



# Introduction to GS1 in Healthcare

**Global GS1 Healthcare Conference  
Buenos Aires, Argentina**





# Agenda

- **GS1 Healthcare – the global perspective**
- AIDC Application Standards [Chuck.Biss@gs1.org](mailto:Chuck.Biss@gs1.org)
- Global Data Synchronisation & Product Classification  
[Pete.Alvarez@gs1.org](mailto:Pete.Alvarez@gs1.org)
- Traceability in Healthcare [Janice.Kite@gs1.org](mailto:Janice.Kite@gs1.org)
- Public Policy [Geraldine.Lissalde.Bonnet@gs1.org](mailto:Geraldine.Lissalde.Bonnet@gs1.org)





# GS1: The Global Language of Business



- a neutral, not-for-profit, international organisation
- dedicated to the design and implementation of **global standards**
- to improve the **efficiency and visibility of supply chains** globally and across sectors





# A need for global standards...



What happens when there aren't global standards?

- Inefficiencies
- Increased risk
- Lost opportunities





# ... to meet the needs of the supply chains in different sectors



**Efficiency**

**Safety**

**Collaboration**

**Sustainability**



**in Retail &  
Consumer Goods**



**in Healthcare**



**in Transport &  
Logistics**

**and  
more...**





# 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 111 countries around the globe  
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...



# Global reach, local presence



**Close to 2 million companies around the world use GS1**  
**Across 150 countries**  
**Over 6 billion transactions a day**



# GS1 Healthcare







# The healthcare supply chain needs global standards



- **Medication errors** result in additional treatments, disabilities and even loss of life
- **Counterfeiting** is an increasing global threat
- **Traceability** from manufacturer to patient is problematic
- **Product recalls** can be difficult to manage, in particular for healthcare providers
- **Manual interventions** in the healthcare supply chain decrease its efficiency and accuracy

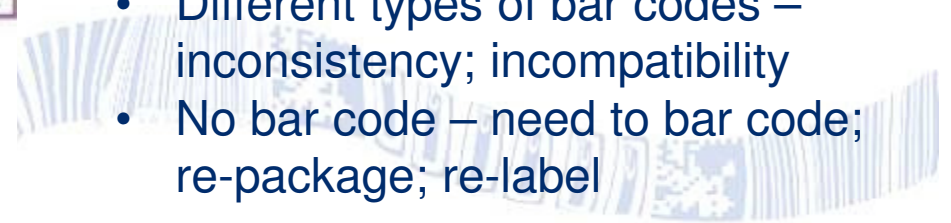




# Lack of standards in Healthcare is inefficient and adds risk...



- 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



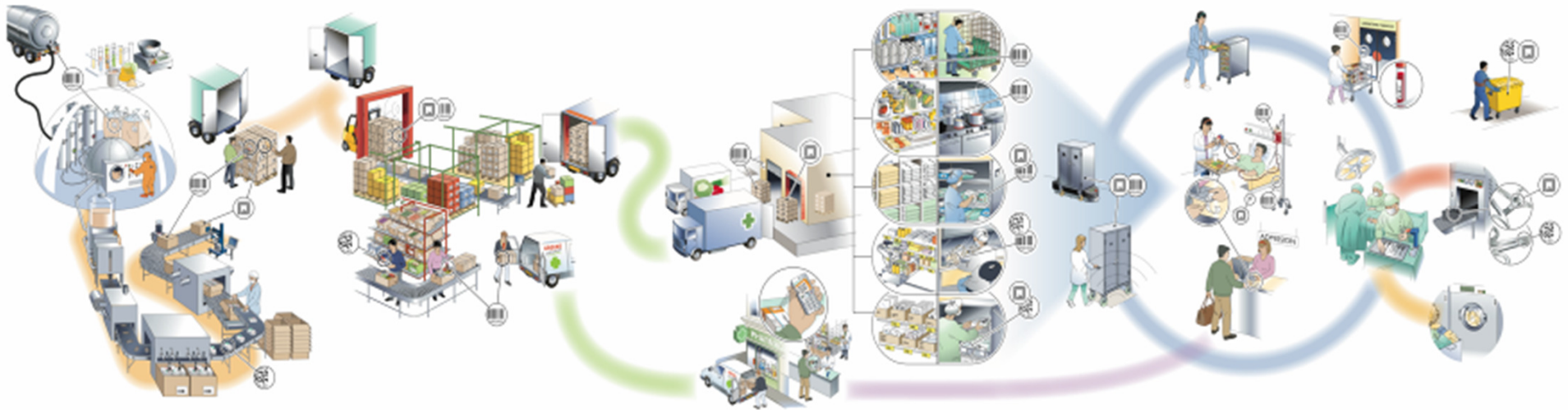
**“CUSTOMIZED ACTIONS MEAN COSTS!!**

***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 Healthcare mission – 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**.



# GS1 Healthcare User Group Supply-side Organisations





# Leading healthcare organisations pave the way...

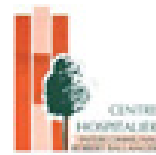
## Buyer/Provider-side Organisations going global



Austria



Austria



France



France



Germany



Germany



Hong Kong



Ireland



Macedonia



Netherlands



Netherlands



Switzerland



USA



USA



USA



USA



# GS1 Healthcare around the World

## Members global user group

### Manufacturers

3M  
Abbott Laboratories  
AbbVie  
Alcon Labs  
Amgen  
Astra Zeneca  
Baxter  
Becton Dickinson  
B. Braun  
Cook  
Covidien  
Edwards Lifescience  
Fresenius  
GE Healthcare  
Genzyme  
Gilead  
GlaxoSmithKline  
Johnson & Johnson  
Medtronic  
Merck & Co.  
Pall Medical  
Pfizer  
Purdue Pharma  
Smiths Medical  
TEVA  
Zimmer  
**Solution provider**  
Avanco  
Axway  
GHX  
Seidenader  
Excellis Health

### Distributors/Healthcare providers/GPOs/T&L

Cardinal Health (U.S.)  
CH Aulnay sous Bois (France)  
Comparatio Health (Germany)  
DHL Exel Supply Chain  
Erasmus MC Rotterdam (NL)  
Filip Vtori hospital (Macedonia)  
UNI.HA (representing 17 French university hospitals)  
Hong Kong Hospital Authorities  
McKesson (U.S.)  
Novation (U.S.)  
Orthopädisches Spital Speising Wien (Austria)  
Premier (U.S.)  
St. James Hospital, Dublin  
Marienhospital Herne (Germany)  
UMC Groningen (NL)  
University Kentucky Healthcare (U.S.)  
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

## Local participation

### Manufacturers

3M  
Bayer  
Becton Dickinson  
Boehringer Ingelheim  
Coloplast  
Draeger Medical  
Genzyme  
Hospira  
Kimberly-Clark  
Novo Nordisk  
Purdue Pharma  
St. Jude Medical  
Stryker  
Teva Pharmaceuticals  
Terumo  
UCB  
Upsher-Smith  
...

### Distributors/Wholesalers

Aexxdis  
Amerinet  
Amerisource Bergen  
CH2  
Depolabo  
Galexis  
GAMMA Wholesale  
Geodis  
McMahon  
Owens & Minor  
...

### Healthcare providers/Retailers

Alfred Hospital (Australia)  
Ascension Health (U.S.)  
Capital District Health (Canada)  
CHU de Québec (Canada)  
CHU Dijon (France)  
HUG Geneva (Switzerland)  
London Drugs (U.K.)  
Mayo Clinic (U.S.)  
Sisters of Mercy (U.S.)  
Sobeys Pharmacy (U.K.)  
UHCS Augusta VA (U.S.)  
Walgreens (U.S.)  
Wal-Mart (U.S.)  
...

### Associations

AHA (U.S.)  
CIP/ACL (France)  
CHeS (U.S.)  
EFPIA (Europe)  
Eucomed (Europe)  
FENIN (Spain)  
GIRP (Europe)  
HDMA (U.S.)  
International Hospital Federation  
JFMDA (Japan)  
Medical Industry Association of Australia  
NACDS (U.S.)  
Patient Safety Foundation (U.S.)  
...

And many more...



# Recognised, open and neutral source



And many more...





# GS1 and Joint Initiative Council (JIC) in Healthcare



International Organisation for Standardization



European Committee for Standardization



Health Level 7 international



International Health Terminology SDO



Clinical Data Interchange Standards Consortium



Integrating the Healthcare Enterprise

## Joint Initiative Council



World Health Organization



World Customs Organization



International Society for Blood Transfusion



European Association of Hospital Pharmacists



European Association of Medical Device manufacturer



International Society for Quality in Healthcare



# Agenda

- GS1 Healthcare – the global perspective
- **AIDC Application Standards**
- Global Data Synchronisation & Product Classification
- Traceability in Healthcare
- Public Policy





# GS1 Enabling AIDC Solutions in Healthcare

**Chuck Biss**

**Senior Director, AIDC Healthcare**

**GS1 Global Office**





# Topics

- Background
- Where we are going
- Where we are today
- What this means to you
- Questions





# Topics

- **Background**
- 
- Where we are going
- Where we are today
- What this means to you
- Questions





# 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 those data** directly into computer systems (i.e., without human involvement).”

*Wikipedia, 2009*





# AIDC Application Standards

Defines  
the **data** to carry  
using specific **data carriers**  
for every healthcare **product**  
at every **packaging level**





# Scope: Data

## Data – a few examples:

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



(01)07612345678900(17)100503

(10)AC3453G3 (21)123







# Scope: Data carriers



(01) 0 0012345 67890 5



100000012345678905

**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**

**Case /  
Shipper**

**Secondary  
package**

**Primary  
package**

**Directly  
on the item**





# Scope: Solutions based on information needs

*AIDC Marking requirements*

Highest

Enhanced

Minimum



Pacemakers, hip replacements, ...

Catheters, needles, ...



Cotton balls, bandages, patient exam gloves, ...



# Topics

- Background
- **Where we are going**
- Where we are today
- What this means to you
- Questions





# AIDC for Healthcare...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**





# Topics

- Background
- Where we are going
- **Where we are today**
- What this means to you
- Questions

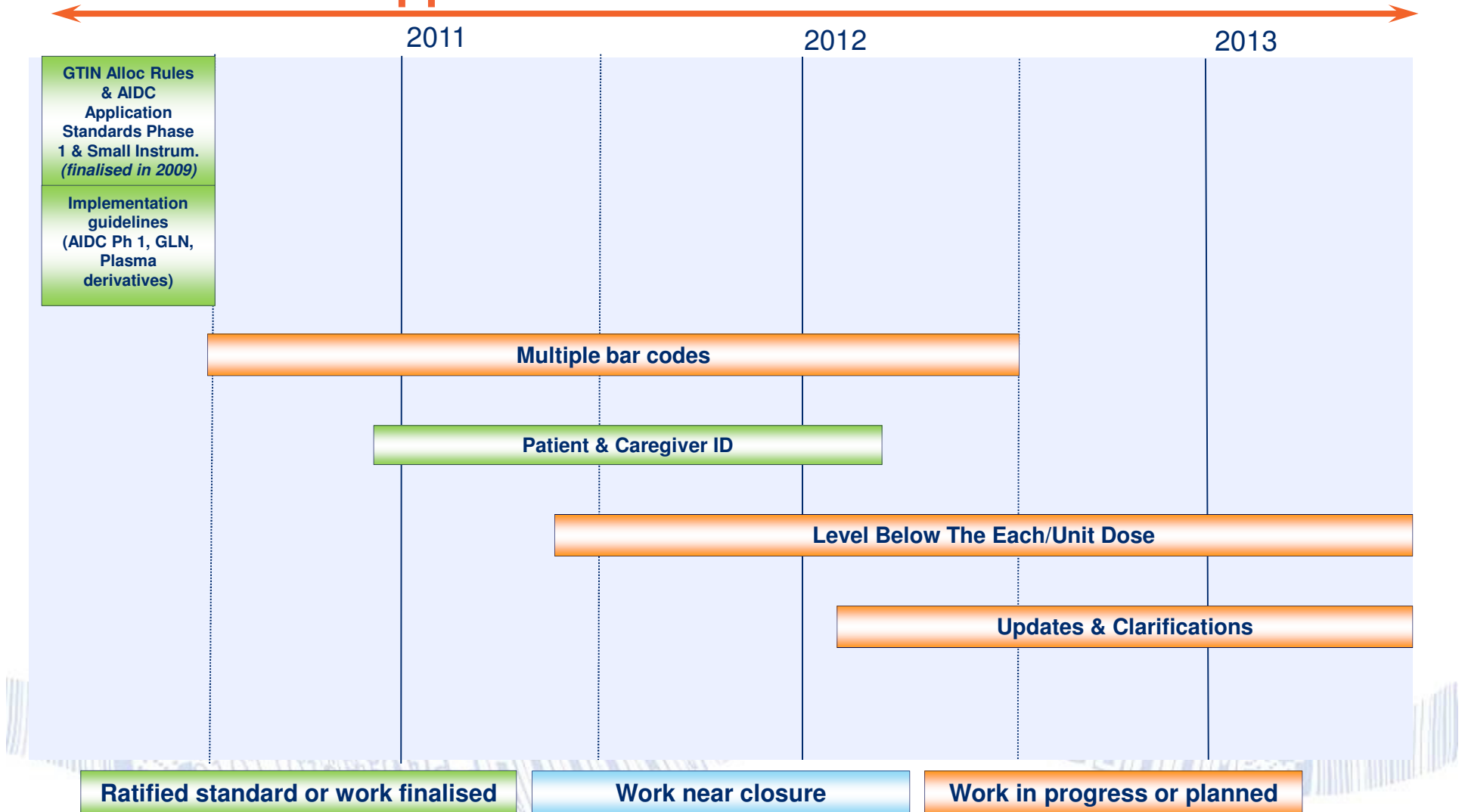






# Roadmap to Global Standards

## AIDC Application Standards for Healthcare





# GS1 General Specifications

Revised!



**GS1 General Specifications**  
Version 12  
*Issue 1, Jan-2012*

**The core standards document of the GS1 System**

Now including AIDC Application Standards for Healthcare

And specific standards for marking re-usable surgical instruments

Contact your GS1 Member Organisation for your copy!





# AIDC Implementation Guide

Version 1.1 Completed!

**How to implement all aspects of the new Healthcare AIDC additions and changes to the GS1 General Specifications**

*Available at:*

*[http://www.gs1.org/sites/default/files/docs/gsmc/healthcare/AIDC\\_Healthcare\\_Imp\\_Guide.pdf](http://www.gs1.org/sites/default/files/docs/gsmc/healthcare/AIDC_Healthcare_Imp_Guide.pdf)*

**AIDC Healthcare  
Implementation Guide**

*Issue 1.1, Dec-2010*

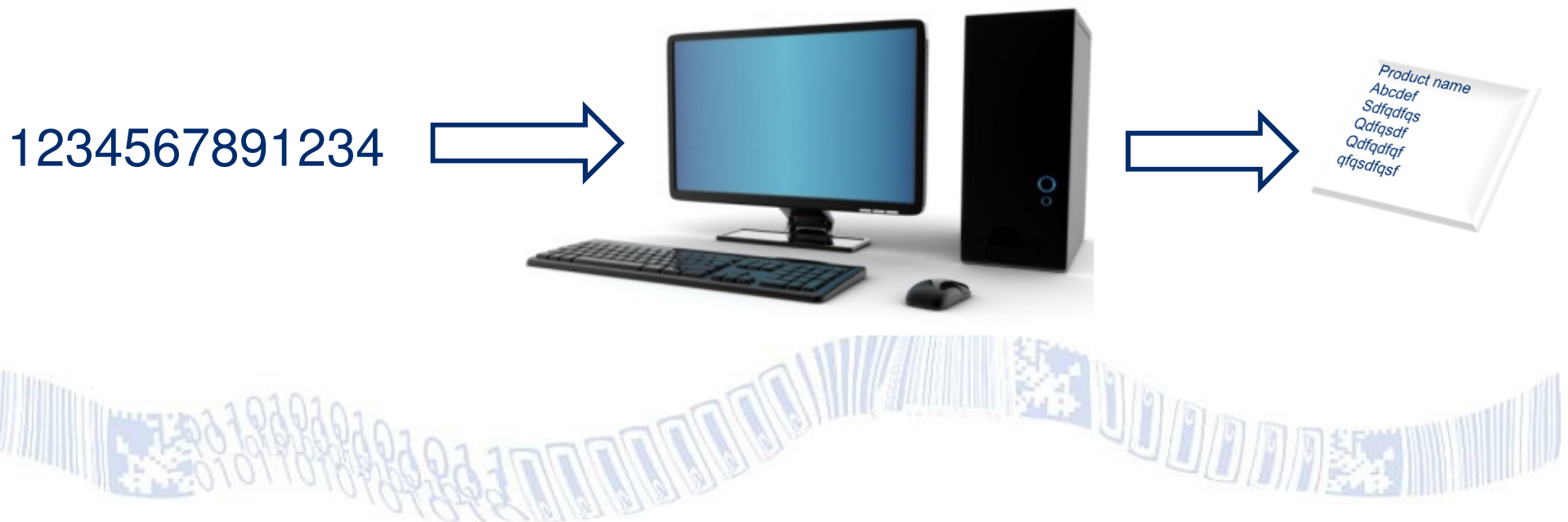




# The foundation of the GS1 System

## GS1 Identification Keys

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





# GS1 Identification Keys



Item identifier = **GTIN**

Global Trade Item Number



Logistics unit  
identifier =

**SSCC**

Serial Shipping Container Code



Location identifier = **GLN**

Global Location Number

And there are more ...

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





# GS1 Identification Keys

**GTIN** = Global Trade Item Number

*Products or Services*

**SSCC** = Serial Shipping Container Codes

*Individual Logistics Units*

**GLN** = Global Location Numbers

*Physical Locations and Legal Entities*

**GRAI** = Global Returnable Asset Identifier

*Returnable Assets*

**GIAI** = Global Individual Asset Identifier

*Fixed Assets*

**GSRN** = Global Service Relation Number

*Recipient of services*

**GSIN** = Global Shipment Identification Number\*

*Multiple Logistic Units for Trade (Shipper Assigned)*

**GINC** = Global Identification Number for Consignment\*

*Multiple Logistic Units for Transport (Transport Company Assigned)*

**GDTI** = Global Document Type Identifier

*Document Type*

*\*Not identified in General Specifications as ID key for healthcare*



# GS1 Application Identifiers

## Key attributes

GS1 General Specifications includes complete list of 100+ GS1 Application Identifiers

### Application Identifiers for healthcare use:

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
17	Expiry Date
21	Serial Number
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)
8017	GSRN (Global Service Relation Number) – Provider
8018	GSRN (Global Service Relation Number) – Recipient



# GS1 Data Carriers

## Bar Codes

- ✓ Affordable & easy implementations
- ✓ Pervasive technology
- ✓ Extensive standardization
- ✓ Proven applications / ROI's
- ✓ Adaptability / flexibility
- ✓ Expandable data capacity
- ✓ Visibility into the movement of physical objects in the supply chain

## RFID

- ✓ Non-line of sight
- ✓ Range
- ✓ Bulk read - Speed
- ✓ Zero Human Involvement Operations
- ✓ Durability
- ✓ Read/Write
- ✓ Visibility into the movement of physical objects in the supply chain at new levels

## Automation

Integration of physical and computer worlds







# GS1 Data Carriers

## Basic bar code system



**Host**

**Scanner / Reader  
Module**

**Bar Code  
Label / Mark**





# GS1 BarCodes for Healthcare



**Composite Component**



**GS1 DataMatrix**

(01) 00012345678905

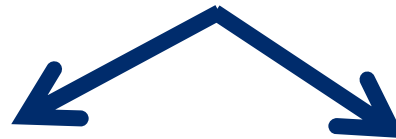




# GS1 Data Carriers for Healthcare



**Camera-based bar code scanners are needed in HC !!**



(01) 0 0012345 67890 5



102300912345678905

**GS1-128 &  
GS1 DataBar**



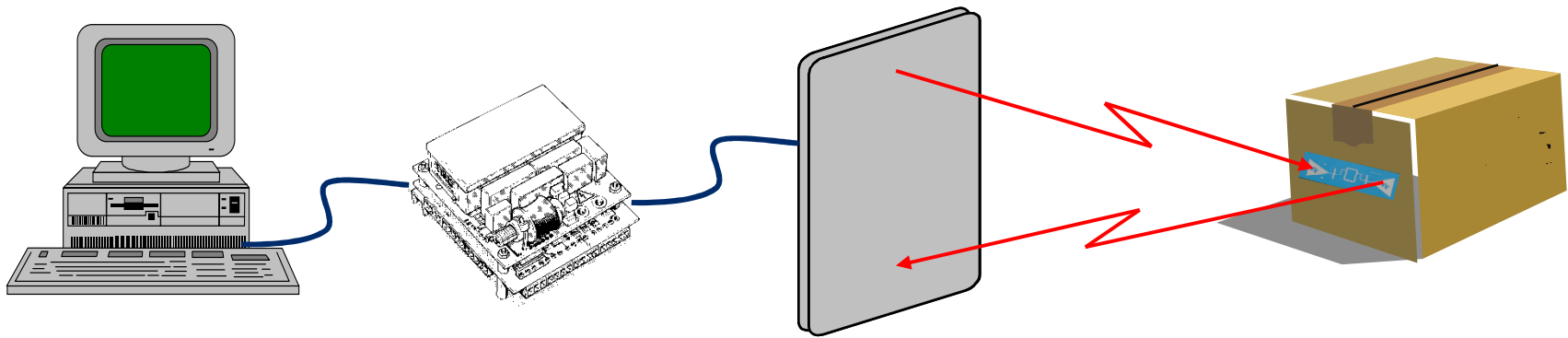
(01)07612345678900(17)100503  
(10)AC3453G3

**GS1 DataMatrix**



# GS1 Data Carriers

## Basic RFID system



**Host**

**Reader  
Module**

**Antenna**

**Tag**





# Topics

- Background
- Where we are going
- Where we are today
- **What this means to you**
- Questions





# **ONE global standard for AIDC in healthcare now available**

Many countries have already adopted  
GS1 Standards  
**We anticipate many more...**





**Putting the standards to work...**





# How YOU can get started



1. Contact your local **GS1 Member Organisation** for guidance
2. **Get familiar** with the standards / guidelines
  - Attend breakout sessions this week!
  - Participate on GS1 implementation projects / team
3. Do a **gap analysis**...your items vs. GS1 Standards
  - Focus on key items and facilities...don't 'boil the ocean'
  - Build action plans, budgets, management approval
4. Implement your **action plan**
  - Start small, conduct Pilot Projects, “learn by doing”, “crawl before you walk / run”...





## AIDC related sessions...

# This Week:

- Tuesday, 13:00 – 14:00  
“Implementation Reality”
  - GLN – GS1 Global Location Number, a basic key for traceability and other business processes  
Dennis Black, Director, e-Business, BD
- Wednesday, 14:00 – 15:00  
“Ask the Experts”
  - Ask the GS1 DataMatrix Expert  
Chuck Biss, Senior Director, AIDC Healthcare, GS1 Global Office



**Join us!!!**

## **Global teams**

- GSMP Level Below The Each Mission Specific Work Group (MSWG)
- GSMP AIDC Healthcare Application Standard Updates Mission Specific Work Group (MSWG)

**Join Us!**

## **Local teams**

- Contact your local Member Organisation representative





# Topics

- Background
- Where we are going
- Where we are today
- What this means to you
- **Questions**





# Agenda

- GS1 Healthcare – the global perspective
- AIDC Application Standards
- **Global Data Synchronisation & Product Classification**
- Traceability in Healthcare
- Public Policy





# GDSN in Healthcare

23 April 2013

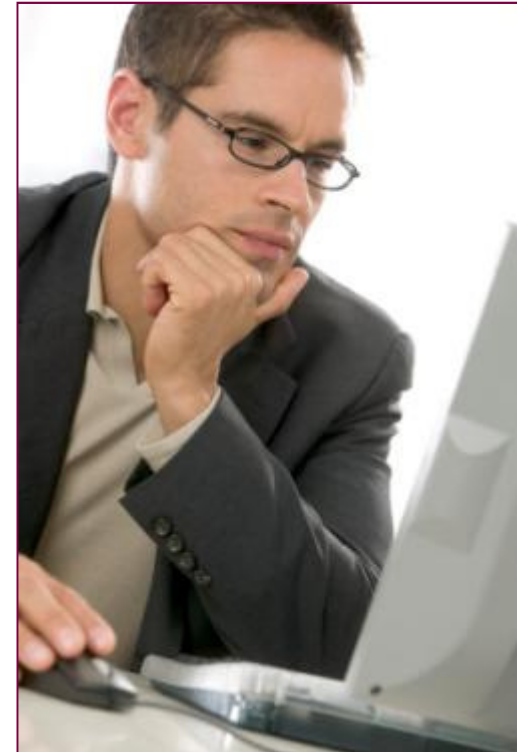




## The master data problem

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?*

Product catalogues - current situation:

- **Varying methods of communicating new items**

- 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 →



- **Varying methods of communicating updates/changes (or not communicating)**

- **Varying descriptions and levels of detail (product attributes)**





# No standardised product ID

## Different products – same number



For example: Part Number 10313 in a major GPO's Product Item Master refers to:

- Medtronic's - "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"
- Hantover's - "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"
- Chattanooga Group's - "ACCESSORY TRACTION REPLACEMENT STRAP XL FOR HALTER THORACIC RESTRAINT"
- HF Scientific's - "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"







# No standardised product information

## Inconsistent packaging data

- Order 20 cases, receive 20 boxes
- No uniform Unit of Measure standard



Unit of Measure

BD  
BDFT  
BN  
BO  
BOLT  
BR  
BRRL  
BX  
BXES  
CO  
COIL  
CR  
CRBY  
CS  
CSES  
CT  
CTON  
DR  
DRUM  
DZ  
DZEN  
EA  
EACH  
FE

Description

BOARD FOOT  
BOARD FOOT  
BUNDLE  
BOLT  
BOLT  
BARREL  
BARREL  
BOXES  
BOXES  
COIL  
COIL  
CARBOY  
CARBOY  
CASE  
CASE  
CARTON  
CARTON  
DRUM  
DRUM  
DOZEN  
DOZEN  
EACH  
EACH  
FEET

Unit of Measure

LOT  
LOTS  
LY  
LYRS  
NU  
NUTS  
OZ  
OZS  
PA  
PADS  
PI  
PINT  
PK  
PKGS  
PL  
PLS  
PR  
PRS  
QR  
QRES  
QT  
QTS  
RE  
REAM

Description

LOT  
LOT (MULTI)  
LINEAR YARD  
LINEAR YARD  
NUT  
NUT  
OUNCE  
OUNCES  
PAD  
PAD  
PINT  
PINT  
PACKAGE  
PACKAGE  
PAIL  
PAILS  
PAIR  
PAIR  
QUIRE  
QUIRE  
QUART  
QUART  
REAM  
REAM





# No standardised location ID

Manufacturer	Manufacturer	
SOUTHLAND TECHNOLOGY 3M	3M 800-327-5380	3M C/O EI
3M CO PHOTO PRODUCTS DIV	3M CO	3M C/O FL
3M DIAGNOSTIC SYSTEMS INC	3M DENTAL 800-237-1650	3M C/O Gc
3M ELECTRICAL SPECIALTIES DIV	3M ESPE DENTAL DIVISION 800-364-3577	3M C/O Hc
3M HEALTH	3M ESPE UNITED STATES	3M C/O IN
3M HEALTH CARE CDI	3M ESPE	3M C/O JA
3M HEARING COMPONENTS	3M HEALTH CARE 800-521-2818	3M C/O LL
3M INDUSTRIAL TAPES LTD	3M HEALTHCARE PRODUCT	3M C/O Nc
3M MEDICAL DEVICE DIV	3M HEALTHCATE	3M C/O Nc
3M MEDICAL IMAGING SYSTEMS DIV	3M MEDSURGE	3M C/O Oa
3M MEDICAL PRODUCTS DIV	3M MINNESOTA MINING MFG OFFICE	3M C/O Ri
3M MEDICAL-SURGICAL DIV	3M MINNESOTA MINNING & MFG.CO.	3M C/O Sa
3M MEDICAL/SURG	3M OCC. HEALTH AND ENV. SAFETY DIV	3M C/O Sc
3M PHARMACEUTICS AND MEDICAL S	3M OCC. HEALTH AND ENV. SAFETY DIV.	3M C/O Th
3M-MEDICAL/SURGICAL	3M SARNs/CDI	3M C/O Th
3M/ OCCUPATIONAL AND SAFETY DIV	3M SURGICAL	3M C/O Th
3M - MINNESOTA MINING & CO	3M UNITEK 800-423-4588	3M C/O Ti
3M FEDERAL GOVERNMENT	3M UNITEK	3M C/O Wc
3M FEDERAL SYSTEMS DEPARTMENT	THREE M/ ESPE	3M C/O Wc
3M HEALTH CARE SYSTEMS	3M COMPANY C/O WAHL CORP.	3M COMM
3M HEALTHCARE \$250 MINIMUM ORDER	MINNESOTA SCIENTIF	3M COMM
3M HEALTHCARE(MINNISOTA MINNING)	CORPORATE ALLIANCE 3M CUSTOMER SERV	3M COMP.
3M MEDICAL - CREDIT CARD	3 M HEALTHCARE	3M COMP.
3M MEDICAL PRODUCTS	3 M UNITEK CORP	3M COMP.
3M OCC. HEALTH AND ENV. SAFETY DIVISION	3-M	3M COMP.
3M OCCUPATIONAL AND SAFETY DIV	3-M COMPANY	3M COMP.
3M SAFETY DIVISION	3-M COMPANY-C/O O	3M COMP.
3M-DENTAL PRODUCTS DIVISION	3-M COMPANY-C/O OEM PRODUCTS	3M CONS
3M-HEALTH CARE	3-M PHARMACEUTICALS	3M CONS
3M DENTAL PRODUCTS DIV.	33M HEALTHCARE	3M CORP
3M UNITEK CORPORATION	3M	3M DENT/
3M UNITEK DENTAL PRODUCTS	3M PUERTO RICO	3M DENT/
3M BIOLOGICAL	3M SPECIALITY CHEMICAL	3M DEUT/
3M ESPE DENTAL PRODUCTS	3M % SAN-MAR	3M HEALT
3M HEALTH CARE (MED/SURG PRODS)	3M (CRJ7242)	3M HEALT
3M C/O CHECKPOINT METO	3M - MINNESOTA MI	3M HEALT
	3M - MINNESOTA MINING & MFG.CO	3M HEALT

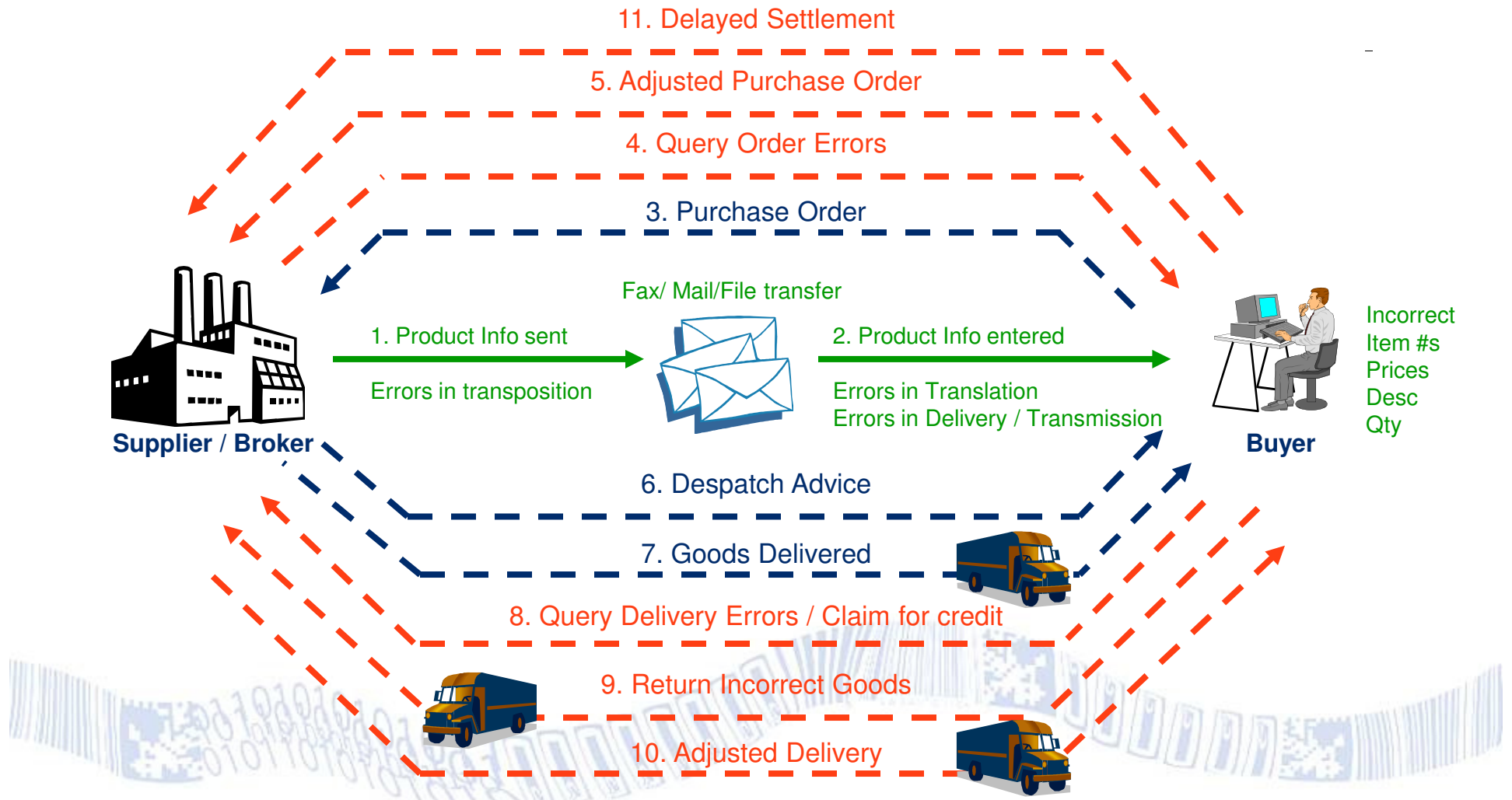
Multiple ways to list a manufacturer:

Who is who?





# Before Data Synchronisation





# Data Quality Industry study: UK

# £1 billion



**ComputerWeekly.com**

HOME IT MANAGEMENT NETWORKS AND COMMUNICATIONS **SOFTWARE** HARDWARE RESEARCH JOBS

You are in: Home > Software > Supply Chain Management Software > Article

**SOFTWARE** Supply Chain Management Software [Send to a friend](#) [Print](#)

- Desktop Software
- Enterprise Software
- Supply Chain Management Software**
- Operating Systems Software
- Systems Management Software
- Service Oriented Architecture (SOA) and Web Services
- Business Intelligence Software
- Database Software
- Storage Software
- Security Software


**Supermarkets back supply chain standard to save £1bn**

Author: Cliff Saran  
Posted: 12:24 08 Oct 2009

[BOOKMARK](#) [Facebook](#) [Twitter](#) [LinkedIn](#)

Supermarkets and big brand suppliers are backing a proposal to bring a product data standard to the UK which could save £1bn in supply chain costs over five years.

The UK's four largest supermarkets, Asda, Morrisons, Sainsbury's and Tesco, together with Mars, Nestle, Procter & Gamble, and Unilever, are among the organisations backing the initiative, which could allow UK retailers and manufacturers to share product data more effectively.



# What is the cost of bad data?



# Managing master data

## *Should we care?*

Critical business processes require reliable product and location data:

- Distribution systems
- Inventory replenishment
- Clinical systems
- Billing/accounts payable
- Traceability systems (pedigree systems, adverse event reporting, product recalls, barcode point-of-care systems,, ...)



**Inaccurate or bad data add cost and risk**





# 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





## What is the solution?

The GS1 **Global Data Synchronisation Network** connects trading partners via a network of interoperable GDSN-certified data pools

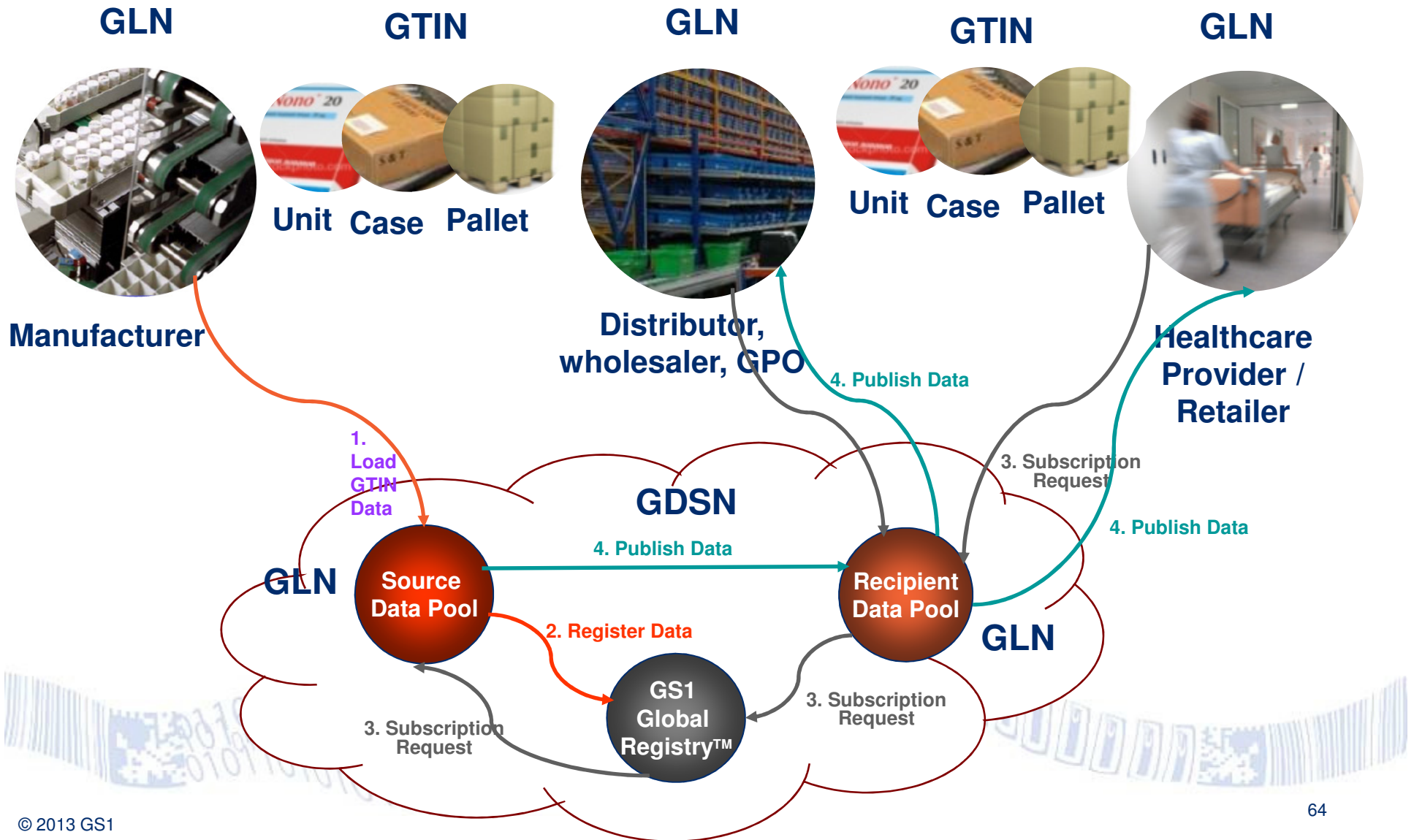


**Enables trading partners to share reliable master data**





# The Global Data Synchronization Network







# After Data Synchronisation





**For more information**



[www.gs1.org/gdsn](http://www.gs1.org/gdsn)





# Contact Details

Peter J Alvarez

GS1 Global Office

E [peter.alvarez@gs1.org](mailto:peter.alvarez@gs1.org)

T +1 609 462 2625





# Agenda

- GS1 Healthcare – the global perspective
- AIDC Application Standards
- Global Data Synchronisation & Product Classification
- **Traceability in Healthcare**
- Public Policy





# Traceability in Healthcare

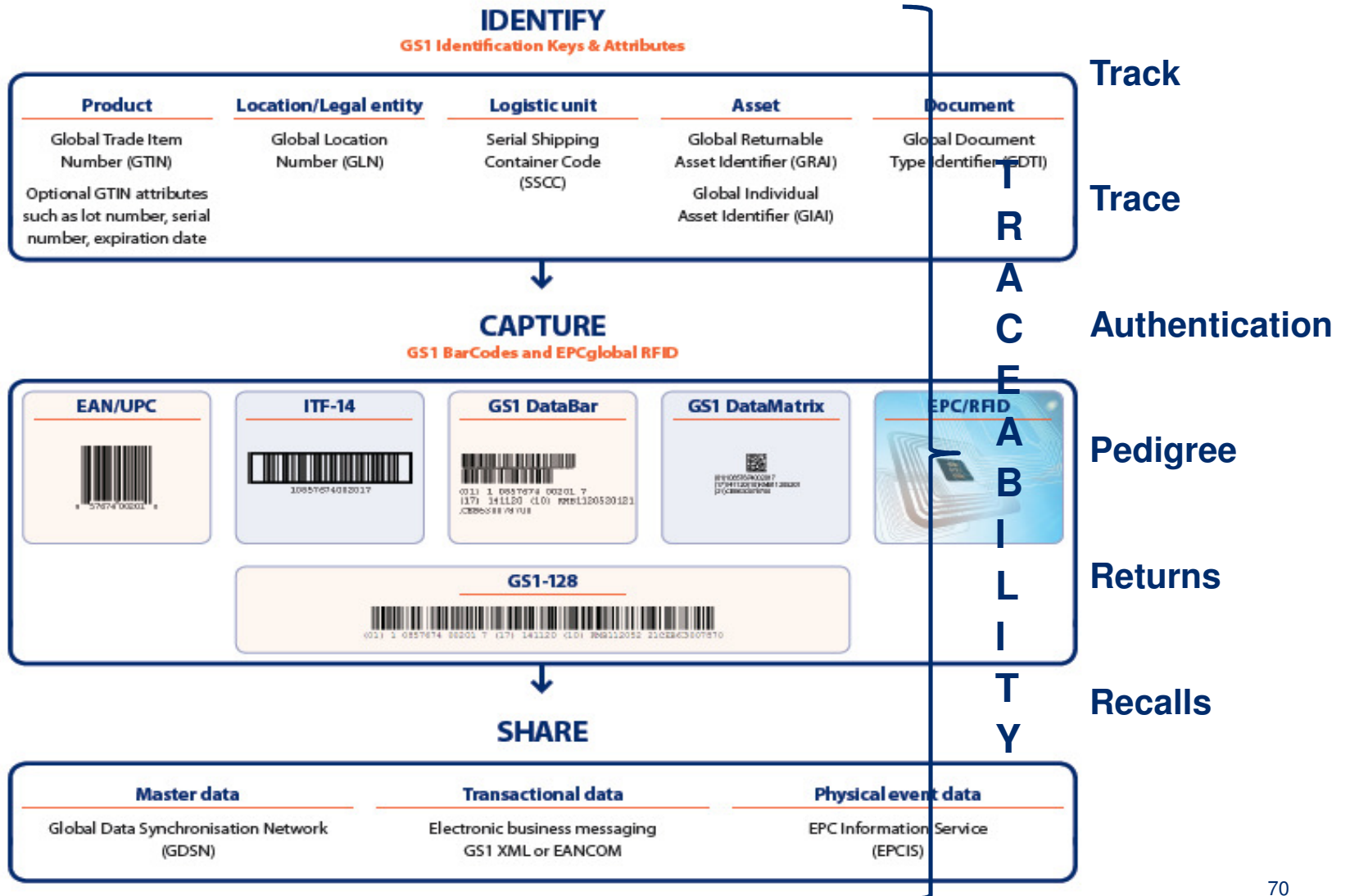
**Janice Kite**

**Traceability Director Healthcare  
Global Office**





# The GS1 System





## 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<sup>1</sup> to Point of Use<sup>2</sup>**

- 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** (e.g. AI 8017; AI 8018)
- 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<sup>1</sup> to Point of Use<sup>2</sup>**

### 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<sup>3</sup> 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 27<sup>th</sup> February 2009**

[http://www.gs1.org/docs/gsm/traceability/Global\\_Traceability\\_Standard\\_Healthcare.pdf](http://www.gs1.org/docs/gsm/traceability/Global_Traceability_Standard_Healthcare.pdf)

## GTSH Implementation Guideline

**PUBLISHED 24<sup>th</sup> April 2009**

[http://www.gs1.org/docs/gsm/traceability/Global\\_Traceability\\_Implementation\\_Healthcare.pdf](http://www.gs1.org/docs/gsm/traceability/Global_Traceability_Implementation_Healthcare.pdf)





# Global Traceability Standard for Healthcare (**GTSH**) and Implementation Guideline (**GTSH IG**)



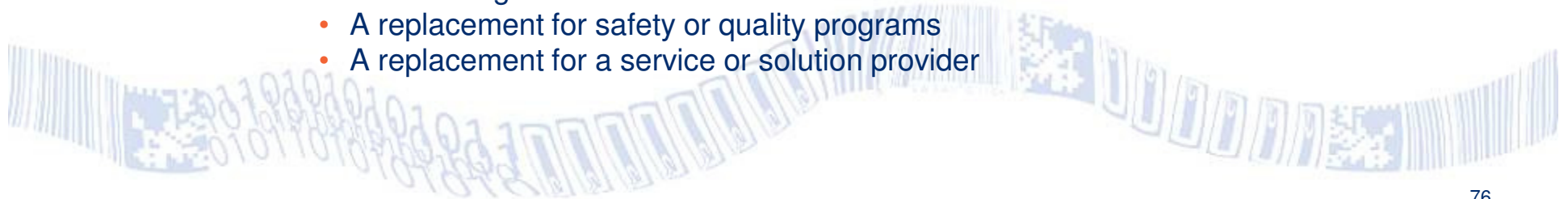


# GTSH: A PROCESS STANDARD

- Definition of 'Traceability' - both track (downstream) & trace (upstream)  
*"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"*
- Defines difference between 'Internal' and 'External' Traceability
- Establishes minimum model for Traceability: "One Up, One Down"
- Establishes key concepts:
  - A. In parallel with the flow of product there has to be a flow of information about the product
  - B. Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
  - C. 'Parties' and 'Roles': Parties can have varying roles
- Details 18 Business Requirements (Needs)
- 30 Business Rules (Controls or Constraints)
- Details the corresponding GS1 [technical] standards used within information technology tools

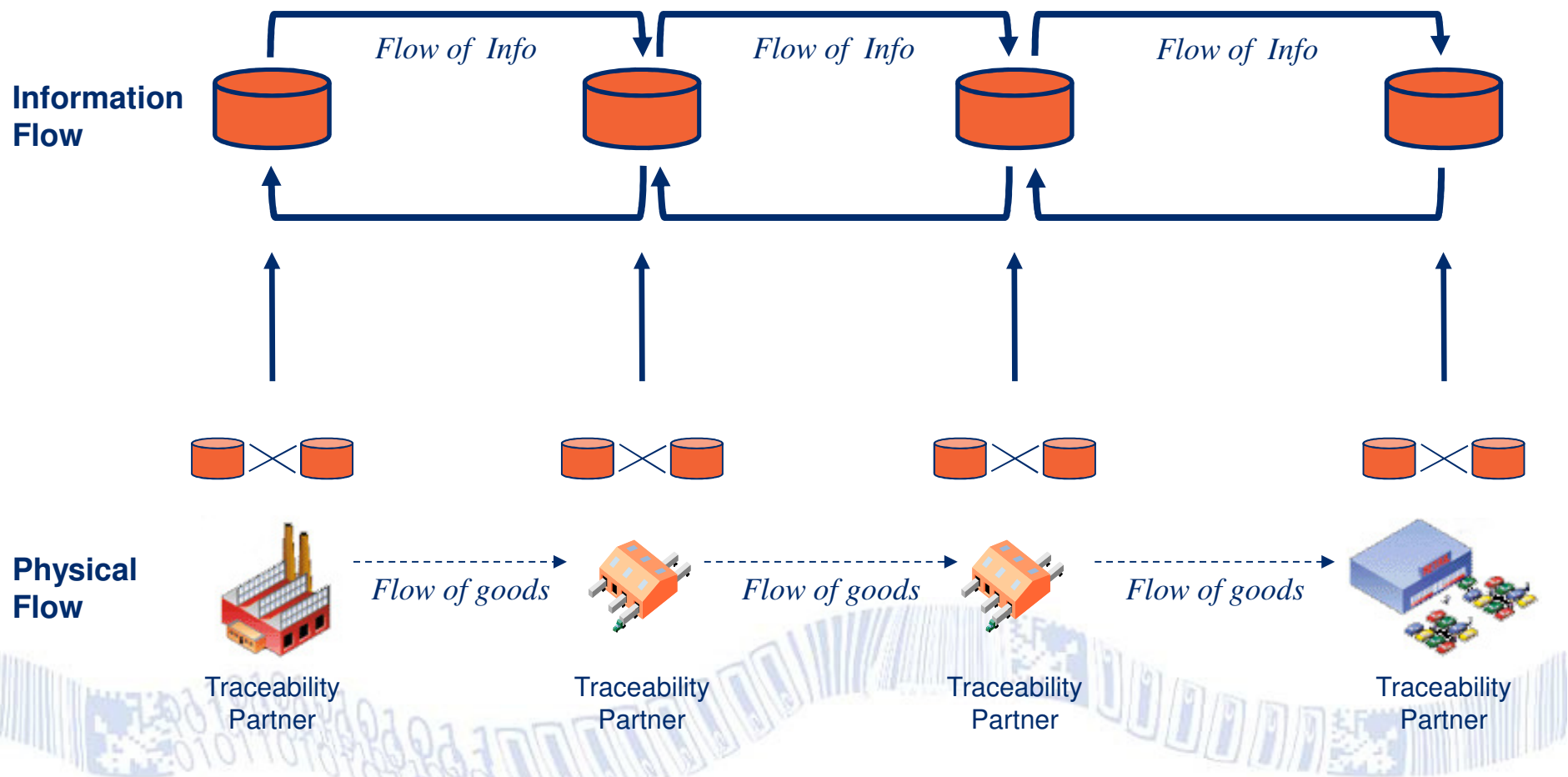
## GTSH is not:

- A law or regulation
- A replacement for safety or quality programs
- A replacement for a service or solution provider





# GTSH "One up, One down"





# GTSH Implementation Guideline

- “The purpose of this document is to assist any/all stakeholders in the global healthcare supply chain to implement a traceability system in line with the GS1 Global Traceability Standard for Healthcare (GTSH) utilising the GS1 System of standards...
- For products, in scope are all pharmaceutical products and all medical device products. Out of scope is implementation of traceability related to non-medical products supplied to Healthcare providers (e.g. food, information technology), blood and blood products.
- For supply chain, the start and end points in scope are from manufacturer of finished goods, including products created in the care facility, throughout the product’s intended useful life. Out of scope is implementation of traceability related to patients and healthcare professionals (HCPs) and End of Life Environmental regulations (e.g. European Waste Electrical and Electronic Equipment (WEEE) Directive)”



# Traceability Standards Development since 2007

**CURRENT FOCUS**





# The GS1 System

## IDENTIFY

GS1 Identification Keys & Attributes

Product	Location/Legal entity	Logistic unit	Asset	Document
Global Trade Item Number (GTIN)  Optional GTIN attributes such as lot number, serial number, expiration date	Global Location Number (GLN)	Serial Shipping Container Code (SSCC)	Global Returnable Asset Identifier (GRAI)  Global Individual Asset Identifier (GIAI)	Global Document Type Identifier (GDTI)

## CAPTURE

GS1 BarCodes and EPCglobal RFID

**EAN/UPC**

**ITF-14**

**GS1 DataBar**

**GS1 DataMatrix**

**EPC/RFID**

**GS1-128**

## SHARE

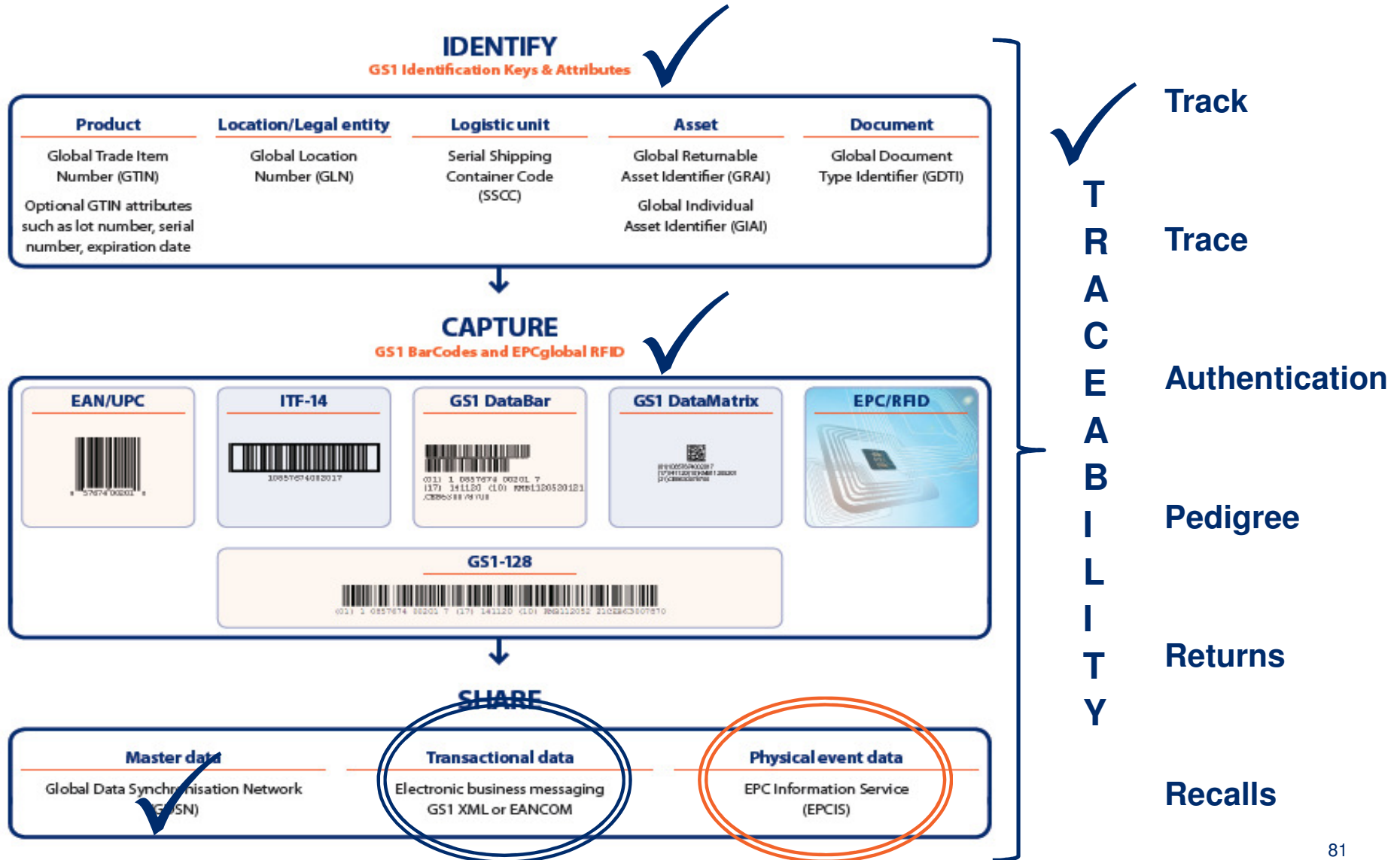
<b>Master data</b> Global Data Synchronisation Network (GDSN)	<b>Transactional data</b> Electronic business messaging GS1 XML or EANCOM	<b>Physical event data</b> EPC Information Service (EPCIS)
--	---	---

TRACK  
 TRACE  
 AUTHENTICATION  
 PEDIGREE  
 RETURNS  
 RECALLS





# TH-II: Physical Event Data





# Physical Event Data > Visibility Recall example

- **What:** what physical objects were involved (e.g. sGTIN in a GS1 Carrier)  
e.g. (01)10222222333334(21)12344(10)A1345B
- **When:** when the event took place (timestamp)  
e.g. 110922 (22<sup>nd</sup> September 2011)
- **Where:** where the event took place (e.g. GLN)  
e.g. 750620605 (Goods In, The General Hospital)
- **Why:** what business process step was being carried out (e.g. receiving, shipping...)  
Receiving

**The 4 W's**



# TH-II Project Strategy

- ✓ Phase I: *March 2009 – September 2011*
  - ✓ Create list of Use Cases
    - Chain of Custody / Chain of Ownership (CoC/CoO)
    - Product Identifier Authentication
  - ✓ Gather Business Requirements for each Use Case
  - ✓ Determine work of Phase II (and subsequent phases)
- ✓ Phase II: *January 2012 – March 2012*
  - ✓ Standards Gap Analysis to identify
    - Technical Models: Centralised, Semi-Centralised, Distributed
    - where a new standard(s) might be necessary
    - where existing standard(s) might need changing
  - ✓ Develop necessary Work Request(s) (WRs)





# TH-II Project Strategy

- ✓ Phase I: *March 2009 – September 2011*
  - ✓ Create list of Use Cases
    - Chain of Custody / Chain of Ownership (CoC/CoO)
    - Product Identifier Authentication
  - ✓ Gather Business Requirements for each Use Case
  - ✓ Determine work of Phase II (and subsequent phases)
- ✓ Phase II: *January 2012 – March 2012*
  - ✓ Standards Gap Analysis to identify
    - Technical Models: **Centralised**, Semi-Centralised, Distributed
    - where a new standard(s) might be necessary
    - where existing standard(s) might need changing
  - ✓ Develop necessary Work Request(s) (WRs)





# Background Information - Standards Gaps vs Models

= First Priority

WR12-126

WR12-127

		Centralized Models			Distributed Models				
Standards Gap		1	2a	2b	3	4	5	6	7
WR12-126	1 Definition of EPCIS events needed to form pedigree	✓	✓	✓	✓	✓	✓	✓	✓
	2 CBV enhancements to support above	✓	✓	✓	✓	✓	✓	✓	✓
	3 Definition of pedigree checks, given events are gathered	✓	✓	✓	✓	✓	✓	✓	✓
WR12-127	4 Central checking service request/response protocol	✓	✓	✓				✓	
	5 Choreography/security for centralized models (including use of ONS for semi-centralized)	✓	✓	✓					
	4 & 5 includes addressing gaps for Product Identifier Authentication (PIA)								
	Choreography/security for distributed models (including use of Discovery Services in some models)				✓	✓	✓	✓	✓
	Enhanced ASN/DA					✓			✓
	“Router” service			✓					



# Traceability in Healthcare MSWGs: Pedigree Security, Choreography and Checking Service (SCCS) MSWG

- Goal

Develop standards to allow pharmaceutical supply chain parties striving to meet pedigree regulation requirements, focused on gathering and checking pedigree event data. Standards will also address data confidentiality and integrity. This MSWG will create A) standard for security framework applicable to EPCIS and Discovery Services and B) pedigree checking service.

- Status

MSWG established and meeting regularly

- Timeline

BRAD eBallot June 2013





# Traceability in Healthcare MSWGs: Enable Network Pedigree MSWG

- Goal

Create new standard to enable Pedigree validation – a ‘profile’ standard above EPCIS that defines the types of EPCIS events and fields... that need to be captured for pedigree data. Will also define which tests need to be performed to verify pedigree data validity and integrity.

- Status

MSWG currently on hold due to US pilots in progress; gap analysis

- Timeline

Scheduled to start Q2 2013





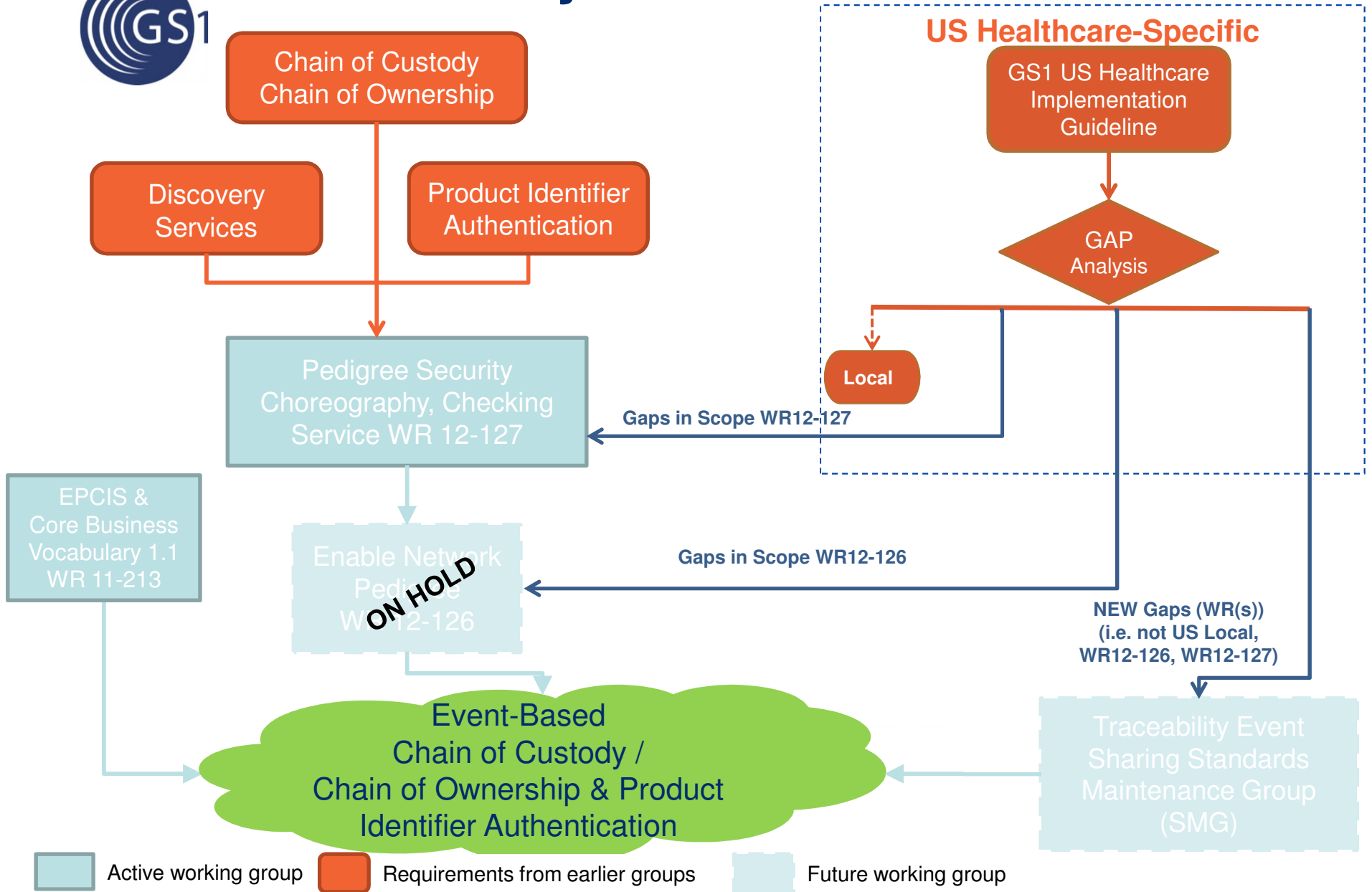
# Where are we now

- **WR12-126**
  - Approval of Statement of Business Need to enable Mission Specific Work Group (MSWG) to form and begin work – by June 2013
  - Completion estimated end Jun 2015
- **WR12-127** <http://community.gs1.org/apps/org/workgroup/gsmppedscsmsgw/>
  - Developing BRAD – scheduled completion end of June 2013
  - Completion estimated end June 2014
- **WR11-213** [http://community.gs1.org/apps/org/workgroup/gsmpepcis1\\_1cbvmswg/](http://community.gs1.org/apps/org/workgroup/gsmpepcis1_1cbvmswg/)
  - BRAD completed to progressed to community review
  - Completion estimated end December 2013



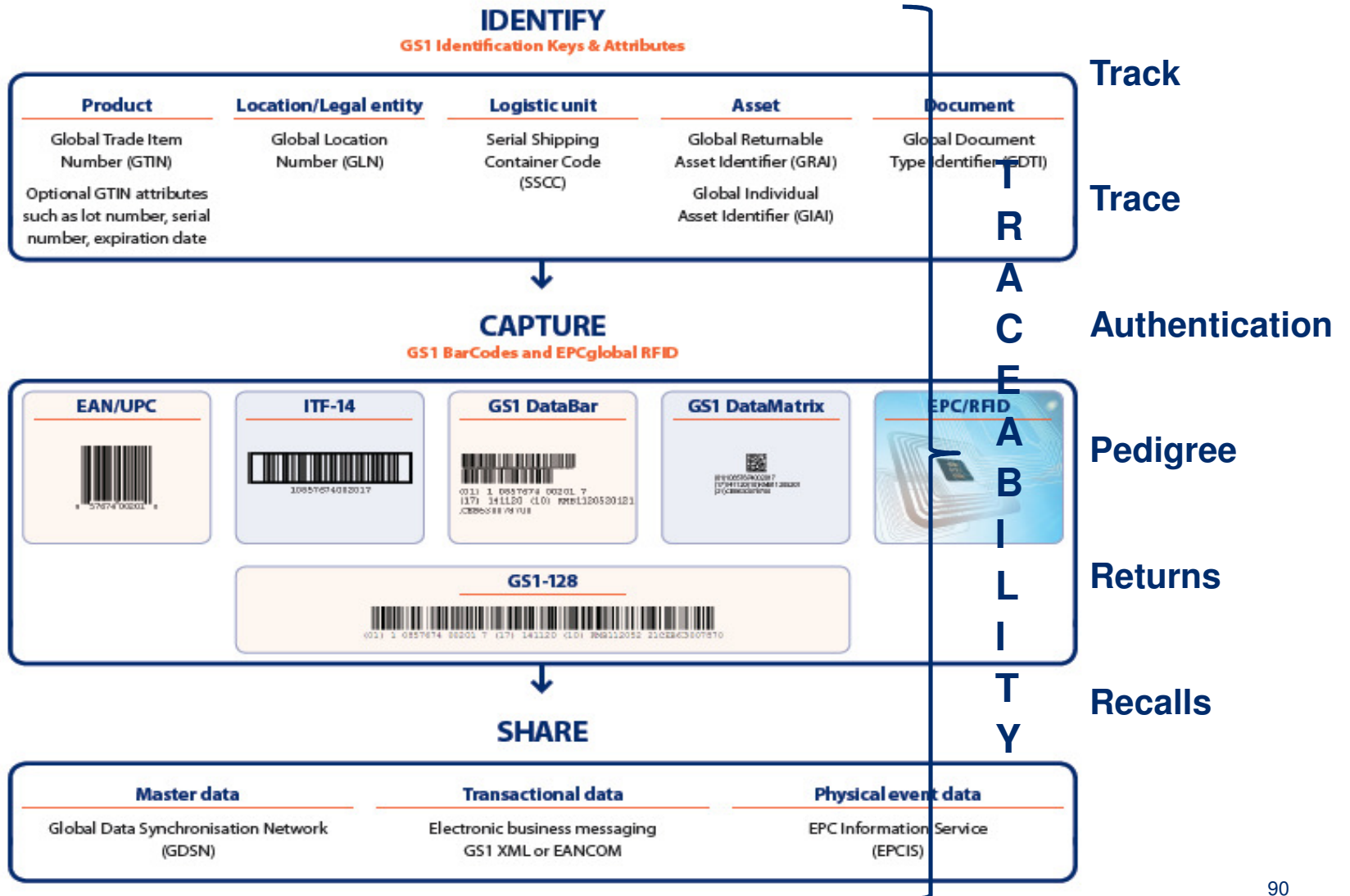


# Traceability Framework





# The GS1 System





# Contact Details

Janice Kite

E [janice.kite@gs1.org](mailto:janice.kite@gs1.org)

W [www.gs1.org/healthcare](http://www.gs1.org/healthcare)





# Agenda

- AIDC Application Standards
- Global Data Synchronisation & Product Classification
- Traceability in Healthcare
- **Public Policy**





# GS1 Healthcare Public Policy

**Introduction to Healthcare  
Public Policy Work Team**

**23<sup>rd</sup> Global Conference Buenos Aires**





# Public Policy Work Team



Jackie Elkin  
Medtronic



Neil Lawrence  
GSK



Géraldine  
Lissalde-Bonnet  
GS1 GO



Ulrike Kreysa  
GS1 GO





## Public Policy WT Charter - *Purpose*

- Provide **strategic leadership in the conduct and interaction** with global public policy makers promoting harmonization of product identification at global level
- Provide a **forum for open exchange of information** between members
- **Monitor the global regulatory landscape** around the topics of healthcare and determine priorities for GS1 to engage in and act upon
- Establish a framework and **repository of global regulations** related to Healthcare : GS1 Healthcare Public Policy DataBase



## Public Policy WT - *Meeting Logistics*

 Meetings are scheduled **bi-weekly** and held via **teleconference**

- Meeting notices are sent to membership via Microsoft Outlook
- Currently scheduled on Wednesdays

CET 16:30 – 17:30

EST 10:30 – 11:30

GMT 15:30 – 16:30



All documents available online in **GS1 HCPP**  
**Community room**

Registration necessary – access only for GS1 Healthcare members





## Public Policy WT Charter - *Purpose*

- Provide **strategic leadership in the conduct and interaction** with global public policy makers promoting harmonization of product identification at global level
- Provide a **forum for open exchange of information** between members
- **Monitor the global regulatory landscape** around the topics of healthcare and determine priorities for GS1 to engage in and act upon
- Establish a framework and **repository of global regulations** related to Healthcare : GS1 Healthcare Public Policy DataBase



# Country development adoption slides

- Developed by GS1 Healthcare Public Policy Work Team
- Complete and updated overview of regulatory dev. worldwide
- **Access to this slide-deck is limited to members of GS1 Healthcare**
- GS1 legal dept. included a **copy-right notice**: should **not be used without GS1 authorisation** and should not be circulated outside of GS1 Members.





## Public Policy WT Charter - *Purpose*

- Provide **strategic leadership in the conduct and interaction** with global public policy makers promoting harmonization of product identification at global level
- Provide a **forum for open exchange of information** between members
- Monitor the global regulatory landscape around the topics of healthcare and **determine priorities for GS1 to engage in and act upon**
- Establish a framework and **repository of global regulations** related to Healthcare : GS1 Healthcare Public Policy DataBase



# GS1 HC Public Policy Database

- Online repository: <http://healthcare.gs1.org/pp/>
- Relevant latest regulatory requirements at national, regional and local levels
- Information received by:
  - worldwide network of over 111 GS1 MOs,
  - members of the global GS1 Healthcare community,
  - Healthcare governmental bodies and regulators
- **Access to this DataBase is limited to members of GS1 Healthcare**



## GS1 Healthcare Public Policy database



### Welcome!

This database provides the latest relevant regulatory requirements, stakeholder agreements and user requests related to Healthcare product identification, product catalogues and traceability, at national, regional and local levels.

### Login



### Not yet a member ?

This information is only accessible for global GS1 Healthcare members and GS1 Member Organisations. Each registration application will require approval by GS1.

- **Register here** to access the GS1 Healthcare Public Policy Database
- **Join GS1 Healthcare**



- Home
- How it works
- Browse DataBase
- Advanced search
- Document Library
- Help

## GS1 Healthcare Public Policy Database - Browse database

This browser shows the regions and countries which are in the database. You can sort them alphabetically following the different sections of the table by clicking on the section title.

For a quick search you can also enter date (dd-mmm-yyyy) or text format

12345...Last							
Region	Country	Enforcement Date	Product Type	Authority	Title	Last Update	
Asia Pacific (AP)	China		Pharma	State Food and Drug Administration (SFDA)	e-coding/serialisation	08-Feb-2013	<span style="background-color: yellow; border: 1px solid black; border-radius: 50%; padding: 2px;">UPDATED!</span>
Central & Eastern Europe (C&EE)	European Union	01-Oct-2012	Med. Dev.	European Commission	Proposal for a Regulation of the Europea ...	06-Feb-2013	<span style="background-color: yellow; border: 1px solid black; border-radius: 50%; padding: 2px;">UPDATED!</span>
Asia Pacific (AP)	Japan	01-Jun-2012	Pharma	Ministry for Health, Labour and Welfare	Revised Implementation Guideline for Bar ...	25-Jan-2013	
Asia Pacific (AP)	India		Pharma	Government of India Ministry of Commerce	Procedure relating to tracing and tracki ...	16-Jan-2013	
Western Europe & EFTA	Germany		Pharm.	Ministry of Health (BfArM)	Informationste ...	15-Jan-2013	
Western Europe & EFTA	Finland		Pharma	Finnish Medicines Agency (Fimea)		07-Jan-2013	
Asia Pacific (AP)	Australia		MedDev/Pharma	NEHTA (National eHealth Transition Autho ...		19-Dec-2012	
Western Europe & EFTA	Netherlands		Pharma			18-Dec-2012	
Central & Eastern Europe (C&EE)	Slovenia		Pharma	Ministry of Health, Agency for Medicinal ...	Rules on labelling and on patient inform ...	14-Dec-2012	
Western Europe & EFTA	European Union	12-Dec-2012	MedDev/Pharma	European Commission Directorate General ...	eHealth Action Plan 2012 -2020 - Innovati ...	12-Dec-2012	

### Disclaimer

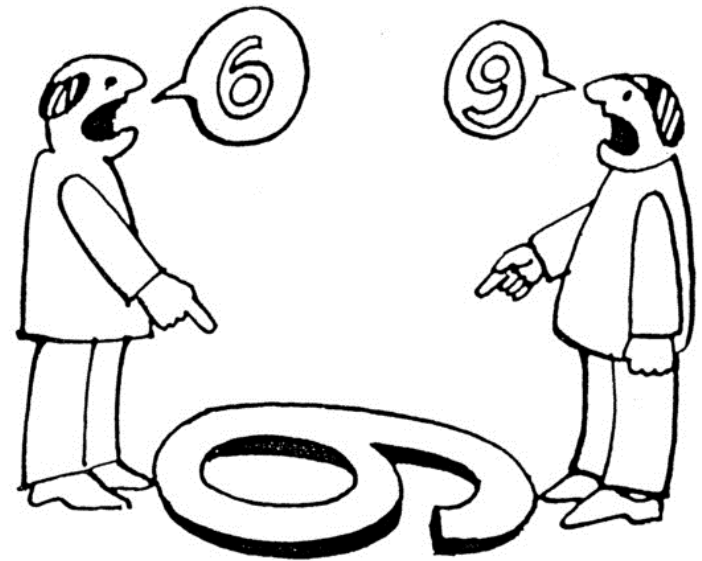
GS1 monitors the quality of the information available on this web site and updates the information regularly. However, GS1 does not guarantee and accepts no legal liability arising from or connected to, the accuracy, reliability, currency or completeness of any information contained on this web site or on any linked site. This web site is not a substitute for independent professional or legal advice on the relevant subject matter.

[Disclaimer/Copyright](#) | [Privacy](#) | [Sitemap](#) | [Contact webmaster](#)



# Public Policy WT Charter - *Communication*

- **Serve as representatives of GS1 Healthcare**, in interactions with local MOs, for communication and consultation with global public policy makers
- Provide a communication plan and structured templates as a means to providing a **consistent approved communications**





## Outreach/Communication:

### Responses, Position Statements, Fact Sheets

- Submission to TGA public consultations
- Letter to Saudi Arabia FDA providing comments on the draft Guidelines on barcoding
- Comments on US FDA UDI proposed rule and on EU draft Recommendation on UDI
- Draft Discussion paper on Mobile Authentication Services for pharmaceuticals





**Join our Public Policy  
Working Lunch  
on Wednesday from 13.00 to 15.00**





# Contact Details

- Ulrike Kreysa  
[ulrike.kreysa@gs1.org](mailto:ulrike.kreysa@gs1.org)
- Géraldine Lissalde-Bonnet  
[g.lissalde@gs1.org](mailto:g.lissalde@gs1.org)

