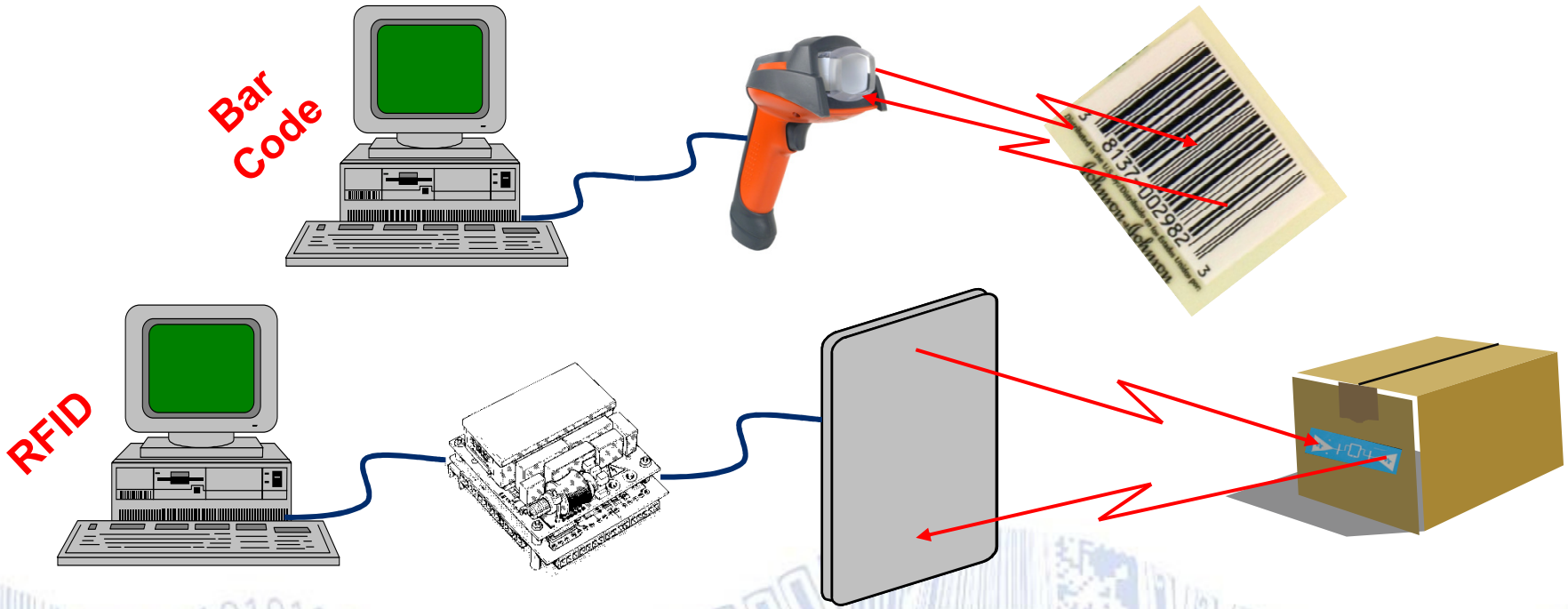
Application Identifiers generally found in Healthcare

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
11	Production
17	Expiry Date
21	Serial Number
710	NHRN – Germany PZN
711	NHRN – France CIP
712	NHRN – Spain CN
713	NHRN – Brazil DRN
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)
8017	GSRN Service Provider
8018	GSRN Service Recipient
8019	Service Relationship Instance Number

GS1 Data Carriers

AIDC - Data Carriers

GS1's ISO compliant machine-readable **Data Carriers** for use with the product (via packaging, label or DPM… Direct Part Marking) containing the Product ID – 1D / Linear & 2D / Matrix bar code symbols, RFID.



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 Bar Code Data Carriers for Healthcare

EAN/UPC

GS1 DataBar

GS1-128

GS1 DataMatrix

ITF-14

Bar Code Data Carrier Examples

Camera-based bar code scanners are needed in Healthcare for 2D Data Carriers AND are a GS1 Healthcare Leadership Team recommendation!!

GS1 System 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/genspecs

GS1 Healthcare GTIN Allocation Rules – GTIN assignektn from a the ONE global standard

- **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/1/gtinrules/index.php/p=static/t=healthcare

Many countries have already adopted GS1 Standards… and we **anticipate many more!**

AIDC related sessions…

This Week:

- **Tuesday, 14:00 – 15:30 and 16:00 – 17:30**
  "UDI Implementation Reality Breakout"
  - Medical devices: How to identify/mark my products
    - Chaired by Jackie Elkin (Medtronic)
    - Panel speakers: Georg Keller (Aesculap AG), Dennis Black (BD), Jay Crowley (USDM Life Sciences)
- **ALL week…**
  Multiple AIDC related presentations during our Plenary Sessions

Looking Forward:

- **Global AIDC teams**
  None active right now… stay tuned for future developments
- **Local AIDC teams**
  Contact your local Member Organisation representative

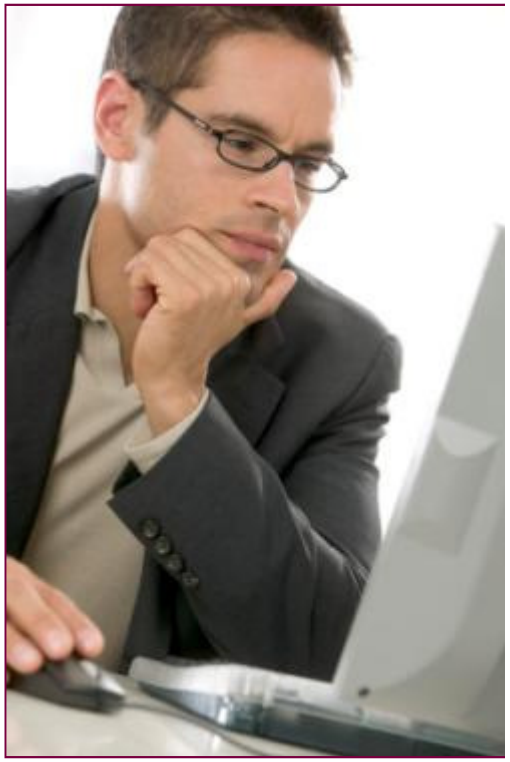
The Global Data Synchronisation Network in Healthcare

21 October 2014

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 needs to **change** any bit of information in their database or **add a new item**, **another database becomes outdated!**

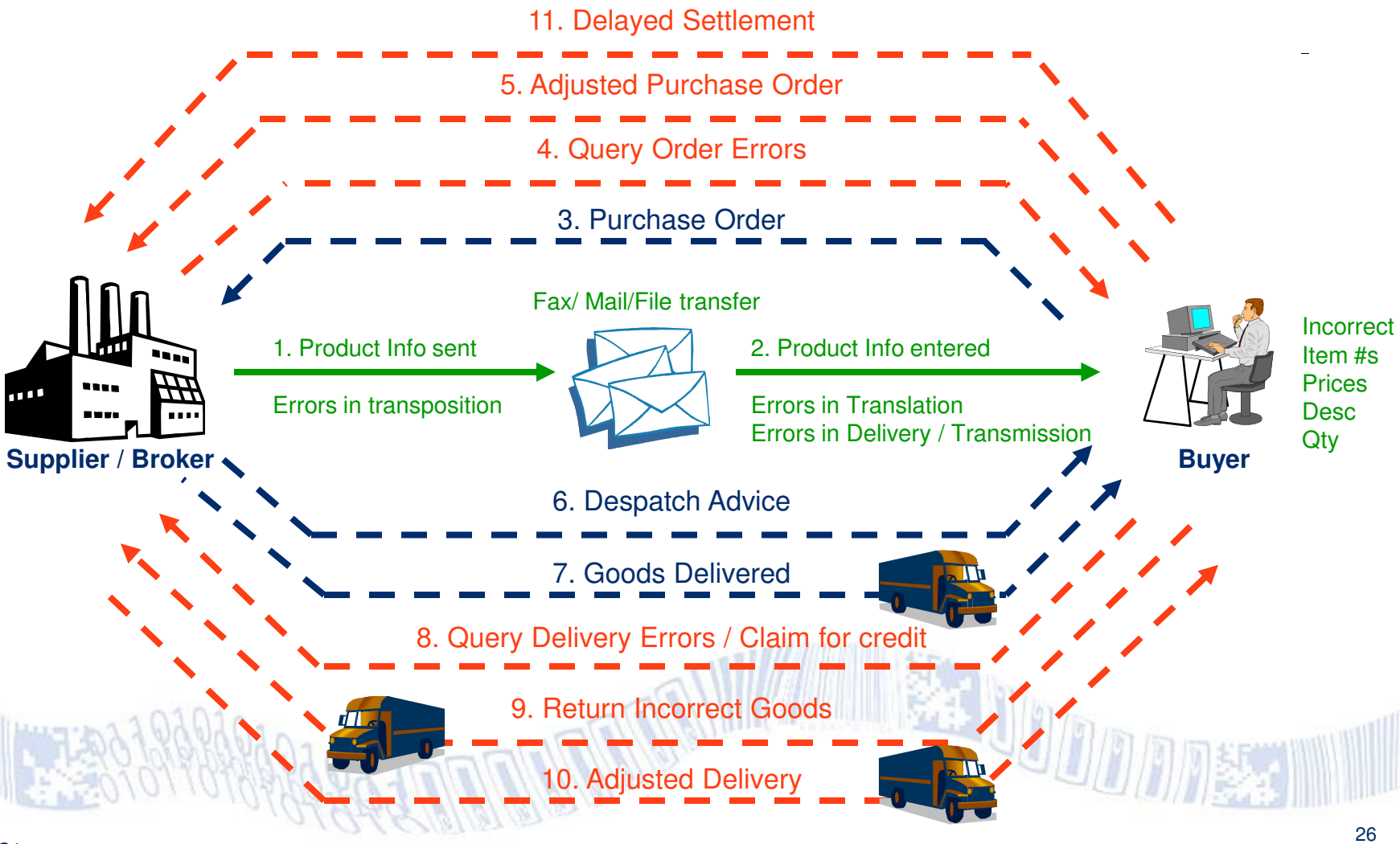


Managing master data
Where does the data come from?

Where does data come from - current situation:

- **Varying methods of communicating information**
  - Supplier A – printed catalog
  - Supplier B – price quote
  - Supplier C – PDF data
  - Supplier D – Excel tables
  - Supplier E – text data
  - Supplier F – link to website

Before Data Synchronisation



The Australian Data Crunch Report puts a cost to the problem!

Potential savings from improved data quality[3]

By conservative estimates, more than $100 million in potential savings can be achieved by addressing product data quality issues by making only minor adjustments to existing processes.

Source; http://www.gs1au.org/assets/documents/industry/healthcare/GS1-Healthcare-Data-Crunch-Report-March-2014.pdf

Managing Master Data
How to improve?

Supplier = data source

Needs single point-of-entry

- One database to load new item data and update data on existing items

Needs security

- Authorization access by supply chain partners

Standards-based

- Standard identification keys
- Predefined (set of) product attributes

Hospital = data recipient

Needs single point-of-truth

- One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

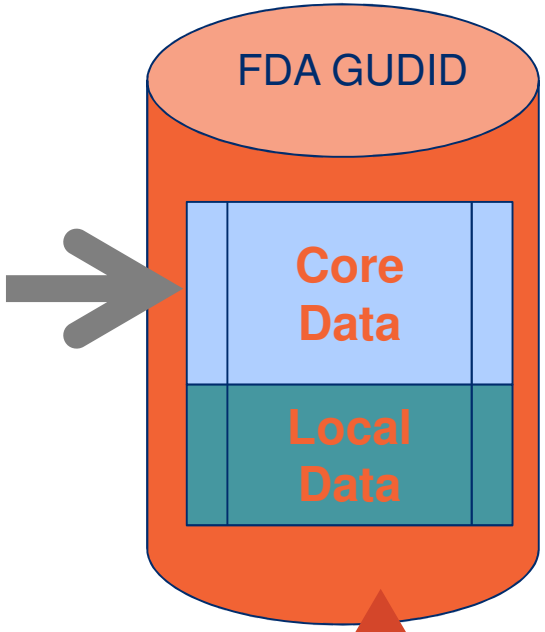
- Standard identification keys
- Consistently formatted information
- Complete information

UDI Databases: Global Core Data + Local Data

READY FOR UDI!

- Packaging Hierarchy, per pack. level
  - DI / Unit of Measure / Quantity
- Unit of Use DI
- Manufacturer Name, Address, Contact info
- Authorized Representatives (list of countries)
- Nomenclature + Term (e.g. GMDN code)
- Brand Name
- Device Model or Version
- Reference Number (REF No./catalog no.)
- Controlled by (e.g. exp. date, lot no., serial no)
- Clinical Size (Size/Volume/Length/Gauge…)
- Special Storage Conditions
- Special Handling Conditions
- Labeled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use + Method
- Restricted number of reuses
- License / Marketing Authorization
- URL for additional information
- Critical warnings / contraindications as labeled
  - labeled as containing Latex
  - labeled as containing DEHP

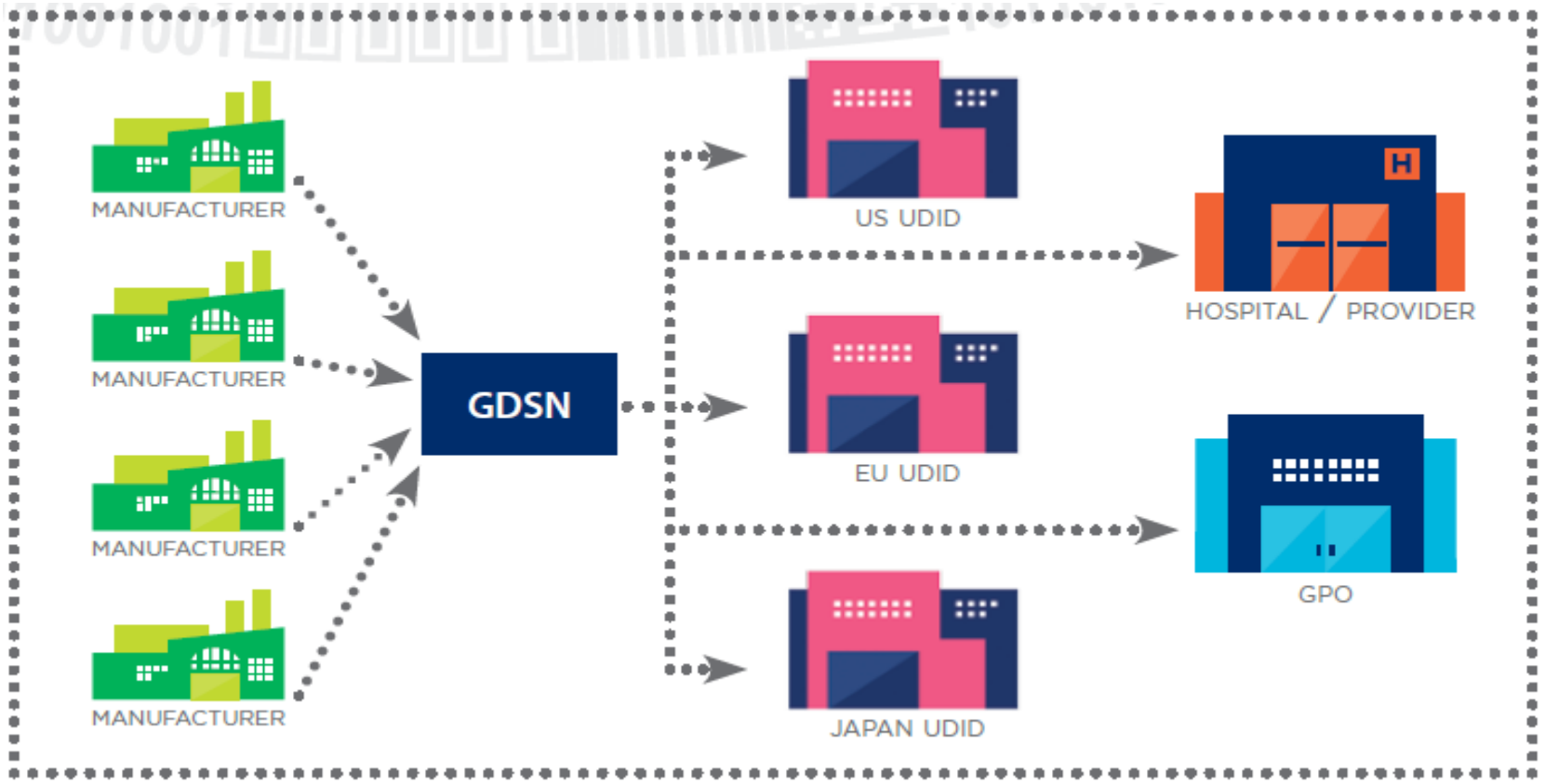
Global core data elements defined by IMDRF



Additional local data elements defined by the FDA

- DUNS no
- Authorization no (510k)
- Product Code
- FDA Listing no
- Product exempt from PMA
- Prescription product
- Kit product
- Combo product
- Contains human cell / tissue
- MR saftey
- …

The right data for the right product to the right recipient



Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection, via the Global Data Synchronization Network.

After Data Synchronisation

The ultimate value of quality data

Healthy patients and happy care givers

GDSN related sessions This Week:

GDSN implementation success story and preparation for UDI databases

- Wednesday, 14:00 – 15:30 and 16:00 – 17:30
- **Panellists:**
  - Volker Zeinar, B.Braun
  - Mark Wasmuth, GMDN
  - Greg Patterson, FSEnet+
  - Dave Ralph, Commport

For more information

www.gs1.org/gdsn

www.gs1.org/healthcare

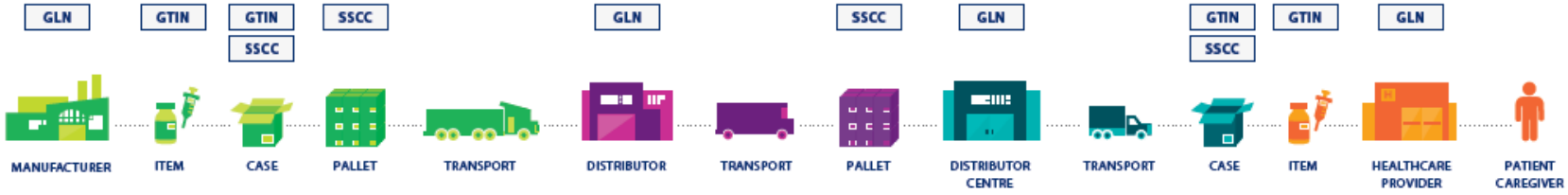
GS1 eCom in Healthcare

Hans Lunenborg
Sectormanager Healthcare
GS1 Netherlands

The GS1 System

IDENTIFY: GS1 Standards for Identification

GLN Global Location Number **GTIN®** Global Trade Item Number **SSCC** Serial Shipping Container Code **EPC** Serialized Global Trade Item Number



CAPTURE: GS1 Standards for Automatic Identification & Data Capture

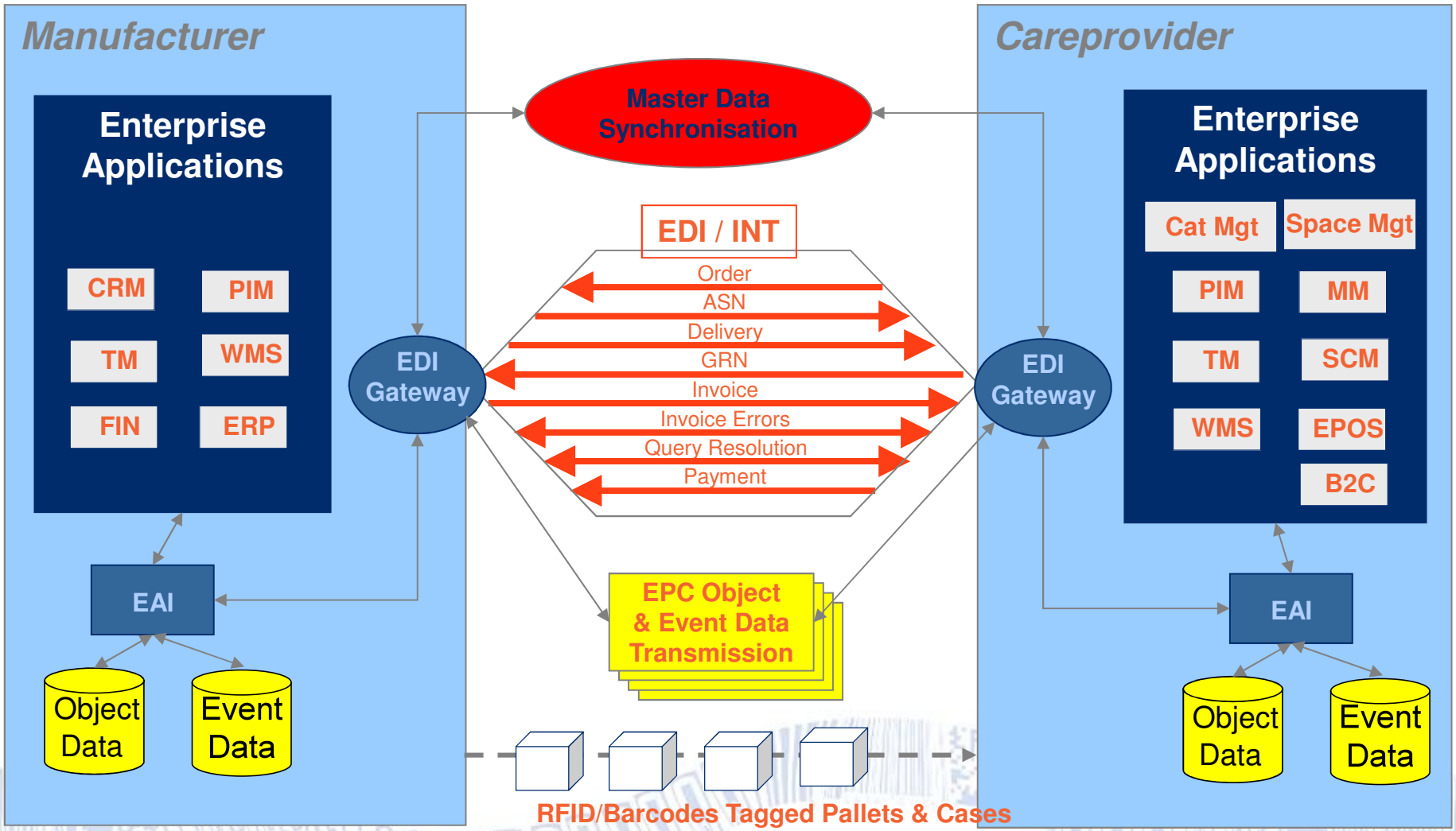
GS1 BARCODES **GS1 EPC/RFID**

EAN/UPC GS1-128 ITF-14 GS1 DataBar GS1 DataMatrix EPC HF Passive EPC UHF Passive

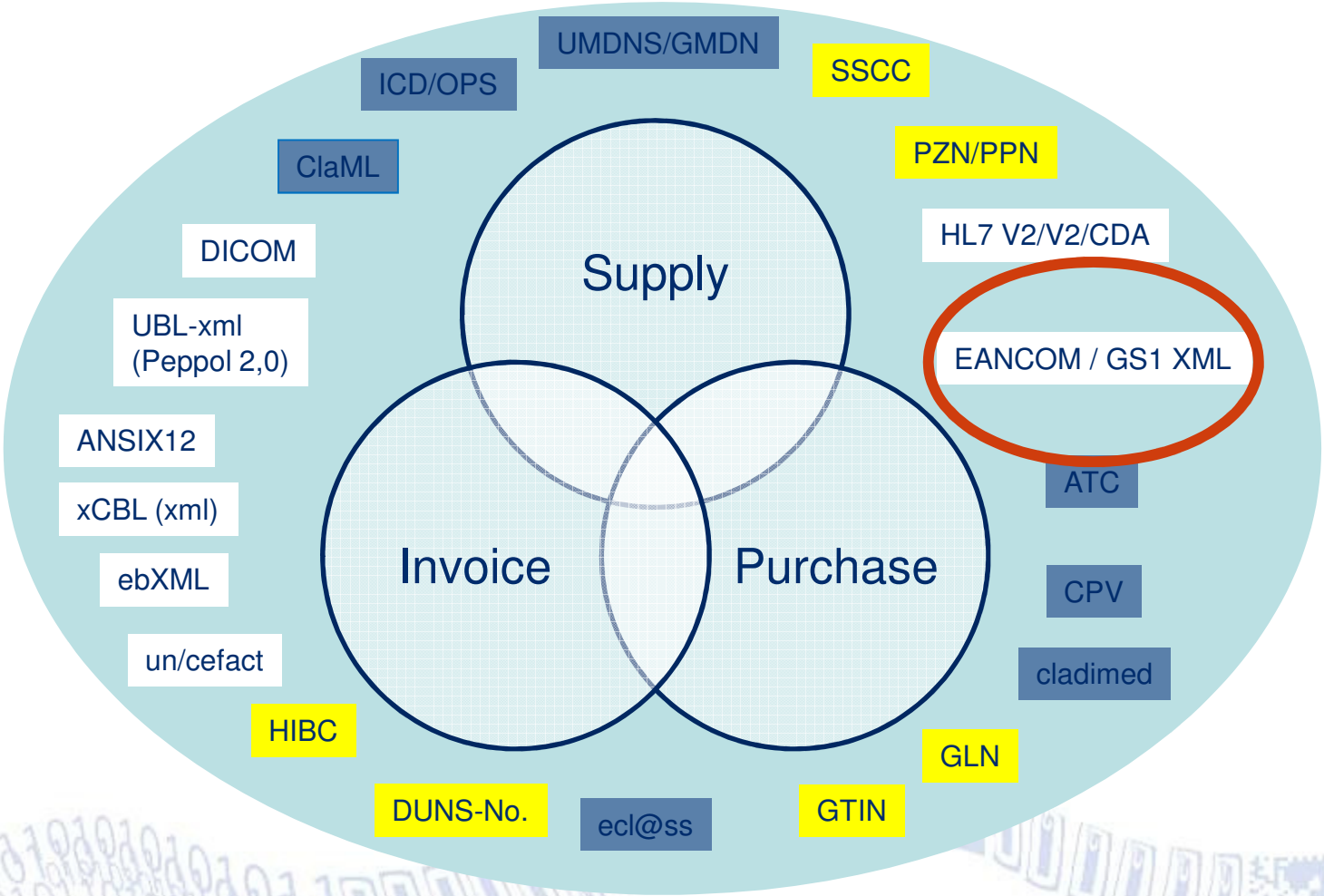
SHARE: GS1 Standards for Automated Data Exchange

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** eCom (EDI) **EVENT DATA** EPC Information Services (EPCIS)

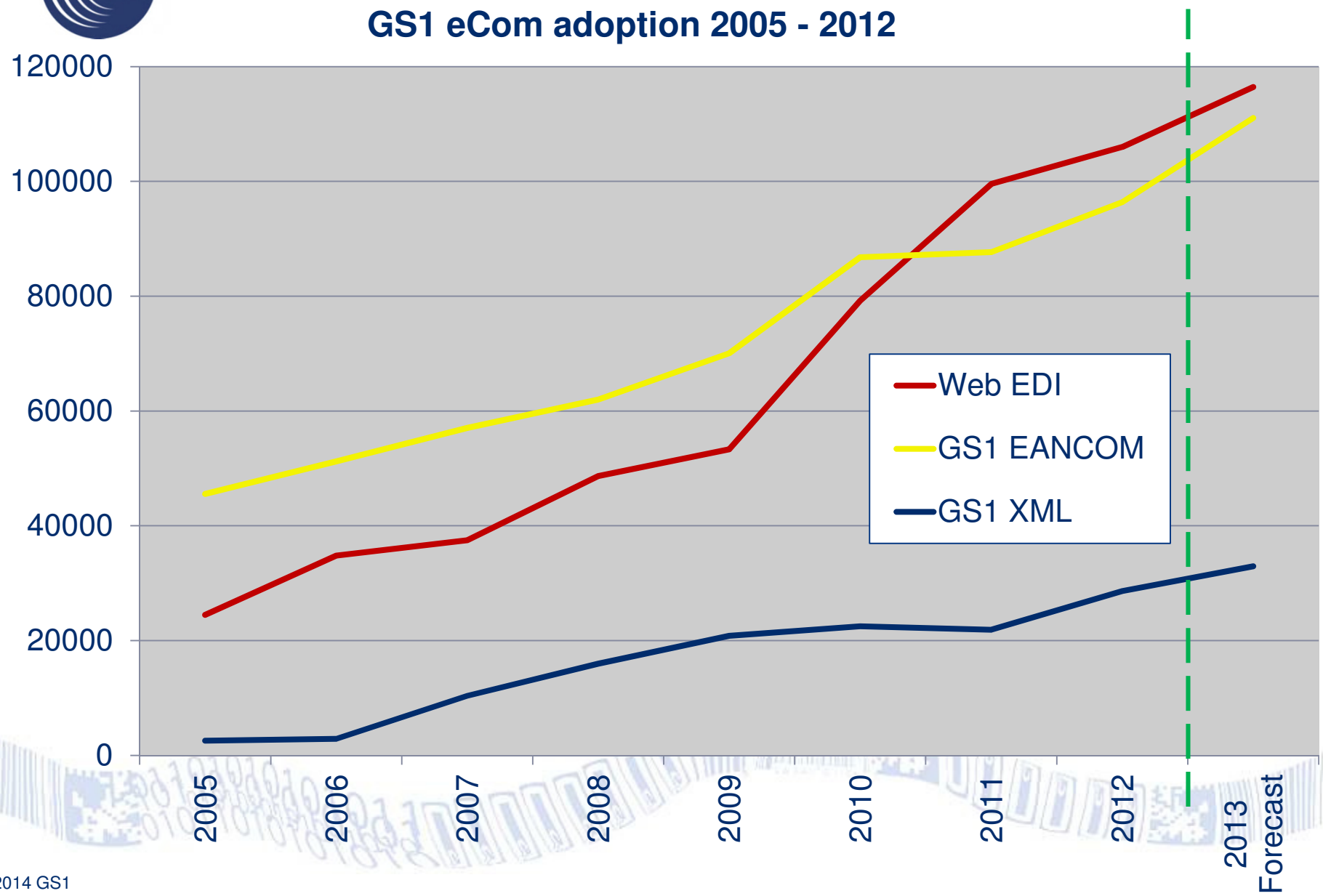
Supply chain visibility according to GS1



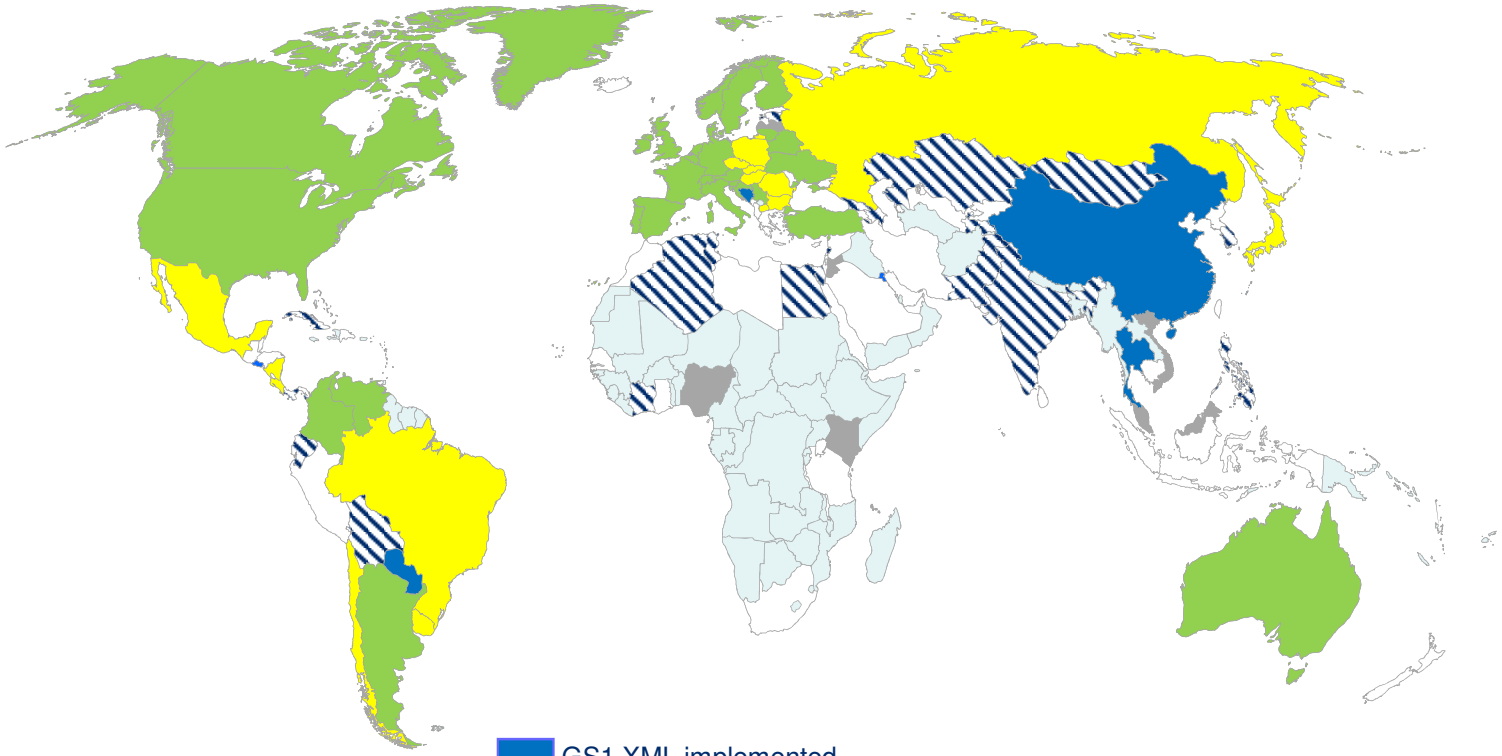
IT Standards of eCommerce



eCom implementation trends



eCom implementation geography



GS1 XML implemented

EANCOM implemented

Both GS1 XML and EANCOM implemented

Only non-GS1 eCom standards implemented

No eCom standards implemented

Non-GS1 member countries (no data available)

Discussions and Statements

Customer:
We only accept format XXX, it is decided in our local GS1 group to use it !

Solution Provider:
You can get each format you want to your customer, costs are xxx !

IT Manufact
Currently we have no resources to do that !

IT Manufact
Why do we use a standard if the same process is used different in different countries !

IT Manufact
Costs for developing and testing of each format are xxx

Board of Manufact
If we are able to harmonize processes in SAP why isn't the healthcare market in different countries able to harmonize?

IT Manufact
If there are some major changes I have to change it several times !

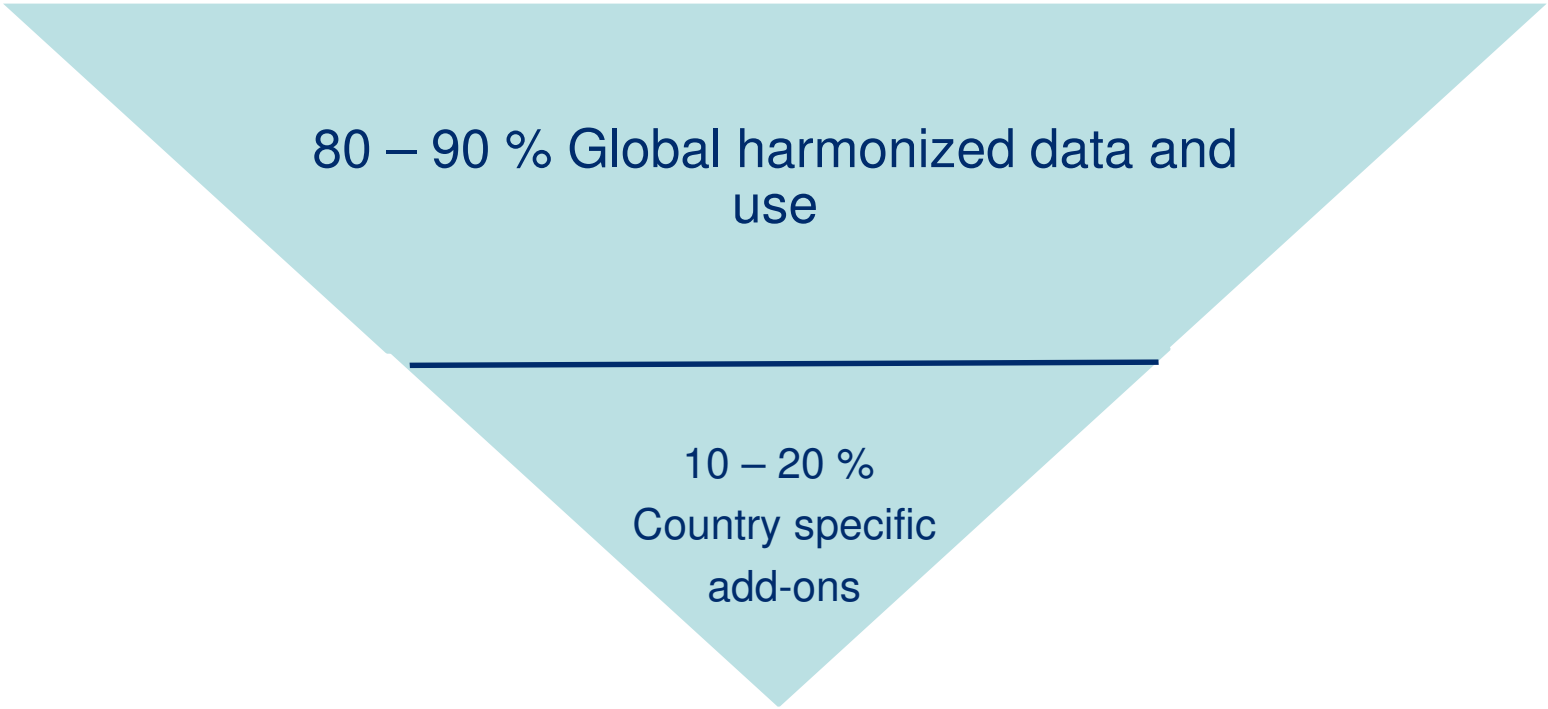
Board of Manufact
How far away are we in using standards even the GS1 standards are not harmonized globally. Do we use the only the GTIN as an result

Board of Manufact
It is responsibility of department Global eCommerce & Auto ID to harmonize standards

Board of Manufact
GS1 is a Global Organization. Our expectations to them were global harmonization of standards !

IT Manufact
Why can't we use what we already have realized

1 Format in EANCOM and GS1-XML ?



Key factor is processes harmonization!!

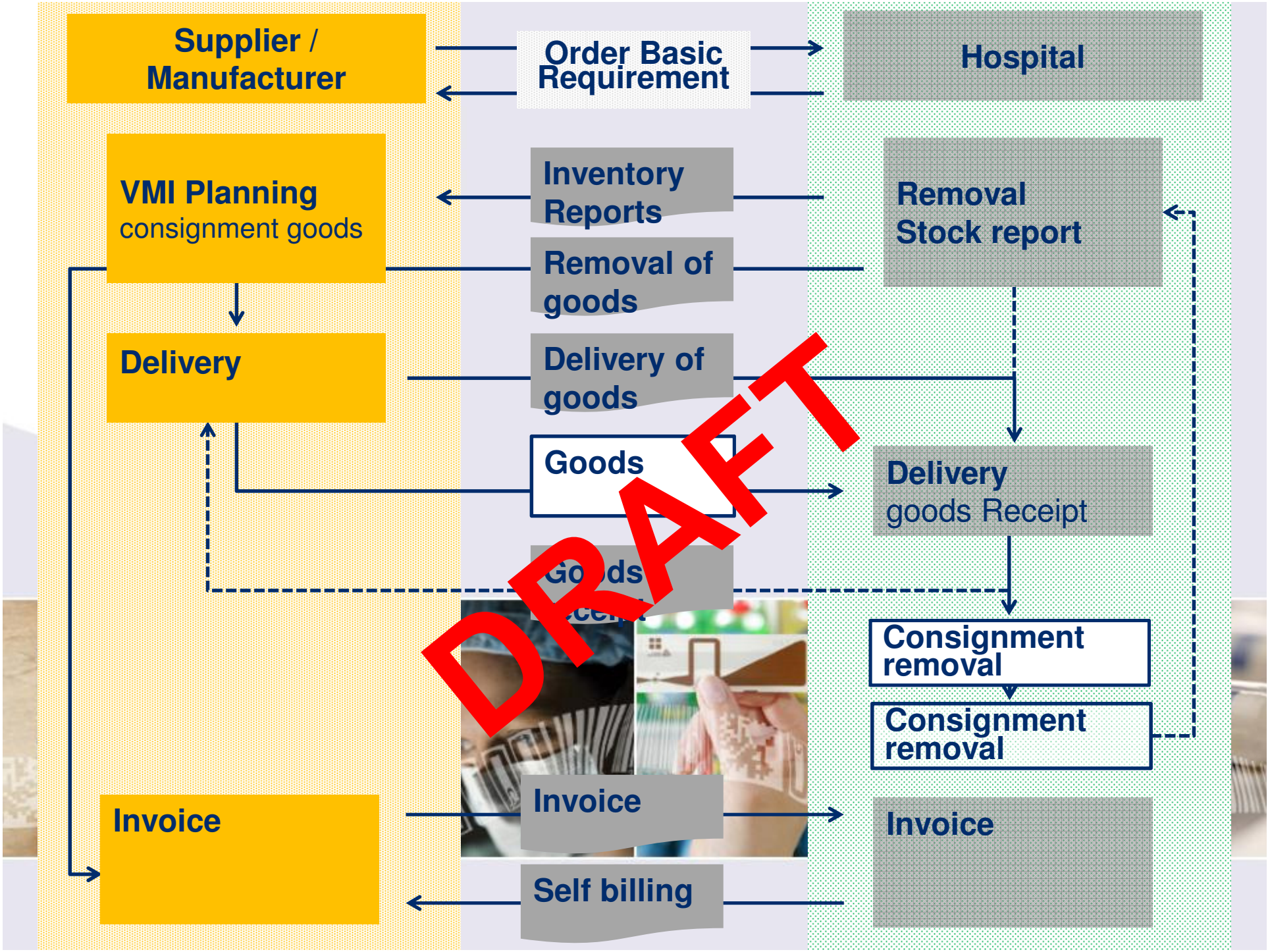
Healthcare Interoperability Model (HIM)

GOAL:

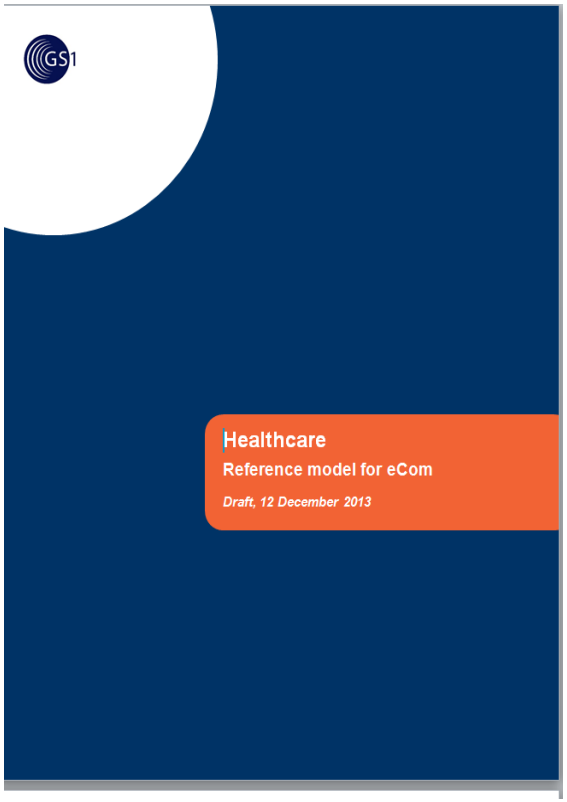
Develop a framework to align GS1 eCom standards so they can be used throughout the Global Healthcare supply chain from supplier to logistic end-user

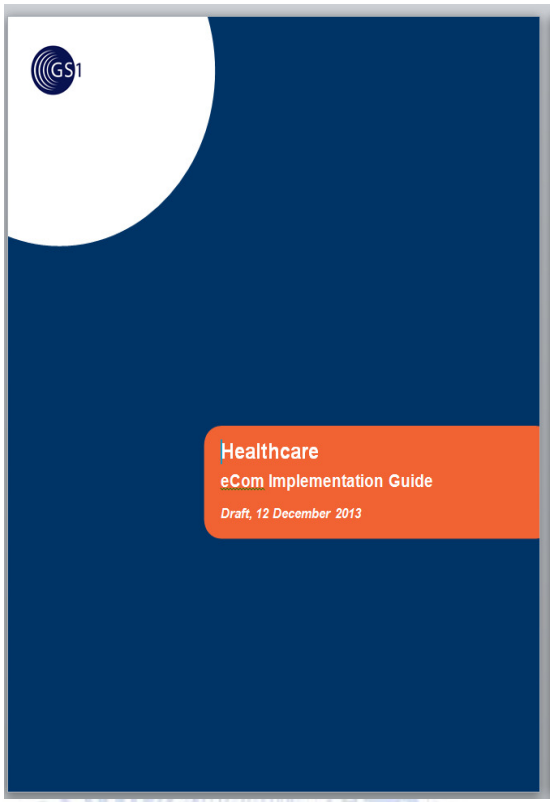
HOW:

Define a common Healthcare Process Model


Supplier / Manufacturer
Order Basic Requirement
Hospital
VMI Planning
consignment goods
Inventory Reports
Removal Stock report
Removal of goods
Delivery
Delivery of goods
Goods
Delivery
goods Receipt
DRAFT
Consignment removal
Consignment removal
Invoice
Invoice
Invoice
Self billing

Process Model





eCom related session…

This Week:

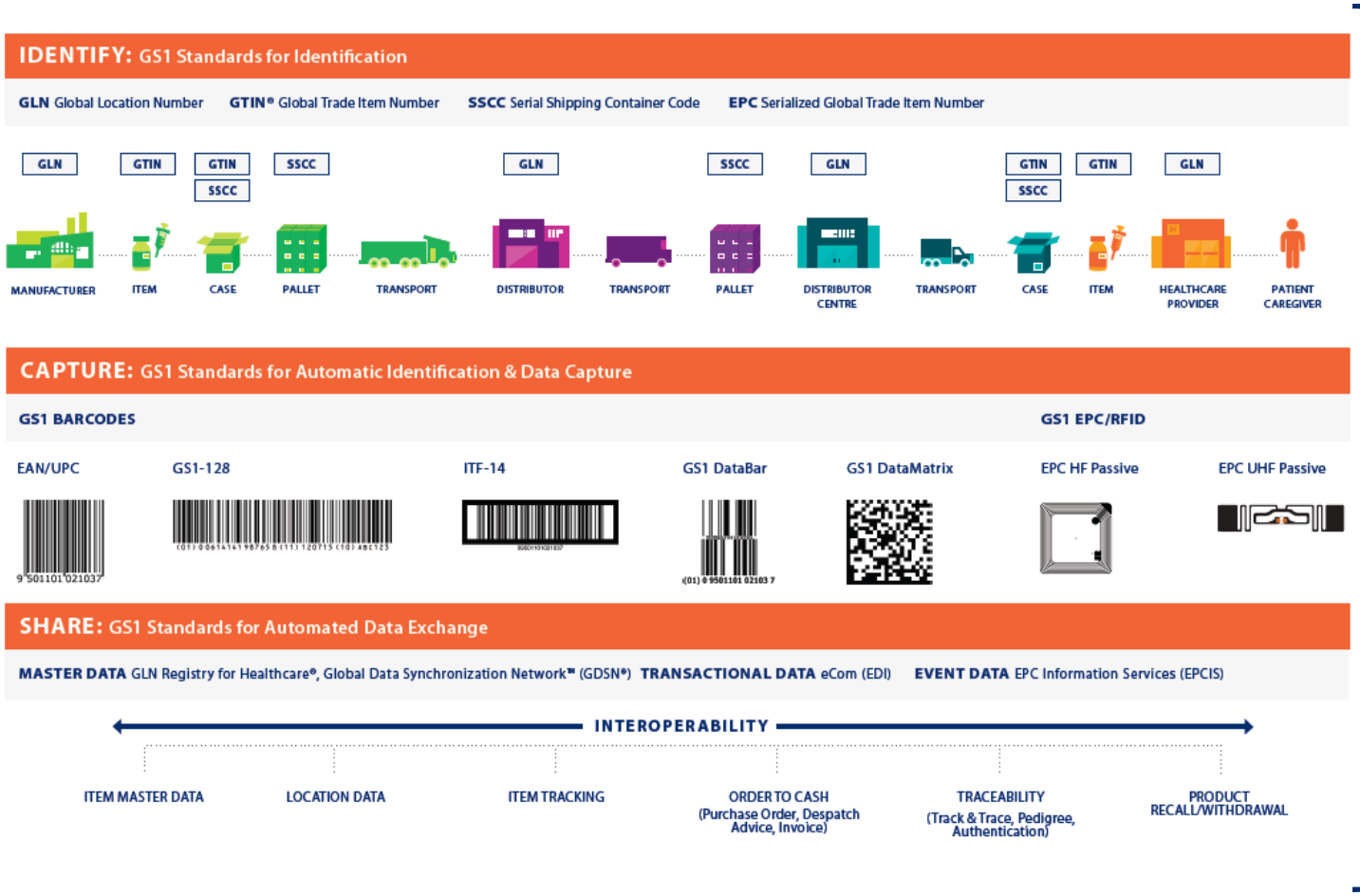
Wednesday, 11:50 – 12:30

Ask the expert meeting on eCom

Traceability in Healthcare

Janice Kite
Traceability Director Healthcare
Global Office

GS1 in Healthcare: global system of standards



TRACEABILITY

- Track
- Trace
- Authentication
- Chain of Custody / Ownership
- Returns
- Recalls

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** ((AI), e.g. Serial No. AI(21)), if applicable, at point of production
- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain
- All **patients and care givers**, when in a care giving environment, are identified with the appropriate GS1 identification Keys and appropriate **AI** (AI 8017, 8018, 8019)
- Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners
- Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

SO THAT:

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights[3] are achievable
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user

Traceability in Healthcare

Objective:

Ensure the GS1 System of Global Standards has both the process and technical standards necessary to achieve the GS1 Members Vision for Traceability in Healthcare

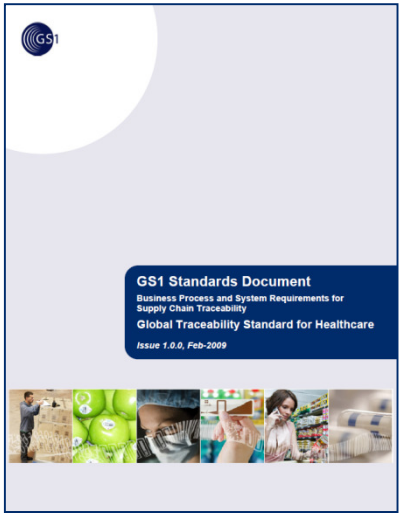
Approach: Two phases

TH-I - Process Standard - December 2007 to April 2009

TH-II – Technical Standards – April 2009 to date & ongoing

Traceability in Healthcare I (TH-I)

DELIVERED:



Global Traceability Standard for Healthcare (GTSH)

PUBLISHED 27th February 2009

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf

GTSH Implementation Guideline

PUBLISHED 24th April 2009

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Implementation_Healthcare.pdf

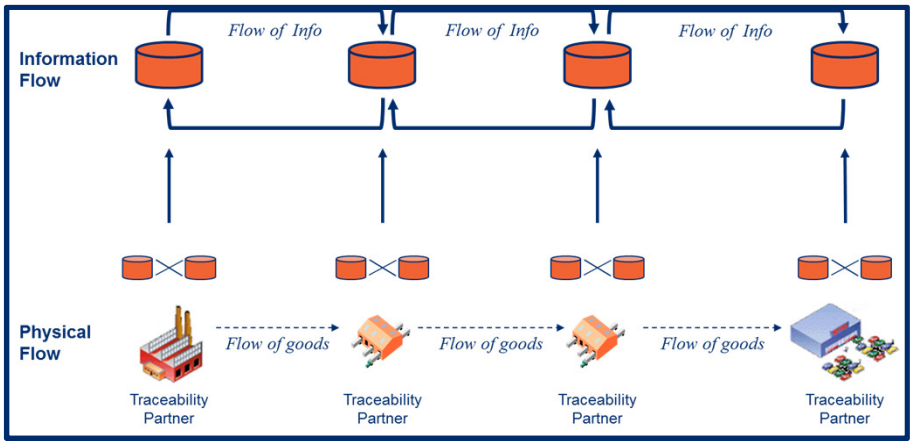
Traceability – a definition

"Traceability is the ability to **track forward** the movement through specified stage(s) of the extended supply chain and **trace backward** the history, application or location of that which is under consideration".

GS1 GTSH Issue 1.0.0, Feb-2009

Global Traceability Standard for Healthcare (GTSH) - Common themes

- PROCESS Standard
- Defines Traceability: both track & trace
- Defines foundational operational model:
  - **one-up / one-down**



  - Physical flow of product **has to be** in parallel to flow of info. about product
  - Inputs (eg receipt) must be linked to outputs (eg dispensing)
  - Parties can have varying roles
  - Business Requirements = Needs
  - Business Rules = control and/or constraints

Current Standards Development: Event-Based Traceability with EPCIS foundation

Four dimensions of any EPCIS **event**:

- **WHAT** objects are the subject of event?

  *Individual objects (**SGTIN**) or groupings (**GTIN + Lot/batch**)*

- **WHEN** did this event take place?

  Date, time and time zone

- **WHERE** did this event take place?

  ***SGLN** of physical location & object's subsequent whereabouts*

- **WHY** did this event take place? *including...*
  - *Disposition (e.g., "expired", "recalled")*
  - *Source/Destination to indicate . . .*
    - *transfer of **ownership/responsibility/custody**,*
    - *intended party/location **endpoints** of the transfer*

Videos: A general introduction to the GS1 Event-Based Traceability healthcare and An introduction dedicated to Solution Providers

Join: Link to Join MSWG: http://community.gs1.org/apps/org/workgroup/gsmppedsccsmswg/

Traceability – THIS WEEK!

TODAY – Two identical sessions: 14:00-15:30 and 16:00-17:30

Traceability implementation for all stakeholders in the supply chain, from manufacturer to patient

This session outlines the foundations for enabling traceability using global standards, showcases standards work in progress to enable "Event Based" Traceability models and looks to the future with presentations from two global manufacturers on how an established traceability system can improve supply chain efficiency, enhance patient safety and enable better engagement with patients.

Thursday: 09:00-11:50 - **PLENARY SESSION – Traceability**

Traceability is today in the focus of many regulatory bodies and worldwide regulations and activities are evolving. This session discusses traceability and authentication, counterfeiting and the need to get the original product to the patient.

Contact

Anouk Chavel
Group Manager Marketing
Healthcare and GDSN
anouk.chavel@gs1.or

Janice Kite
Traceability Director Healthcare
janice.kite@gs1.org

Chuck Biss
Senior Director
AIDC Healthcare
chuck.biss@gs1.org

Pete Alvarez
Senior Director
Industry Engagement, GDSN and
GLN Registries Framework
peter.alvarez@gs1.org

Hans Lunenborg
Sector Manager Healthcare
hans.lunenborg@gs1.nl