



The world of GS1 standards in healthcare

Geneva, 22 June 2010





GS1 Healthcare Topics

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





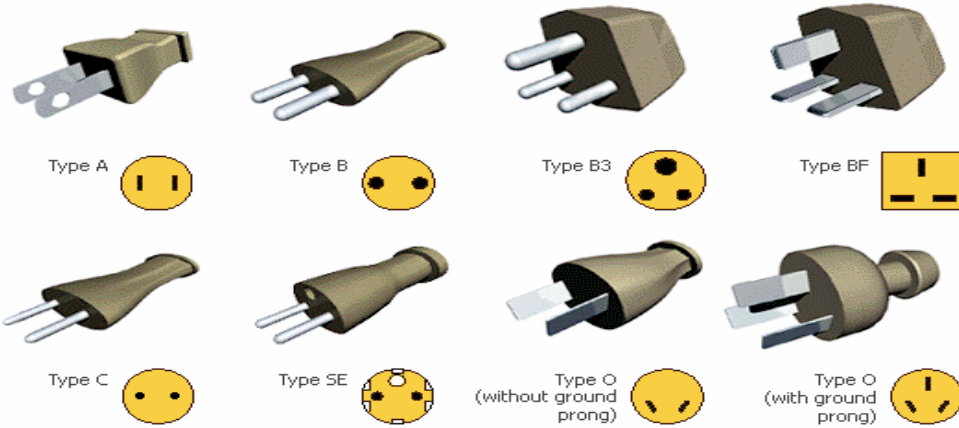
GS1 Healthcare Topics

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





Healthcare Lack of global standards...





Healthcare Global standards in Retail



Over 1 million companies use global standards to manage the supply chain of consumer products.

6 billion 'beeps' per day.

US\$ 17 billion annual cost savings in the grocery sector alone.





Healthcare

Global standards in Healthcare?





Healthcare

Global standards in Healthcare?



A manufacturing headache...

Country A



Country B



Country C



Country E



Country D





Healthcare Global standards in Healthcare?

(Re-)Labeling and re-packaging by Healthcare providers...



Security, traceability and efficiency in healthcare

are currently at the forefront of
government regulations and industry
concerns around the world.

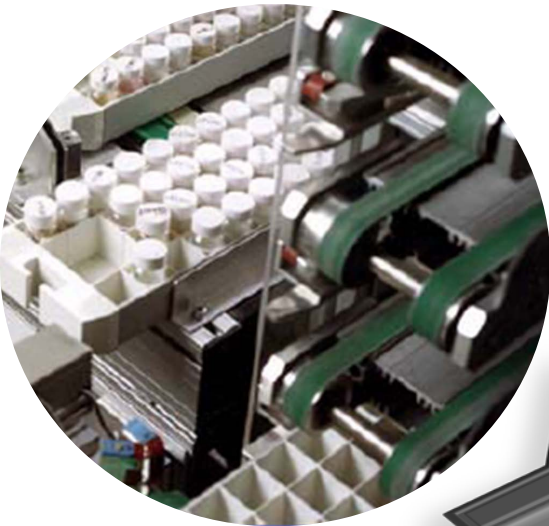


Healthcare Challenges & opportunities

- 1. Improving patient safety**
- 2. Increasing supply chain efficiency**
- 3. Ensuring regulatory compliance**



The healthcare supply chain... *simplified*



Manufacturer



Healthcare provider



Distributor, wholesaler, GPO, ...



Patient

The healthcare supply chain ... *in real life*





GS1 Healthcare Topics

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





GS1 Standards in Healthcare ...

Our vision

GS1 Healthcare envisions a future where the healthcare sector utilises GS1 global standards for all items, locations, people and processes to drive patient safety and supply chain efficiency improvements-- starting with the manufacturer and ending with the patient.



Speak one language

across country or regional borders
between supply chain partners and
within an organisation

Sector-wide implementation of global
supply chain standards needed



An integrated approach

- Standardised identification keys
 - *Products, locations, assets, ...*
- Standardised data carriers
 - *Bar codes & RFID*
- Standardised sharing of static data
 - *Data on products & locations*
- Standardised sharing of dynamic data
 - *Event data*
- Standardised electronic communication



Global reach

Open standards

Proven standards

**Meeting the challenges
of today's Healthcare supply chain:
patient safety, security, visibility, efficiency, accuracy, ...**



GS1 Healthcare Topics

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





Healthcare The role of GS1

GS1 is a not-for-profit organisation dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

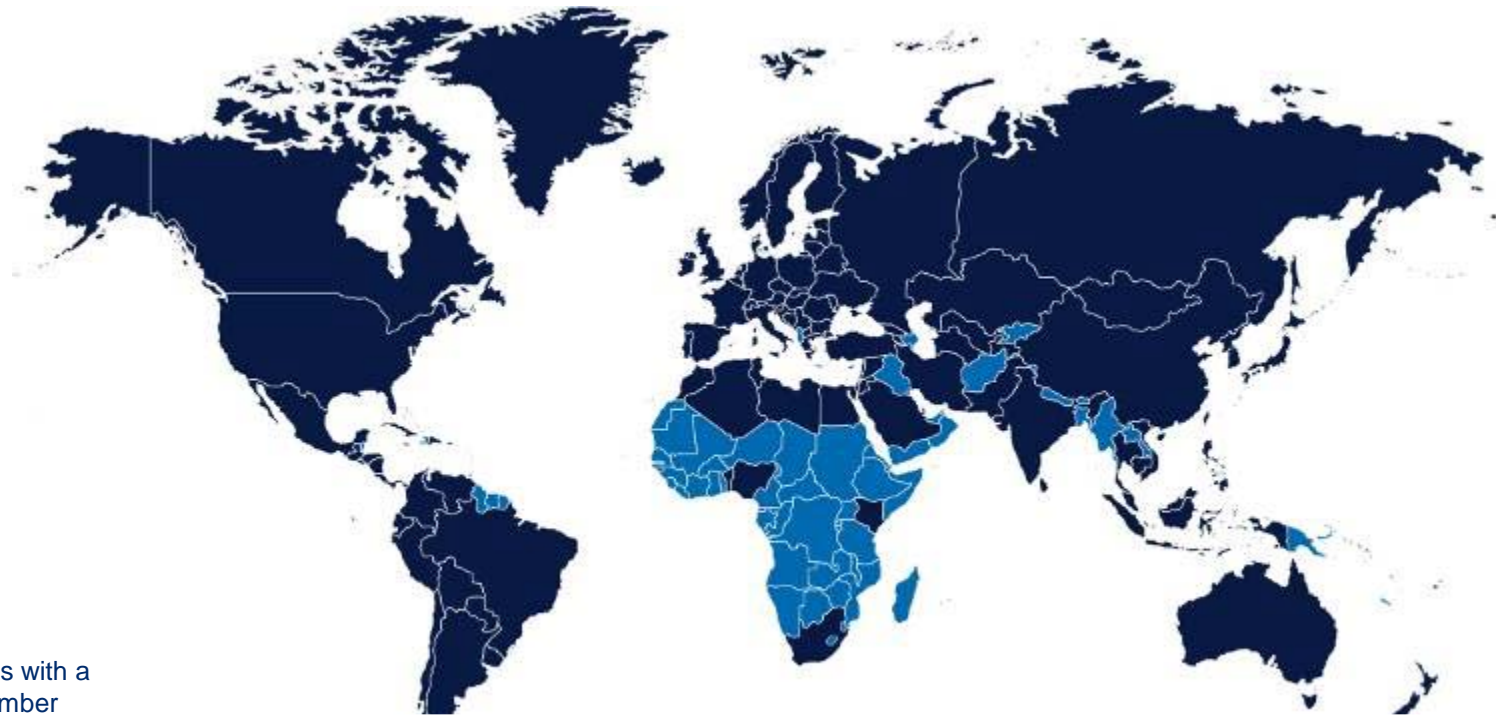
- **30** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day





Healthcare

GS1 around the world



■ Countries with a GS1 Member Organisation

■ Countries served on a direct basis from GS1 Global Office (Brussels)

108 Member Organisations - 150 Countries served

Global reach, local presence

GS1 Healthcare

Global, Voluntary 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 Increasing global recognition

A world map is centered on the slide, surrounded by logos of various healthcare organizations and regulatory bodies. The logos are arranged in a grid-like fashion around the map, representing global reach. The logos include:

- GS1 Healthcare** (top left)
- UimHA** (top center)
- NFU** (top center)
- JUVA DE NEDERLIJCH** (top center)
- Council of Europe** (top right)
- www.coe.int** (top right)
- afssaps** (middle left)
- Department of Health** (middle left)
- SWISSmedic** (middle left)
- edqm** (middle right)
- European Directorate for the Quality of Medicines & HealthCare** (middle right)
- Public Health Agency of Canada** (middle left)
- MEDBUY** (middle left)
- HealthPRO** (middle left)
- CareNET** (middle left)
- FDA** (middle left)
- Amerinet** (middle left)
- Novation** (middle left)
- PREMIER** (middle left)
- 厚生労働省** (middle right)
- Ministry of Health, Labour and Welfare** (middle right)
- CH FDA** (middle right)
- 醫院管理局** (middle right)
- HOSPITAL AUTHORITY** (middle right)
- MINISTRY FOR HEALTH, WELFARE AND FAMILY AFFAIRS** (middle right)
- ETCO** (bottom left)
- Cenabast** (bottom left)
- Government of India** (bottom center)
- nehta** (bottom right)
- MINISTRY OF HEALTH** (bottom right)
- MANATU HIAOORA** (bottom right)

And many more...

Working with International Organisations



World Health Organization



International Organisation for Standardization



European Committee for Standardization



Health Level 7



International Society for Blood Transfusion



International Society for Quality in Healthcare



United Nations



World Customs Organization



North Atlantic Treaty Organization

Local Healthcare user groups driving adoption



 **GS1 Healthcare Global work groups**

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

Meet bi-weekly via conference call
and 3 times per year in the global conferences.

Healthcare GS1 Standards for Healthcare

**Standards development continues,
but set of global standards available to build on:**

- 
- ✓ AIDC Application Standards for 90% of medical products
 - ✓ AIDC Application Standards for small instruments
 - ✓ Healthcare extension in next GDSN release
 - ✓ Global Traceability Standard for Healthcare



GS1 Healthcare Topics

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



Healthcare **How to get started**



1. Contact your local **GS1 Member Organisation** for guidance
2. **Join a local user group** to work with other healthcare stakeholders to advance the sector-wide implementation of standards
3. **Join the global user group** to work with other healthcare stakeholders to develop global standards and support global harmonisation





Enabling AIDC solutions in healthcare worldwide

Chuck Biss

GS1 Global Office





GS1 Healthcare Topics

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





GS1 Healthcare 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





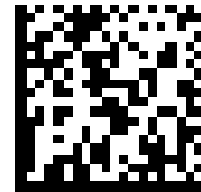
Healthcare AIDC Application Standards

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



Data – a few examples:

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



(01)07612345678900(17)100503

(10)AC3453G3 (21)123





(01) 0 0012345 67890 5



100000012345678905

**GS1-128 &
GS1 DataBar**



(01)07612345678900(17)100503

(10)AC3453G3

GS1 DataMatrix



EPC / RFID

Healthcare Scope: All healthcare products

Pharma / Vaccine / Nutritional



Medical devices



Retail

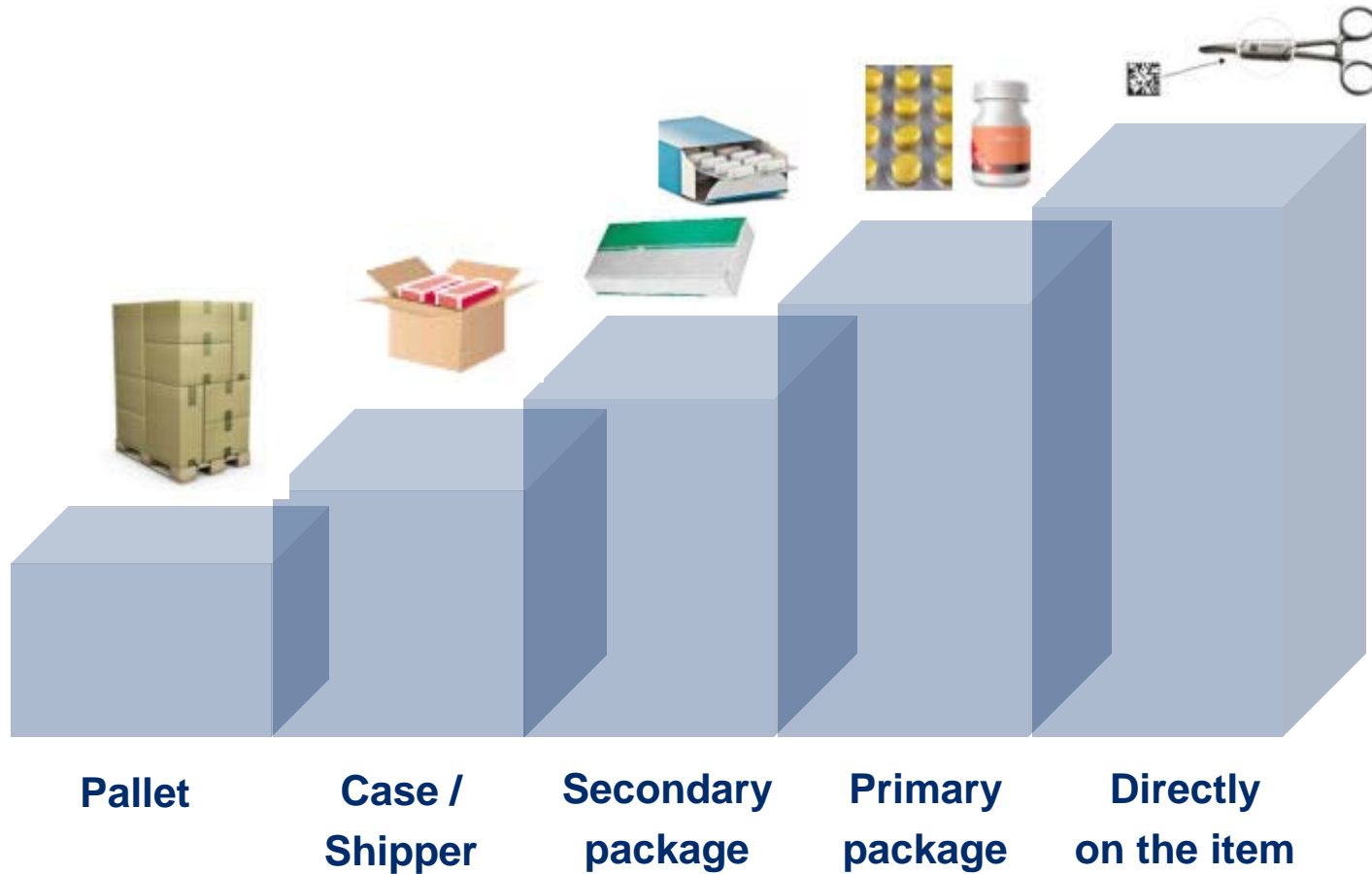


Non-retail





Healthcare Scope: All packaging levels





Healthcare

Scope: Risk-based solutions

AIDC Marking requirements

Highest

Enhanced

Minimum



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



Catheters, needles, ...



Pacemakers, hip replacements, ...



GS1 Healthcare Topics

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





Healthcare 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...





Healthcare AIDC for Healthcare...Why?

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





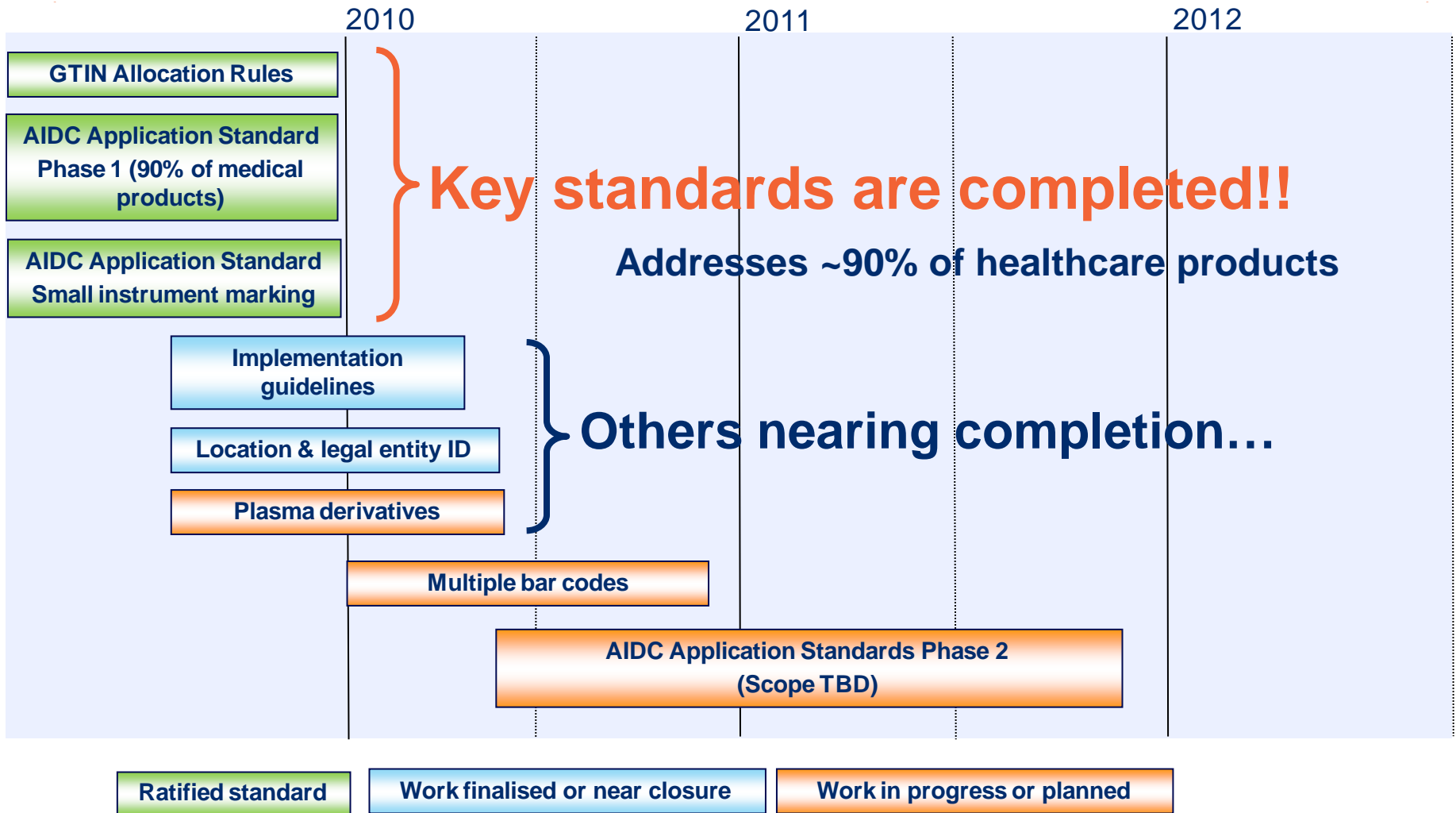
GS1 Healthcare Topics

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





Healthcare Roadmap to global standards





Healthcare

GS1 General Specifications

Revised!



The core standards document of the GS1 System

Now including AIDC Application Standards for Healthcare

And specific standards for marking re-usable surgical instruments

GS1 General Specifications

Version 10

Issue 1, Jan-2010

Contact your GS1 Member Organisation for your copy!





Healthcare AIDC Implementation Guide

In final draft!

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

Coming soon!!

AIDC Healthcare
Implementation Guide

Issue 1, Draft 10, 28-Jan-2010





AIDC Application Standards for Healthcare and Product Marking Grid

Description of the Example Product Hierarchy	MINIMUM Level of AIDC Marking (Retail)		MINIMUM Level of AIDC Marking (Non-Retail)		ENHANCED Level of AIDC Marking		HIGHEST Level of AIDC Marking	
	Pharmaceuticals	Medical Devices	Pharmaceuticals	Medical Devices	Medical Devices	Medical Devices	Pharmaceuticals	Medical Devices
	Distributed and/or Sold Primarily Via Retail Channels	Distributed and/or Sold Primarily Via Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Primarily Via Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels	Distributed and/or Sold Via Retail and/or Non-Retail Channels	Distributed and/or Sold Primarily Via Non-Retail Channels
DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 consumer bandage Primary Package: 1 bandage in pouch Secondary Package: 12 pouched bandages in one carton Case: 12 cartons (144 bandages) Pallet: 200 cases (28,800 bandages)	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 empty syringe Primary Package: 1 empty syringe in blisterpack Secondary Package: 12 empty blisterpacked syringes in one carton Case: 12 cartons (144 syringes) Pallet: 200 cases (28,800 syringes)	DPM: 1 contact lens Primary Package: 1 contact lens in vial Secondary Package: 2 vials of 1 contact lens each in one carton Case: 12 cartons (24 contact lenses) Pallet: 100 cases (2,400 lenses)	DPM: 1 catheter (temporary) Primary Package: 1 catheter in blisterpack Secondary Package: 6 blisterpacked catheters in one carton Case: 24 cartons (144 catheters) Pallet: 200 cases (28,800 catheters)	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 re-usable scalpel handle Primary Package: 1 re-usable scalpel handle in pouch Secondary Package: 6 pouched re-usable scalpel handles in one carton Case: 15 cartons (90 scalpel handles) Pallet: 200 cases (18,000 handles)	
Direct Part Mark (AIDC marked directly onto a single, unpackaged, unlabeled item)	No marking 	No marking 	No marking 	No marking 	No marking 	No marking 	GTIN Serial No. - Not for Implants Hospital: - 8003/8004 - optional  	
Primary Package (AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of 1 single item, or a group of items for a single therapy such as a Kit.)	No marking (mark with GTIN if no Secondary Package) 	No marking (mark with GTIN if no Secondary Package) 	GTIN 	No marking (mark with GTIN if no Secondary Package) 	No marking (mark with GTIN if no Secondary Package) 	GTIN Lot Expiry Hospital: AI(01)+AI(21)+AI(7003) 	GTIN Lot Expiry Serial No. Potency (kits) Hospital: - 8003/8004 - optional  	
Secondary Packaging (AIDC marked onto the next level of packaging, containing one or more single items in their Primary Packaging)	GTIN 	GTIN 	GTIN Lot Expiry 	GTIN Lot Expiry 	GTIN 	GTIN Lot Expiry 	[Need 2 marks] GTIN Lot Expiry Serial No. Potency Hospital: AI(01)+AI(21) + AI(7003)  	
Case / Shipper (AIDC marked onto a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Serial No. - Potency Logistics: - SSCC Hospital: - SSCC Hospital: AI(01)+AI(21) + AI(7003)  	
Pallet (AIDC marked onto a pallet. May contain one or more Case / Shippers.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Serial No. Logistics: - SSCC  	

GS1 Identification Keys

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

1234567891234



Healthcare 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**



Healthcare 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*

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)

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



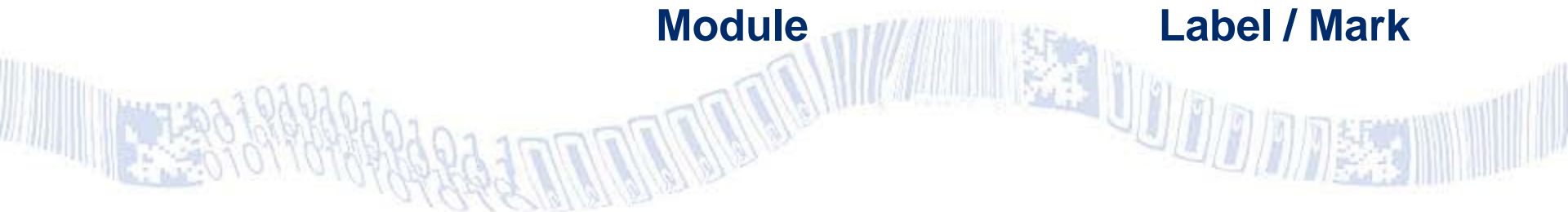
Basic bar code system



Host

**Scanner / Reader
Module**

**Bar Code
Label / Mark**





Healthcare GS1 BarCodes for Healthcare



EAN/UPC



GS1 DataBar

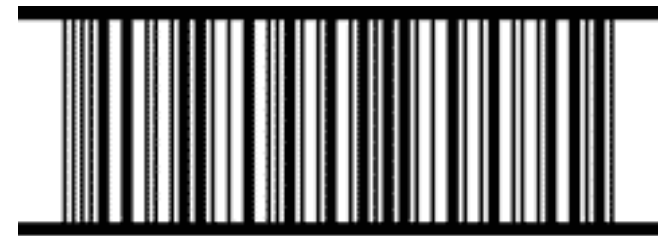


GS1-128



GS1 DataMatrix

(01)00012345678905



ITF-14

Composite Component



(02) 5 0123456 78901 7 (37) 000288 (02) 5 0123456 11111 5 (37) 000045

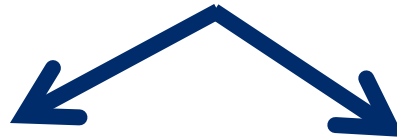


Healthcare

GS1 Data Carriers for Healthcare



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



(01) 0 0012345 67890 5



102700912345678905

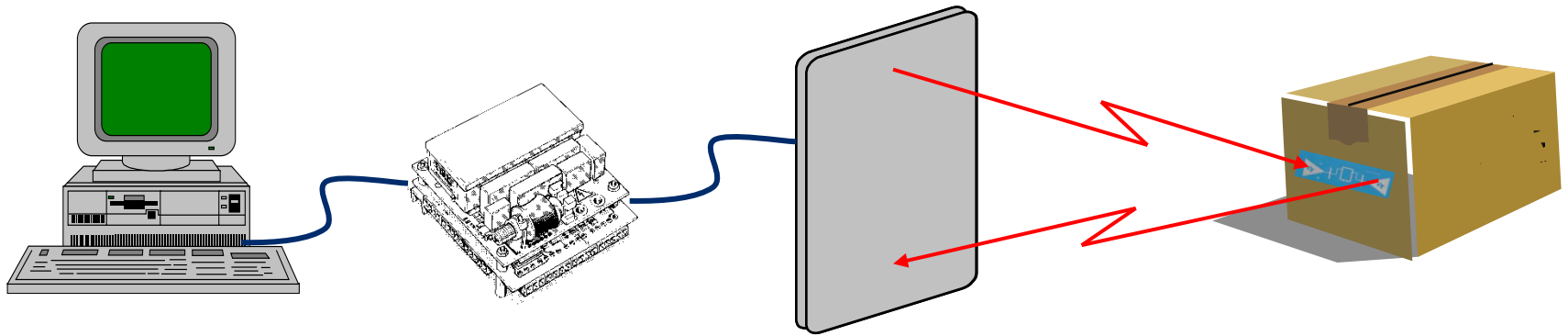
**GS1-128 &
GS1 DataBar**



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

GS1 DataMatrix

Basic RFID system



Host

**Reader
Module**

Antenna

Tag





GS1 Healthcare 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...





Healthcare 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”...



Healthcare AIDC sessions this week

This Week:

- Wednesday, 11:15 – 12:45 (breakout sessions)
Roundtable discussion groups
 - First steps for AIDC product marking - Manufacturers focus
 - First steps for AIDC product marking - Providers focus
- Wednesday, 14:00 – 15:30 (breakout session)
Roundtable discussion group
 - Defining the next steps for AIDC in Healthcare identification and marking - Healthcare AIDC Phase 2
- Thursday, 11:15 – 12:45 (breakout session)
Roundtable discussion group
 - Implementing Global Location Numbers (GLN) and the role of the GLN registries

Global teams

- Implementation Guideline
- Blood / Plasma Derivatives
- Location and Legal Entity ID
- Patient and Caregiver ID
- Multiple Barcodes
- Barcode / EPC Interoperability
- Serialization
- Phase 2: AIDC Application Standards

Local teams

- Contact your local Member Organisation representative

Join Us!



GS1 Healthcare Topics

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





Making electronic product catalogues through a single point-of-entry a reality

Peter Alvarez

GS1 Global Office





GS1 Healthcare Topics

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





GS1 Healthcare Topics

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





Healthcare **Managing master data**

Critical business processes require reliable product and location data:

- Distribution systems
- Inventory replenishment
- 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






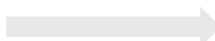




Healthcare **Managing master data *today***

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)**





Healthcare **No standardised product ID**

Different products – same number

For example:

Part Number 10313 in Premier Inc. 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

<u>Unit of Measure</u>	<u>Description</u>	<u>Unit of Measure</u>	<u>Description</u>
BD	BOARD FOOT	LOT	LOT
BDFT	BOARD FOOT	LOTS	LOT (MULTI)
BN	BUNDLE	LY	LINEAR YARD
BO	BOLT	LYRS	LINEAR YARD
BOLT	BOLT	NU	NUT
BR	BARREL	NUTS	NUT
BRRL	BARREL	OZ	OUNCE
BX	BOXES	OZS	OUNCES
BXES	BOXES	PA	PAD
CO	COIL	PADS	PAD
COIL	COIL	PI	PINT
CR	CARBOY	PINT	PINT
CRBY	CARBOY	PK	PACKAGE
CS	CASE	PKGS	PACKAGE
CSES	CASE	PL	PAIL
CT	CARTON	PLS	PAILS
CTON	CARTON	PR	PAIR
DR	DRUM	PRS	PAIR
DRUM	DRUM	QR	QUIRE
DZ	DOZEN	QRES	QUIRE
DZEN	DOZEN	QT	QUART
EA	EACH	QTS	QUART
EACH	EACH	RE	REAM
FE	FEET	REAM	REAM



Healthcare No standardised location ID

Manufacturer	Manufacturer	
SOUTHLAND TECHNOLOGY 3M	3M 800-327-5380	3M C/O EC
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 INI
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 NF
3M MEDICAL DEVICE DIV	3M HEALTHCARE	3M C/O NC
3M MEDICAL IMAGING SYSTEMS DIV	3M MEDSURGE	3M C/O OY
3M MEDICAL PRODUCTS DIV	3M MINNESOTA MINING MFG OFFICE	3M C/O RE
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 UNITEK	3M C/O W.
3M FEDERAL GOVERNMENT	THREE M/ ESPE	3M C/O WW
3M FEDERAL SYSTEMS DEPARTMENT	3M COMPANY C/O WAHL CORP.	3M COMMI
3M HEALTH CARE SYSTEMS	MINNESOTA SCIENTIF	3M COMMI
3M HEALTHCARE \$250 MINIMUM ORDER	CORPORATE ALLIANCE 3M CUSTOMER SERV	3M COMPJ
3M HEALTHCARE(MINNISOTA MINNING)	3 M HEALTHCARE	3M COMPJ
3M MEDICAL - CREDIT CARD	3 M UNITEK CORP	3M COMPJ
3M MEDICAL PRODUCTS	3-M	3M COMPJ
3M OCC. HEALTH AND ENV. SAFETY DIVISION	3-M COMPANY	3M COMPJ
3M OCCUPATIONAL AND SAFETY DIV	3-M COMPANY-C/O O	3M COMPJ
3M SAFETY DIVISION	3-M COMPANY-C/O OEM PRODUCTS	3M CONST
3M-DENTAL PRODUCTS DIVISION	3-M PHARMACEUTICALS	3M CONSI
3M-HEALTH CARE	33M HEALTHCARE	3M CORPI
3M DENTAL PRODUCTS DIV.	3M	3M DENTA
3M UNITEK CORPORATION	3M PUERTO RICO	3M DENTA
3M UNITEK DENTAL PRODUCTS	3M SPECIALITY CHEMICAL	3M DEUTE
3M BIOLOGICAL	3M % SAN-MAR	3M HEALT
3M ESPE DENTAL PRODUCTS	3M (CRJ7242)	3M HEALT
3M HEALTH CARE (MED/SURG PRODS)	3M - MINNESOTA MI	3M HEALT
3M C/O CHECKPOINT METO	3M - MINNESOTA MINING & MFG.CO	3M HEALT

Multiple manufacturer names

Order with whom?



Healthcare Data errors in healthcare

Data error	% of total	Manu- facturer	Distributor	GPO	Healthcare 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: US Department of Defense Study

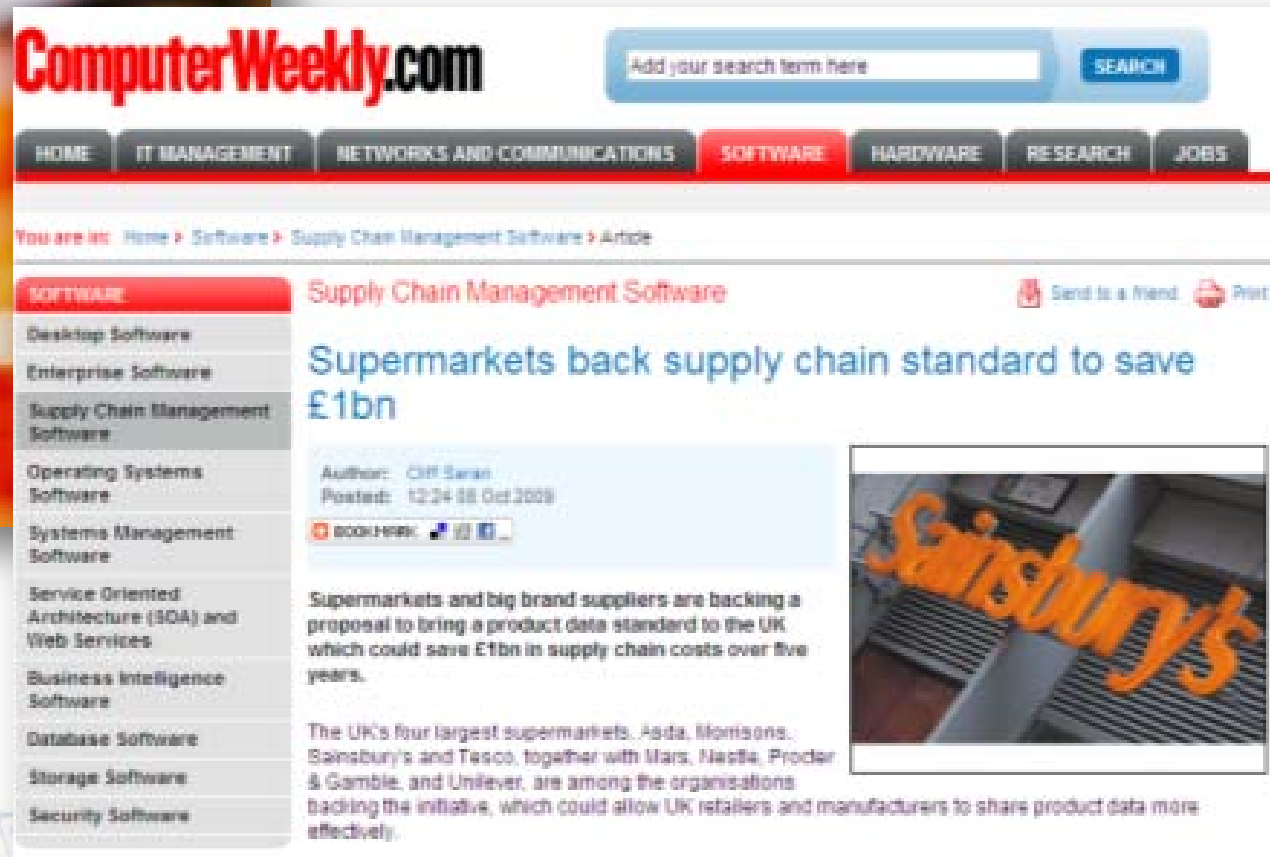


Healthcare **Bad data add cost and risk**

- **Inaccurate and inconsistent data in the Healthcare supply chain add billions of \$, €, ... in costs**
 - Supply chain information inefficiencies
 - Inaccurate data in transactions
 - Purchase orders and invoices with errors
 - Manual work-around processes to correct errors
- **Inaccurate and inconsistent data add risk to patient safety**
 - Disruptions may result in the inavailability of products to treat a patient
 - Medication errors due to incorrect relabeling



For reference: Data errors in Retail...



ComputerWeekly.com

Add your search term here **SEARCH**

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

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

SOFTWARE

- 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

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


Supermarkets back supply chain standard to save £1bn

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

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

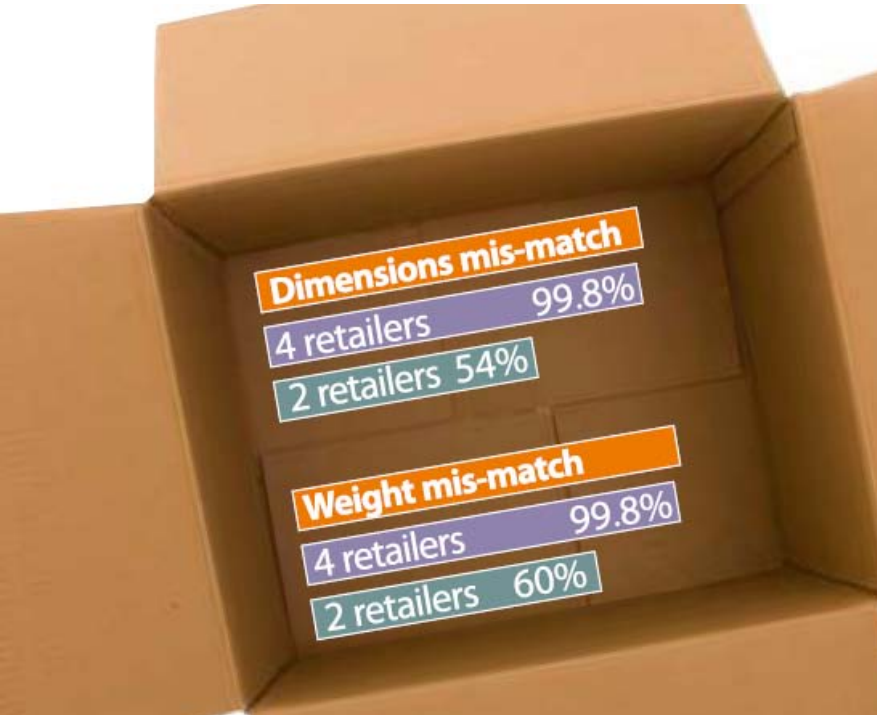
Supermarkets and big brand suppliers are backing a proposal to bring a product data standard to the UK which could save £1bn in supply chain costs over five years.

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.





Healthcare A few examples





Healthcare **Managing master data *tomorrow***

Supplier = data source

Needs single point-of-entry

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

Needs security

- Authorisation access by supply chain partners

Standards-based

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

Hospital = data recipient

Needs single point-of-truth

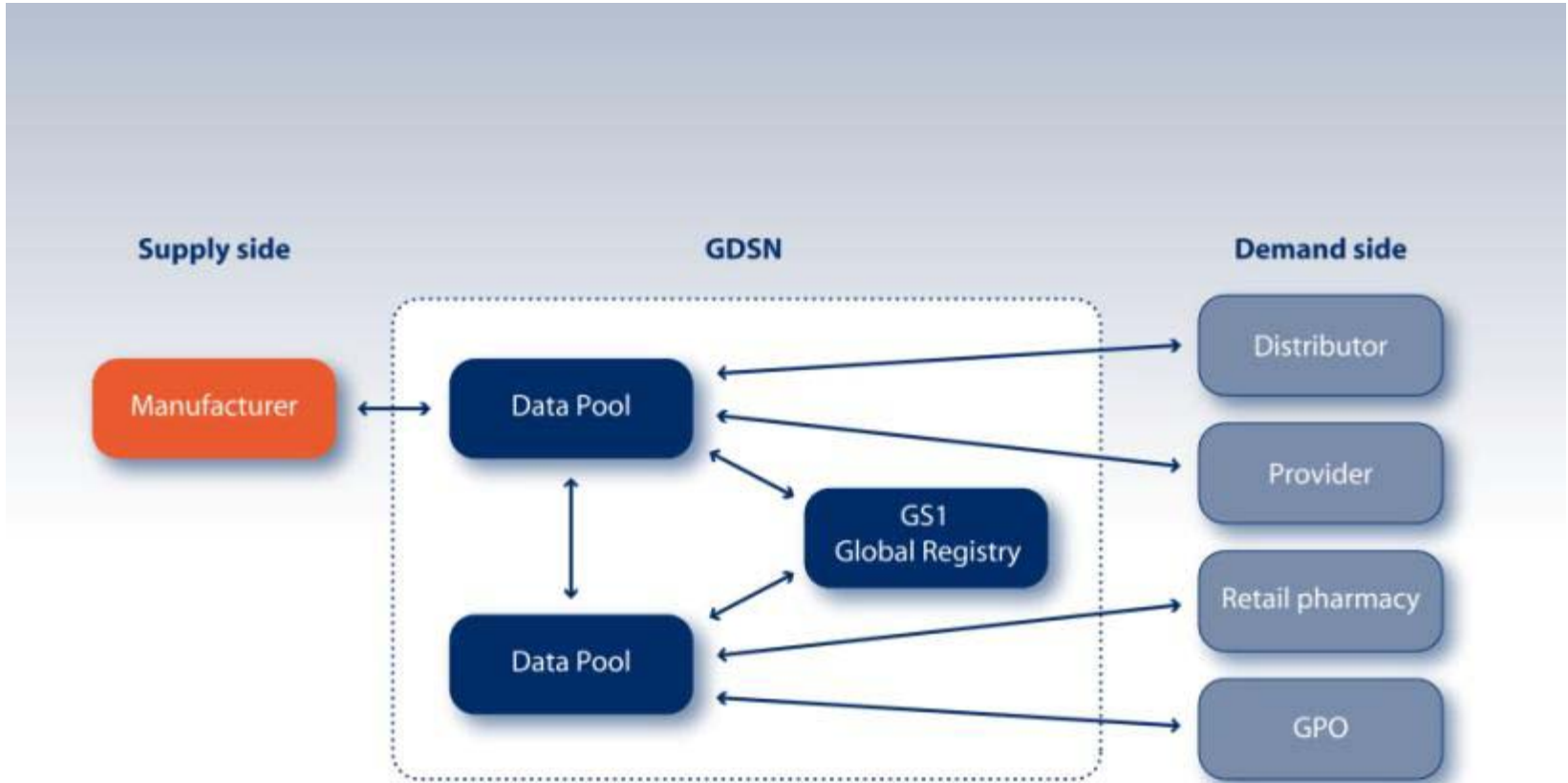
- One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

- Standard identification keys
- Consistently formatted information
- Complete information



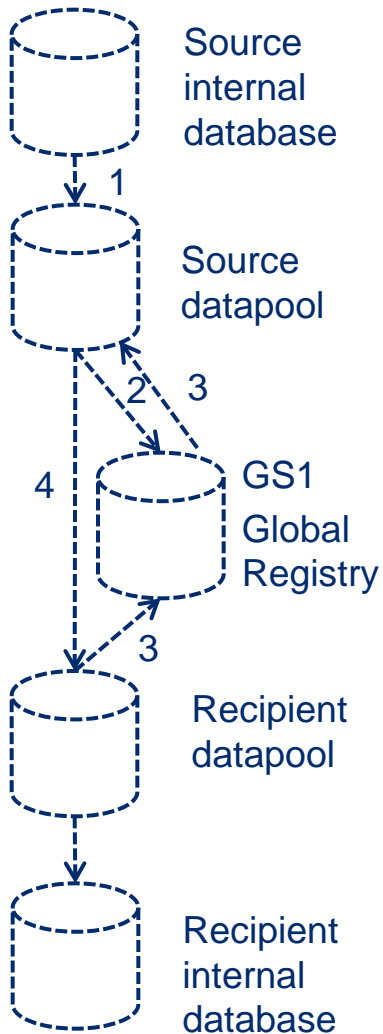
Healthcare Global Data Synchronisation



↔ GDSN data exchanges



Healthcare How GDSN works



1. Load data

- The seller registers product and company information in its data pool

2. Register data

- A small subset of this data is sent to the GS1 Global Registry

3. Request subscription

- The buyer, through its own data pool, subscribes to receive a seller's information

4. Publish data

- The seller's data pool publishes the requested information to the buyer's data pool

5. Confirm & inform

- The buyer sends a confirmation to the seller via each company's data pool, which informs the seller of the action taken by the buyer using the information



GS1 Healthcare **GDSN data attributes**

25 mandatory attributes

- 8 mandatory attributes required to register products in the GS1 Global Registry
- 17 mandatory attributes to operate in the GDSN

200+ optional attributes

- Trading partners decide whether to exchange additional information
- There are currently 203 optional GDSN attributes which support healthcare specific needs
- 33 new data requirements are being added to the GDSN standard





GS1 Healthcare Topics

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





Healthcare **GDSN for Healthcare...Vision**

All product information for every item is current, correct, and available **via a single globally-accessible network**





GS1 Healthcare Topics

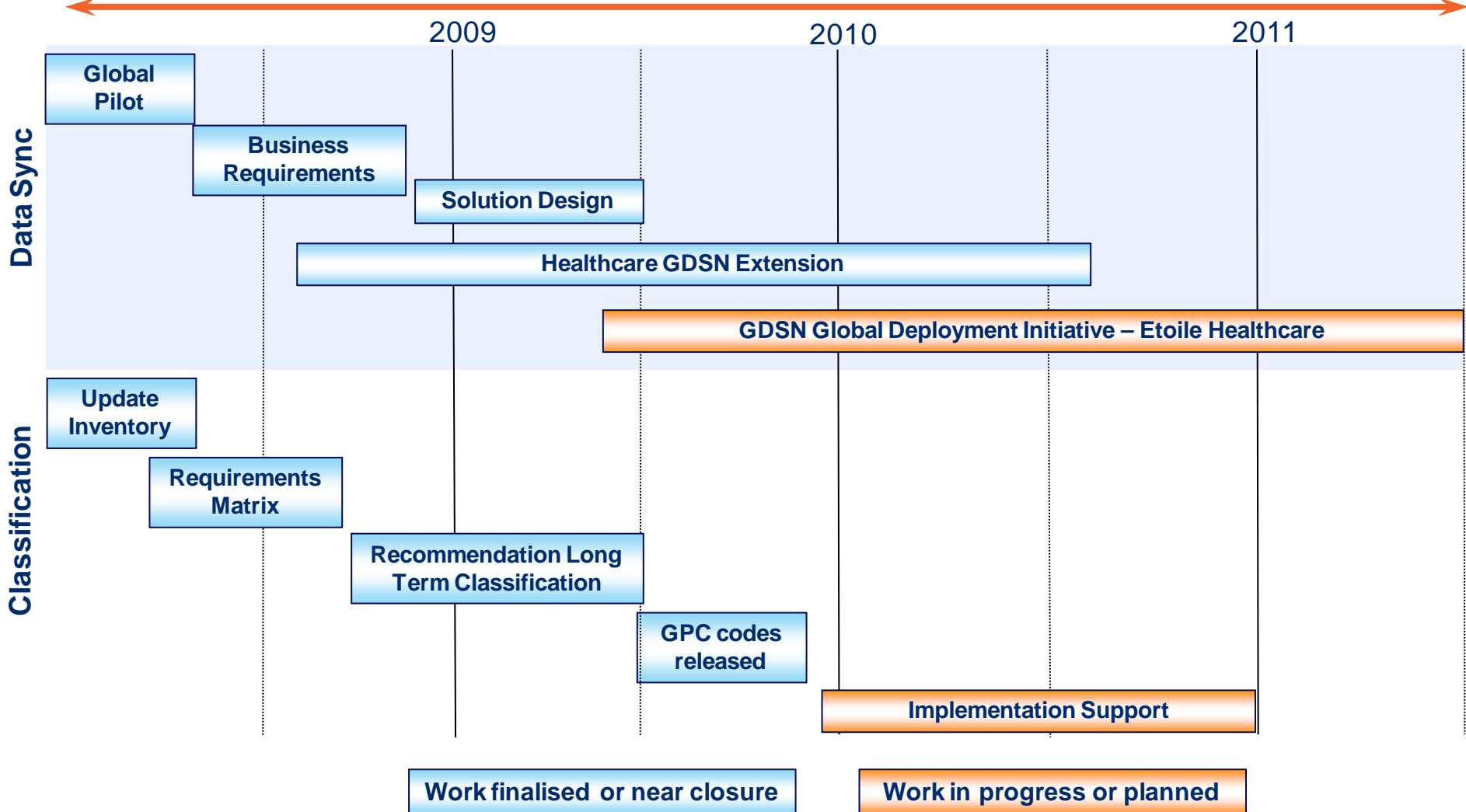
- Background
- Where we are going
- **Where we are today**
- What this means to you
- Questions





Healthcare Roadmap to global standards

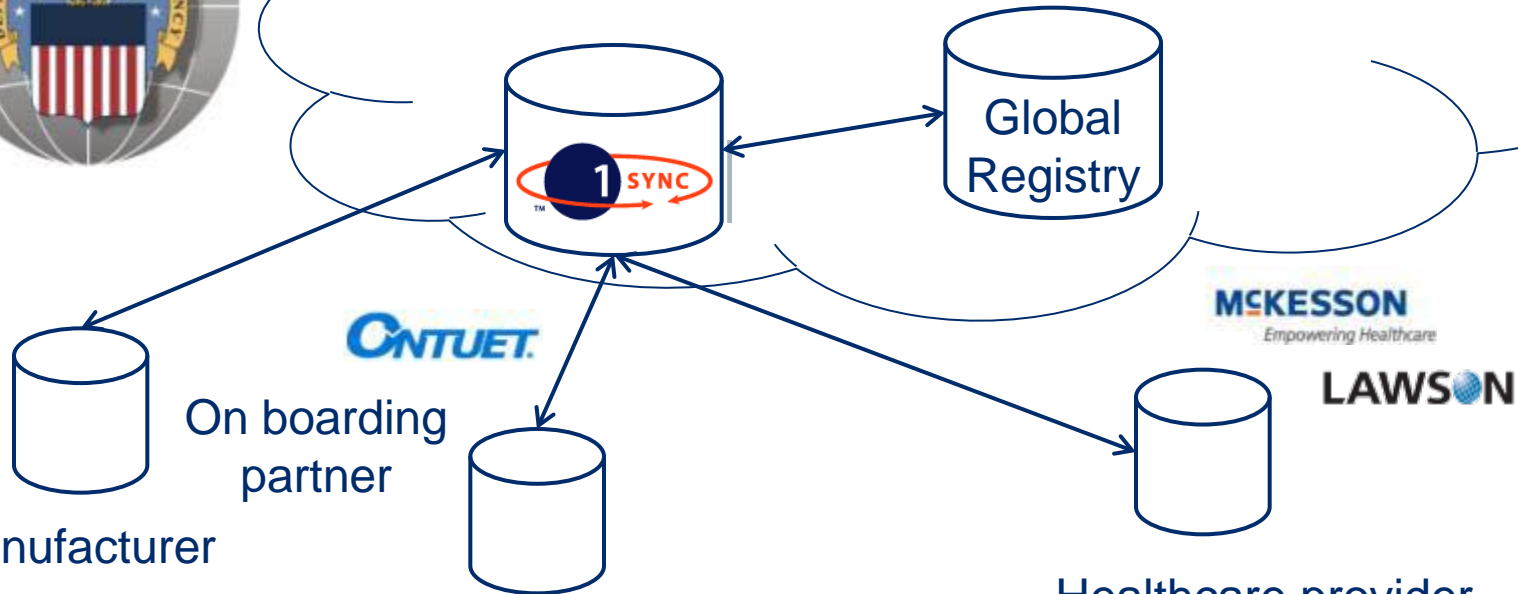
Data Synchronisation & Product Classification for Healthcare



US Department of Defense Pilot (2007)



GS1 GDSN
Global Data Synchronisation Network

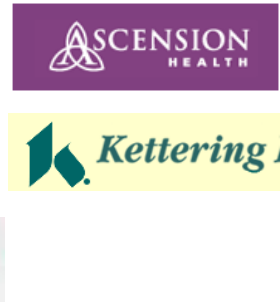


Manufacturer

On boarding partner

Distributor/Wholesaler/GPO

Healthcare provider





Healthcare Results 2007 DoD Pilot

- **Opportunities identified to save costs**
 - Better contract price available
 - Saved \$18.7M so far at 30 + hospitals
- **Opportunities identified to increase DoD eCommerce**
 - Moved \$7.766M to eCommerce services
- **Created robust DoD & VA Med Surg product data bank of 1 million + records**
 - Accurate master records for 93% (\$407M) of DoD buys
 - Joint DoD & VA access to pricing, packaging, product ID
- **Created active collaboration with Healthcare Industry**
 - Ongoing pilots with manufacturers and PV distributors
 - PDU as goal within Healthcare Standards Organizations

GS1 Healthcare Global GDSN Pilot (2008)



U.S.

Australia





Healthcare Results 2008 Global GDSN Pilot



Demonstrated that the GDSN works across international boundaries

- Interoperability among data pools
- The technology works in various settings

Report available at www.gs1.org/healthcare



Global GDSN Implementation Initiative for Healthcare

A global implementation initiative to use the GDSN's unique position to **meet current and emerging requirements for electronic product catalogue data**, including pending regulatory demands and commercial needs for reliable product data between healthcare trading partners.



40 GDSN implementation attributes for healthcare

Global Trade Item Number (GTIN)

Pack Level

Manufacturer Part Number

Hierarchy (Parent GTIN)

Hierarchy (Child GTIN)

Hierarchy (Quantity of Children)

Publisher Global Location Number (GLN)

Target Market

Brand Owner and GLN

Manufacturer Name and GLN

Functional Name

Brand Name

Description

Height + Unit of Measure

Width + Unit of Measure

Depth + Unit of Measure

Gross Weight + Unit of Measure

Net Content + Unit of Measure

Consumer Unit Y/N

Orderable Unit Y/N

Invoice Unit Y/N

Shipping Unit Y/N

Base Unit Y/N

Variable Unit Y/N

Returnable Package Y/N

Marked with Lot Number Y/N

Bar code Type

GPC code

Optional Classification Agency

Optional Classification Agency Value

Start Date

Effective Date

Shelf Life From Production

Shelf Life From Delivery

Contains Blood

Implantable

Contents of Concern

Reusability Types

Brand or Generic Flag

Does Product Contain Latex



Global GDSN Implementation Initiative for Healthcare



- Launched June 2009
- Today:
 - Participation: 26 healthcare organisations
 - Connections: 57 live
 - Finalised Phase 2 report: sharing lessons learned
- Next step:
 - Expansion to more countries and more participants



GS1 Healthcare Topics

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





ONE global standard for data synchronisation in healthcare





Putting the standards to work...





Goal: Single global source of truth for product data



Healthcare GDSN session this week

This Week:

- Wednesday, 14:00 – 15:30 (breakout session)
Roundtable discussion groups
 - Electronic product catalogues, UDI databases and the GDSN:
Making it work



 **GS1 Healthcare** **Join us!!!**

Global teams

- Global GDSN Implementation Initiative

Local teams

- Contact your local Member Organisation representative or a GDSN-certified data pool

Join Us!



GS1 Healthcare Topics

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





Global standards to achieve end-to-end traceability

Janice Kite

GS1 Global Office





GS1 Healthcare Topics

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





GS1 Healthcare Topics

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





Healthcare Traceability in Healthcare

“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



Develop a suite of standards
to **enable traceability** of healthcare products
from point of production to point of use





GS1 Healthcare Traceability matters because of...

- ... regulatory compliance
- ... anti-counterfeiting/diversion
- ... product recalls
- ... adverse event reporting and post-market surveillance
- ... medical error reduction
- ... documenting medical product use in Electronic Health Records (EHR) and Hospital Information Systems (HIS)
- ... efficient logistics management



Traceability is currently at the forefront of government regulations and industry concerns around the world...

A few examples:



FDA Amendments Act of 2007

Authority to develop regulations establishing a Serialised Numerical Identifiers (SNI) system for drugs

Authority to develop regulations establishing a Unique Device Identification (UDI) system for medical devices



“Pharma Package” - Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector

Recast of Medical Device Directive - To establish a UDI System

GS1 Healthcare Regulatory compliance (cont'd)



Brazil - Law 11.903/2009 - To establish a national drug traceability and authentication system



Colombia - Decree 4725/2005 - To establish a national traceability system



Turkey – To establish a national traceability system for drugs and medical devices using DataMatrix



China – Shanghai Regulation 7 November 2006 – established a traceability system for implantable medical devices in 2007

And many more...



GS1 Healthcare Topics

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





Healthcare GS1 Vision for Traceability in Healthcare

Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production¹ to Point of Use²

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Lot/Batch No. AI(10)), if applicable, at point of production
- Identification remains with/on the item throughout its intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Keys** (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
- Agreed **master data** is captured and shared (e.g. via GDSN) on demand amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) on demand amongst traceability stakeholders

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)... **SO THAT:**

2. The terms use or used can also mean consumed, infused, implanted, destroyed



Healthcare GS1 Vision for Traceability in Healthcare

Full actionable, global visibility of finished pharmaceuticals and medical devices in healthcare from Point of Production¹ to Point of Use²

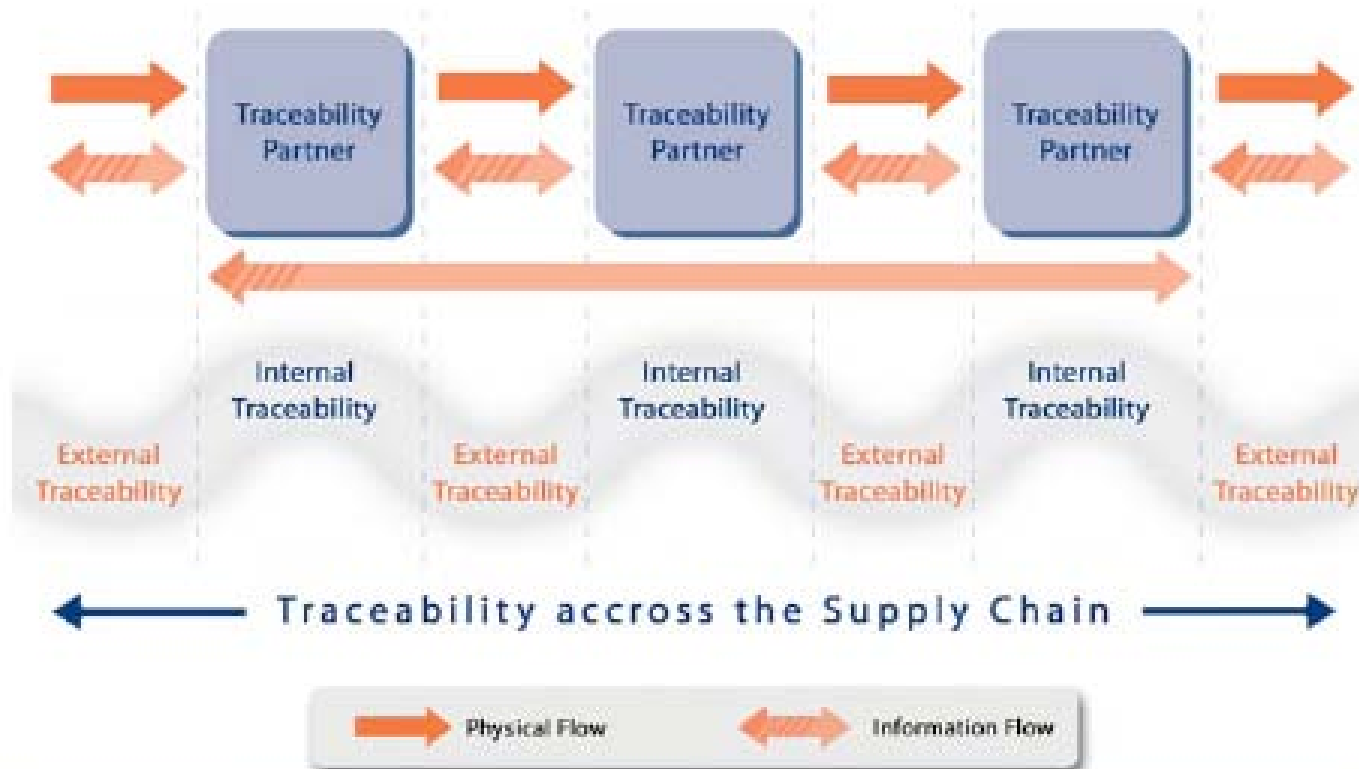
SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time on demand
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time on demand
- 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

Traceability across the supply chain





GS1 Healthcare Topics

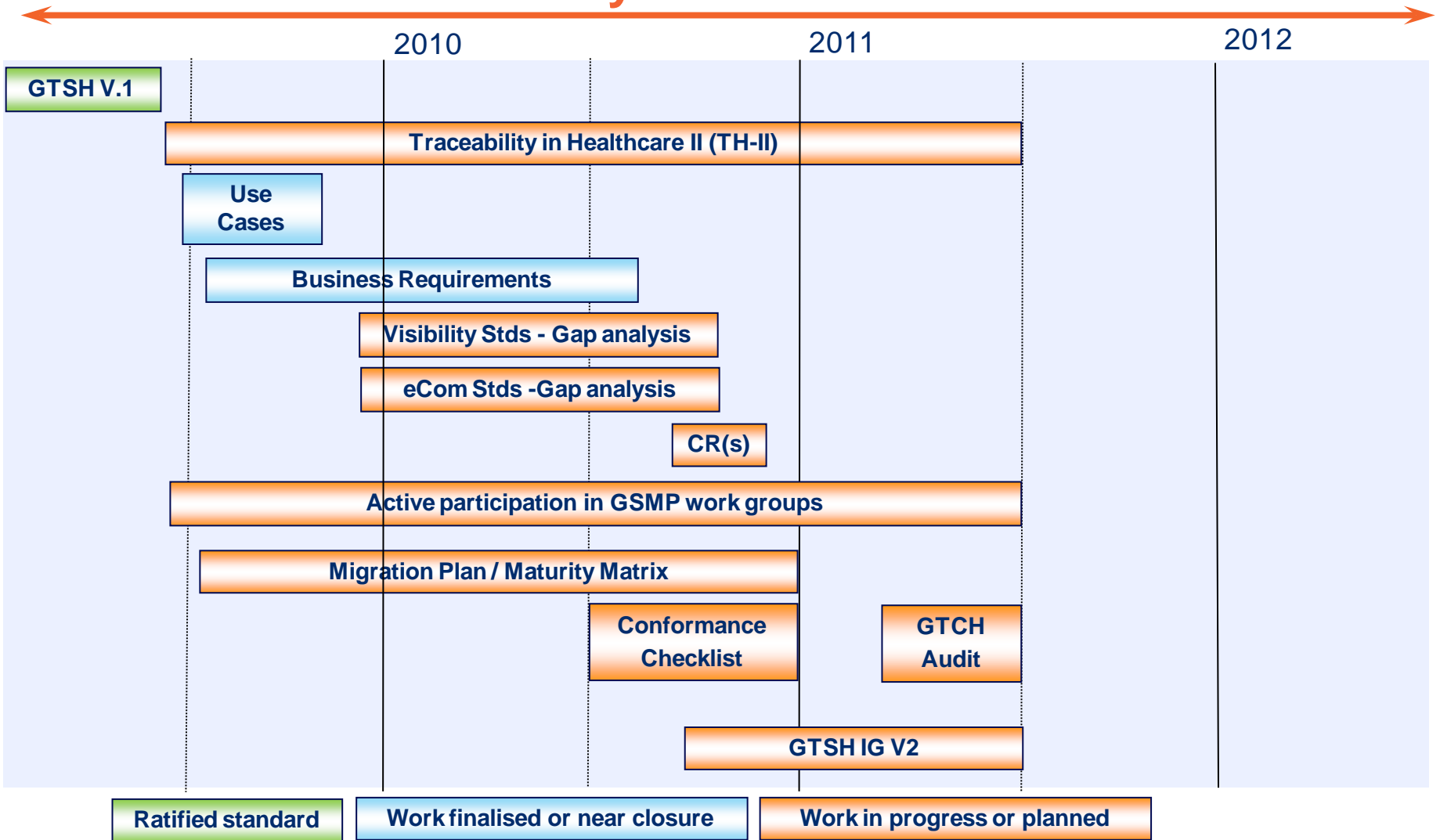
- Background
- Where we are going
- **Where we are today**
- What this means to you
- Questions





Healthcare Roadmap to Global Standards

Global Traceability Standards for Healthcare



Ratified standard

Work finalised or near closure

Work in progress or planned



GS1 Standards Document

Business Process and System Requirements for
Supply Chain Traceability

Global Traceability Standard for Healthcare

Issue 1.0.0, Feb-2009

Global Traceability Standard for Healthcare

Business process and system
requirements for supply chain
traceability

Published 27 February 2009

Available at www.gs1.org



Healthcare Implementation guide



**GS1 Global Traceability
Standard for Healthcare (GTSH)
Implementation Guide**
Issue 1, April-2009

GTSH Implementation Guide

To assist stakeholders to implement a traceability system in line with the GTSH utilising the GS1 System of Standards

Published 24 April 2009

Available at www.gs1.org





Healthcare Traceability – a business process



Global Traceability Standard for Healthcare (GTSH)
A Process Standard enabled by the GS1 System of Standards
And GTSH Implementation Guideline



✓ **Unique identification**

- Global product identification number
- Lot/batch number or serial number (unique number at the unit level)

✓ **Data capture**

- Bar coding or radio frequency identification (RFID)

✓ **Links management**

- Managing identification from point of production to point of use

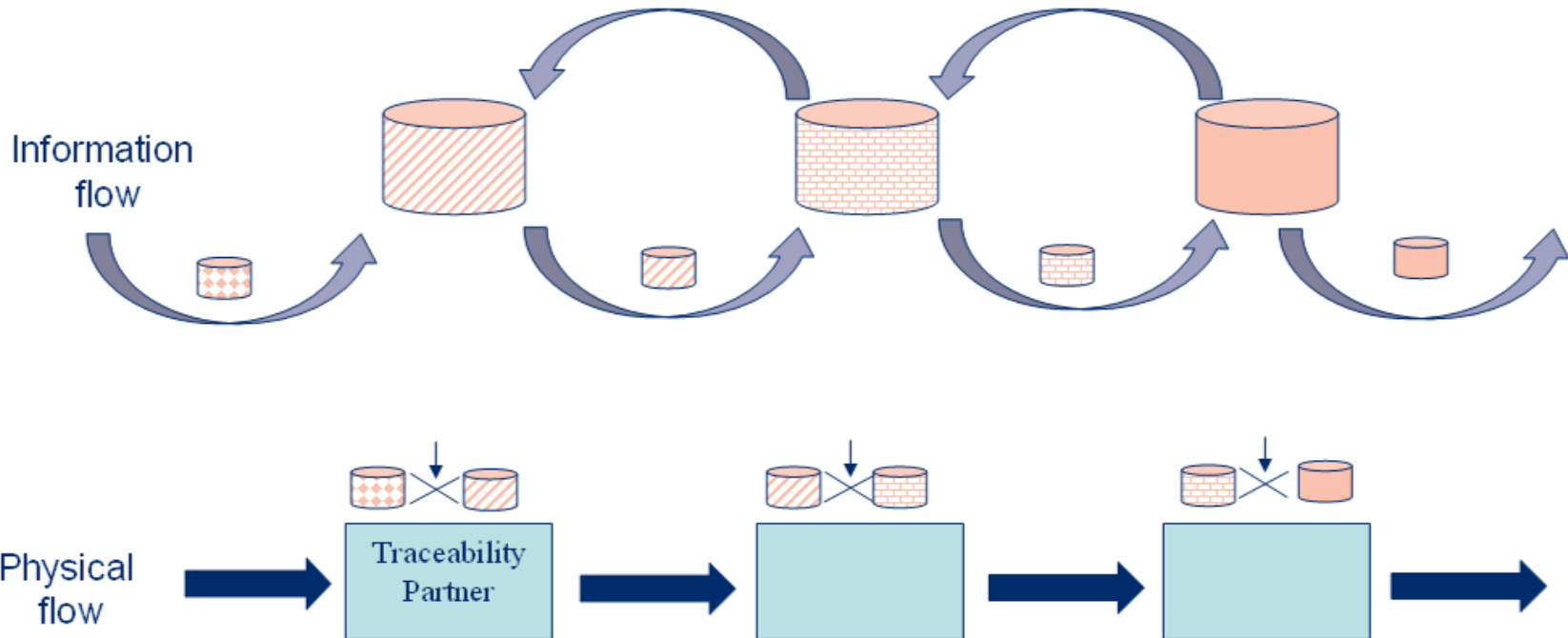
✓ **Data communication**

- Associate the physical flow of products with the information flow
- Different information sharing models

GS1 Healthcare Information Sharing Model 1

One up, one down

- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor

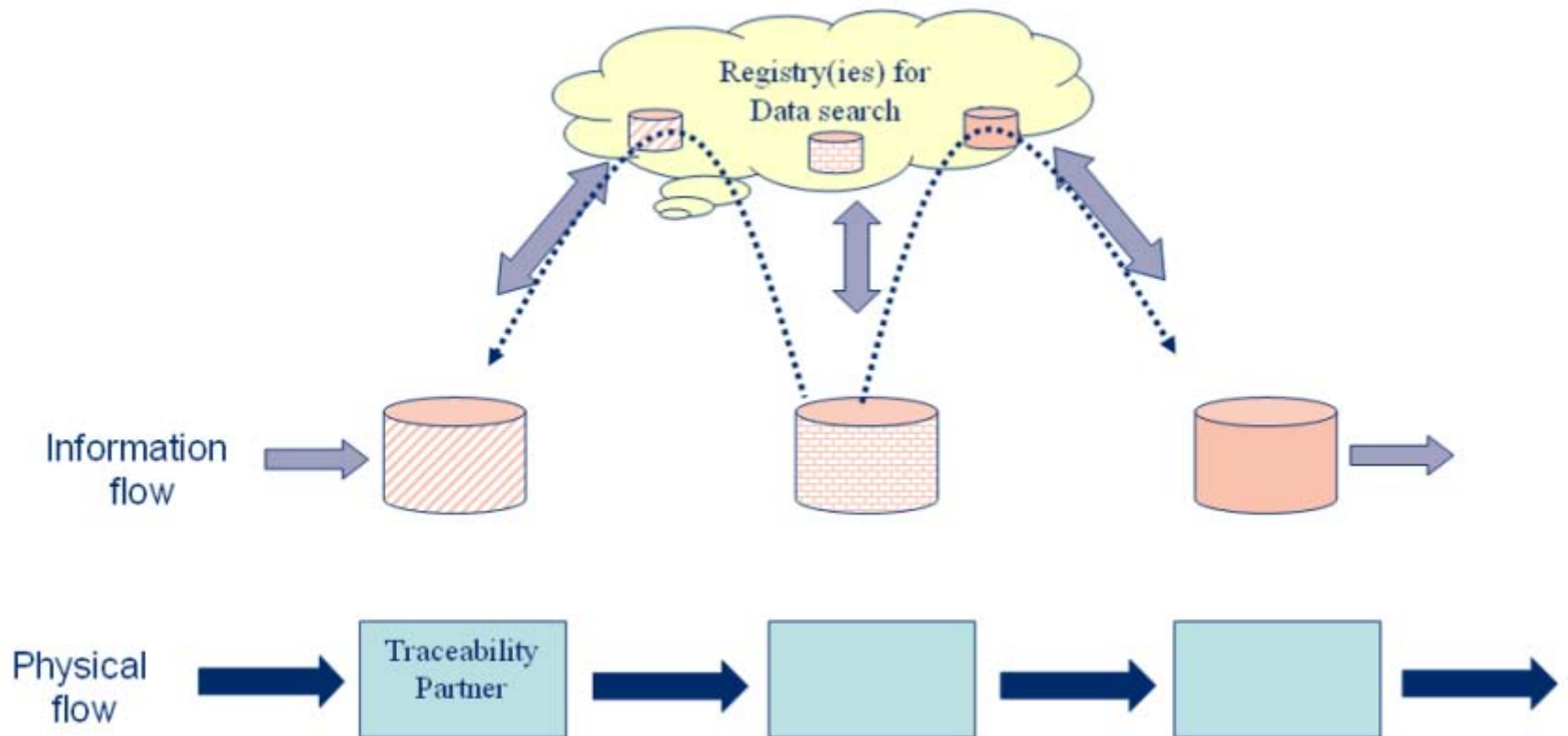




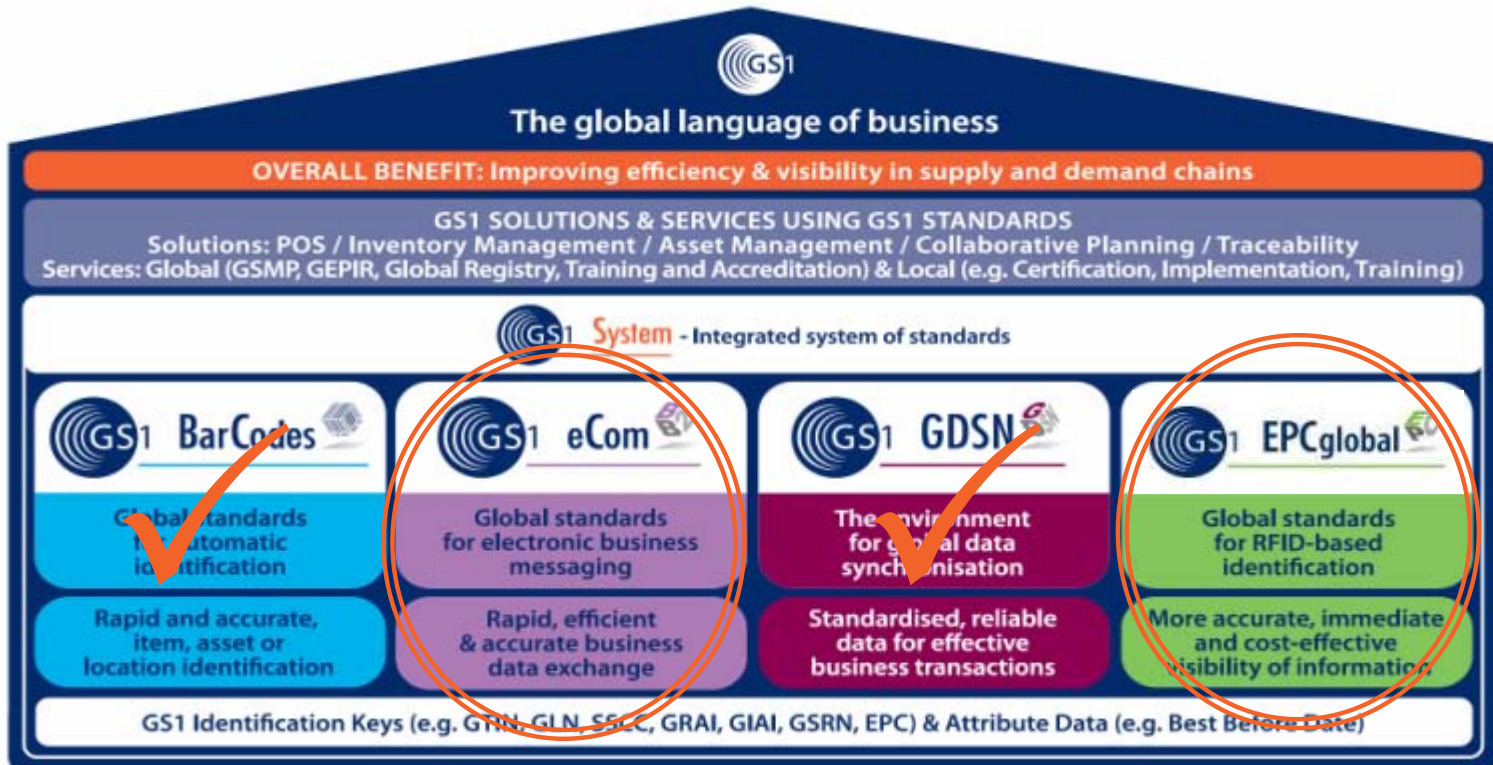
Healthcare Information Sharing Model 4

Distribution Information Sources

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.



Traceability in Healthcare II (TH-II)

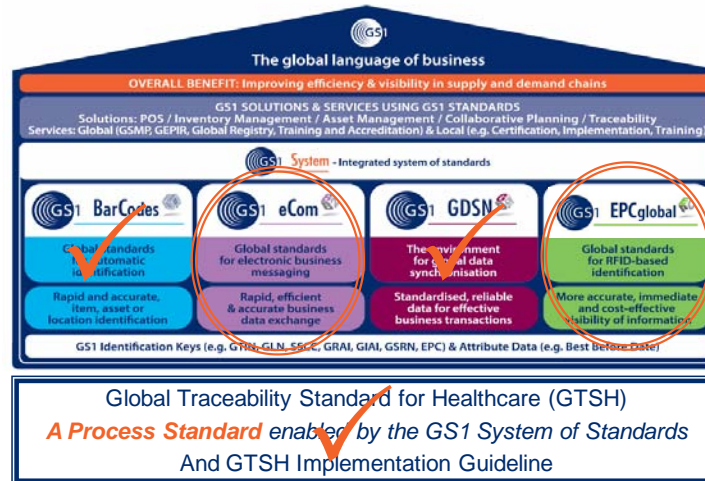


Global Traceability Standard for Healthcare (GTSH)
A Process Standard enabled by the GS1 System of Standards
 And GTSH Implementation Guideline



Healthcare Traceability in Healthcare II (TH-II)

- Focus on EPCglobal and eCOM areas:



- Identified, prioritised and drafting **Core Use Cases (Sub-Teams)**:
 1. Chain of Custody
 2. Chain of Ownership
 3. Product Identifier Authentication
 4. Product Recall } Combined. Business Requirements gathered



GS1 Healthcare Topics

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





**ONE global process
standard for traceability in
healthcare now available**

**A suite of global standards
to enable traceability in
healthcare available in 2011**





Putting the standards to work...





Healthcare How YOU can get started



1. Contact your local **GS1 Member Organisation** for guidance
2. **Get familiar** with the standards / guidelines
 - Attend breakout session this week!
 - Participate on GS1 implementation projects / team
3. Do a **gap analysis** 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"...



Healthcare Traceability session this week

This Week:

- Thursday, 11:15 – 12:45 (breakout session)
Roundtable discussion groups
 - Traceability in Healthcare: Which model?



 **GS1 Healthcare** **Join us!!!**

Global teams

- Global TH-II Team - Product Identifier Authentication

Local teams

- Contact your local Member Organisation representative

Join Us!





GS1 Healthcare Topics

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

