



Global standards to achieve end-to-end traceability

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Healthcare Topics

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



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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”.

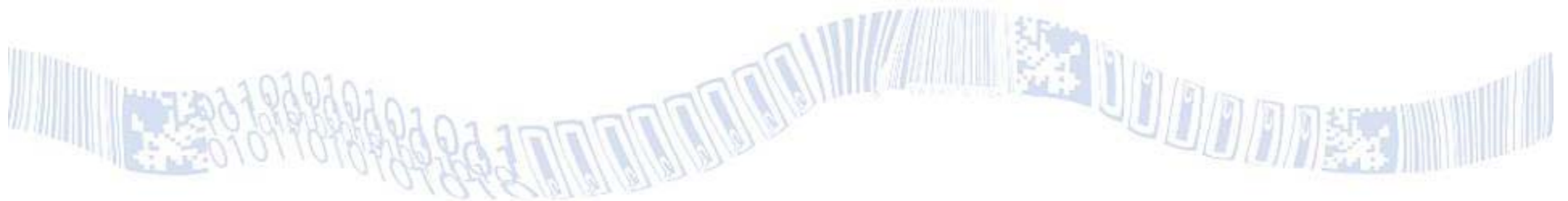
GS1 GTSH Issue 1.0.0, Feb-2009





GS1 Healthcare Traceability Standards

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



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



Healthcare Regulatory compliance

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

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...

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Healthcare Traceability in Healthcare...Vision

Full actionable visibility of all items in healthcare is possible from point of production to point of use across geographies globally

- All authentic **items** are identified with the appropriate **GS1 identifier** (e.g. GTIN) at point of production
- Identification remains with/on the item throughout its intended useful life
- All **physical locations** are identified with the appropriate **GS1 identifier** (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 identifier
- 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



Healthcare Traceability in Healthcare...Vision

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 (**EHR**) are updated with agreed traceability information, including Care Giver identification / information
- **Counterfeit** products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective



Healthcare Topics

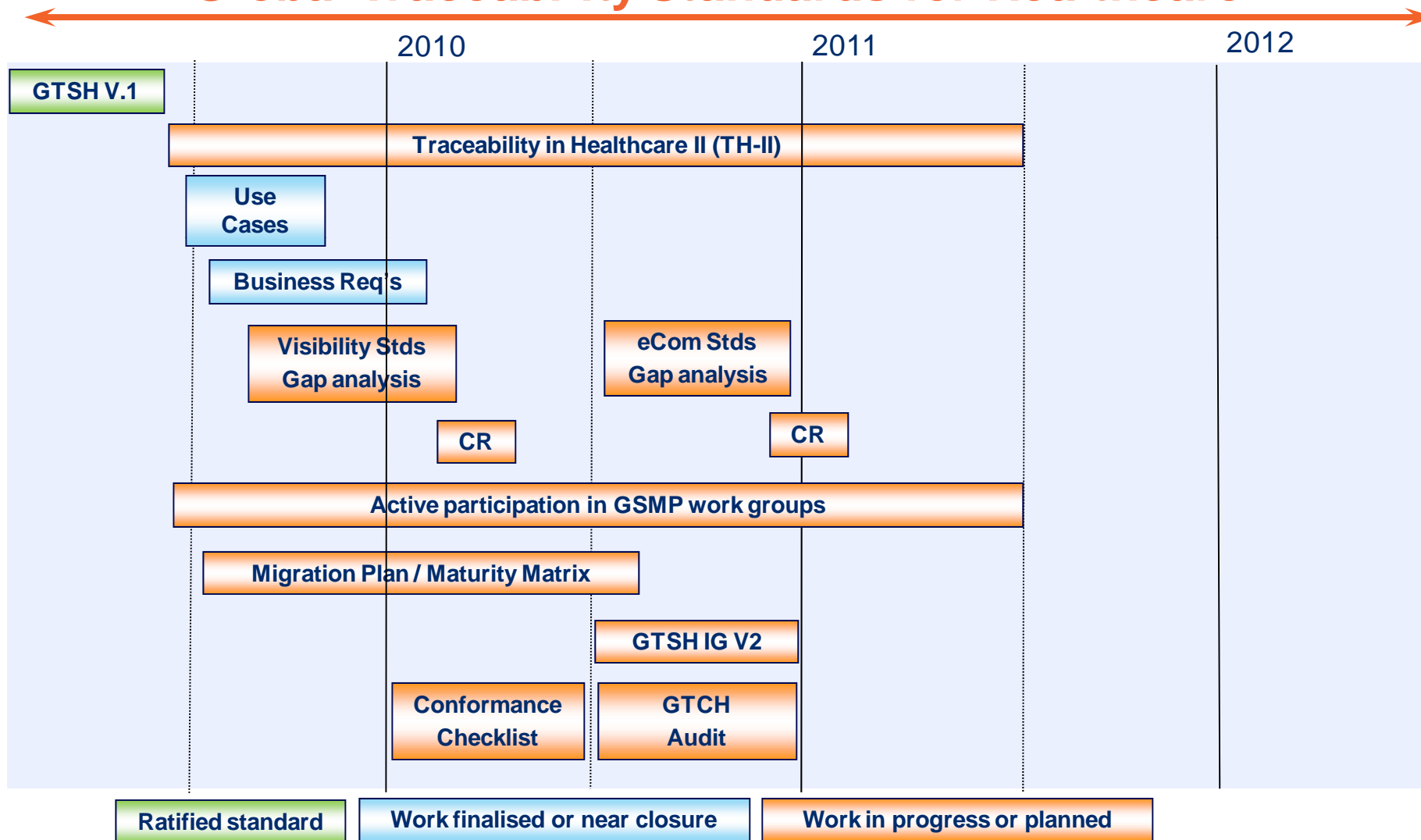
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Healthcare Roadmap to global standards

Global Traceability Standards for Healthcare





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

GTSH Implementation Guide

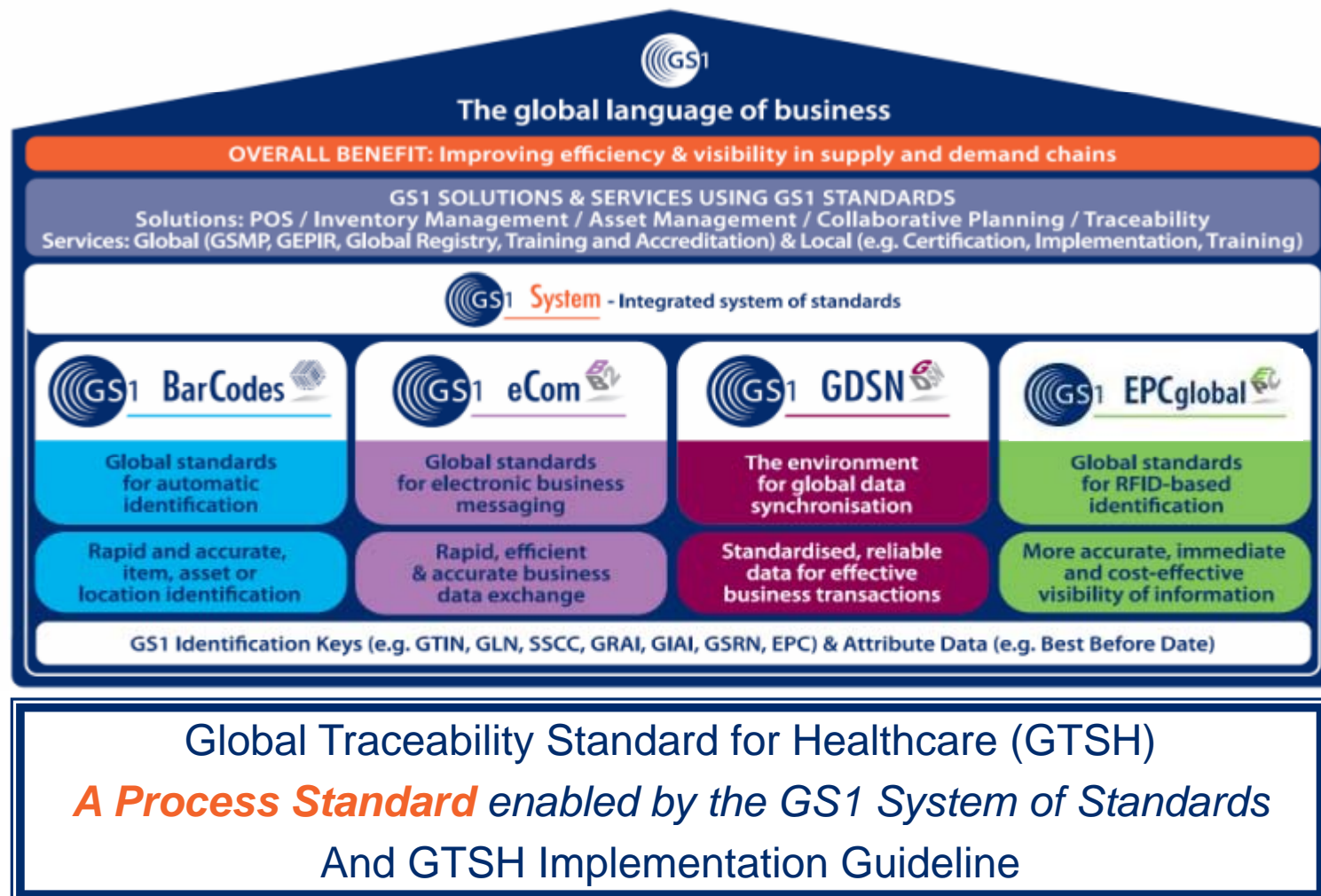
To assist stakeholders to implement a traceability system in line with the GTSH utilising the GS1 System of Standards

Published 24 April 2009

Available at www.gs1.org



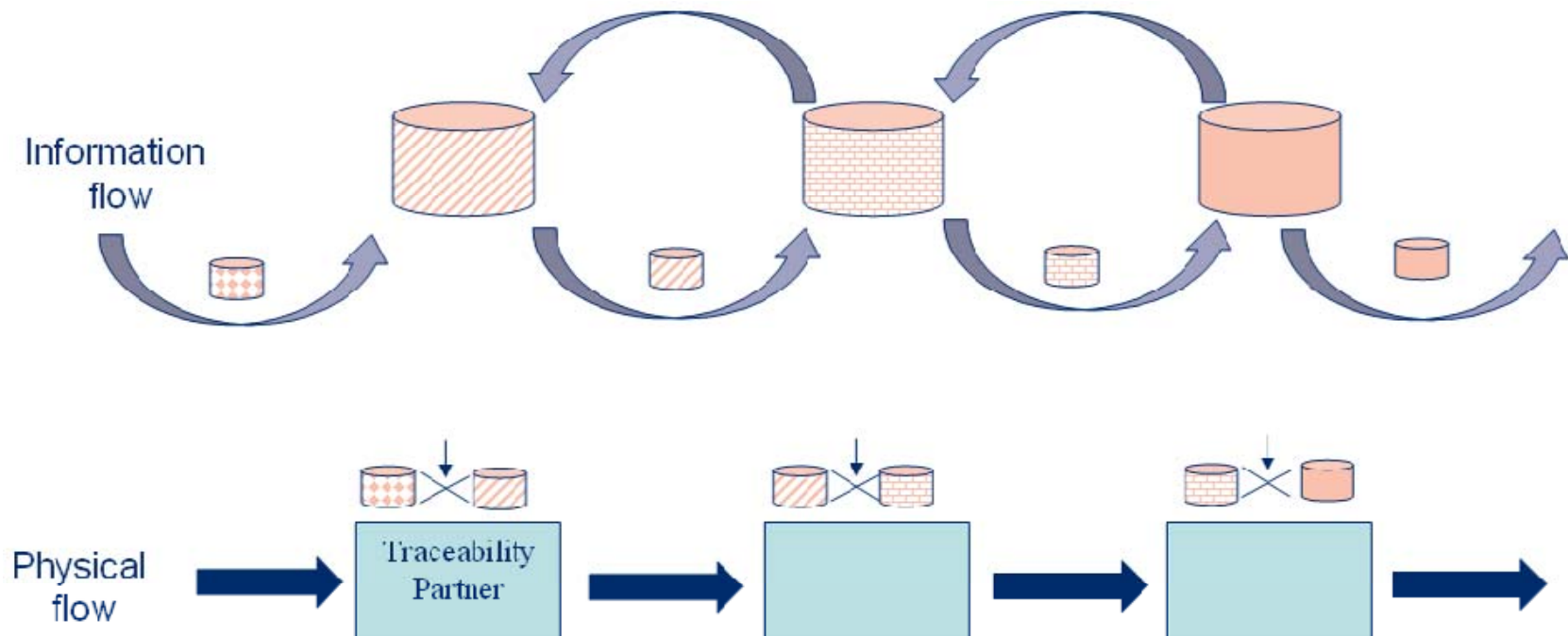
GS1 Healthcare Traceability – a business process



GS1 Healthcare Information Sharing Model 1

One up, one down

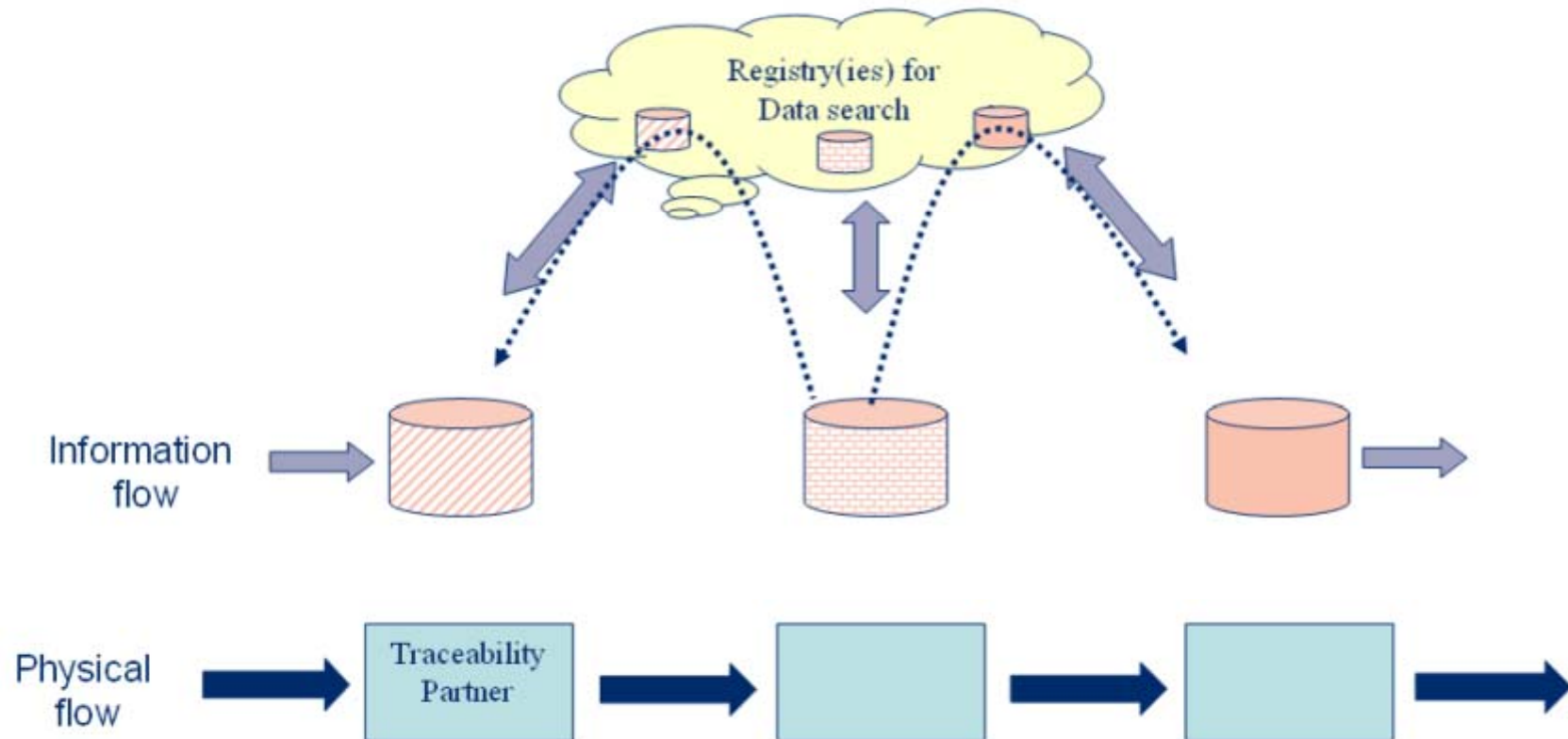
- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor

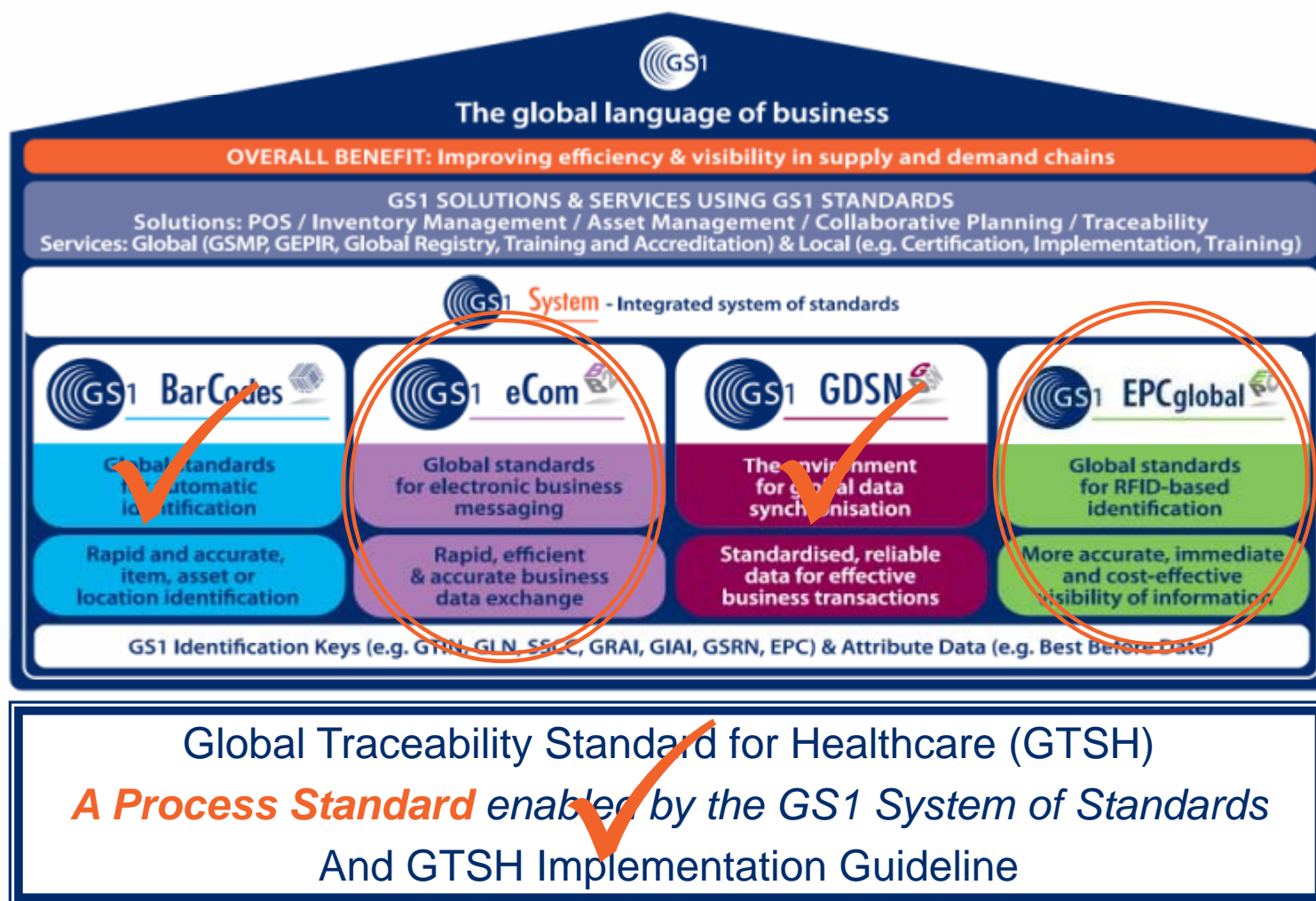


GS1 Healthcare Information Sharing Model 4

Distribution Information Sources

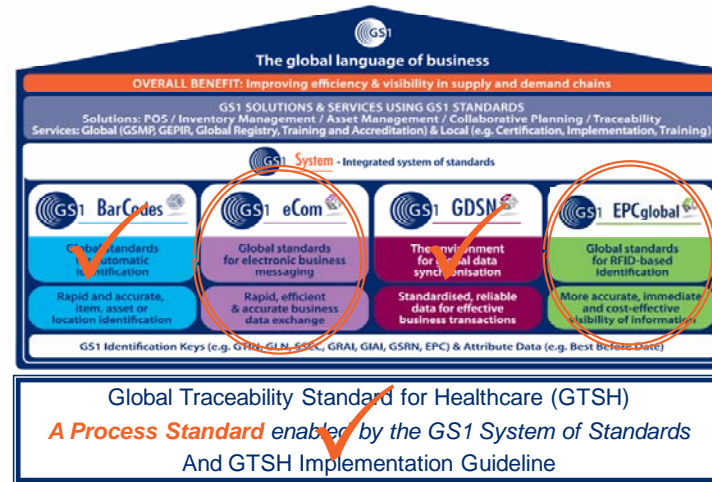
Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism.





GS1 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

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**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 at work...



Healthcare **How our hospital got started**

- **Participated** in French Hospital Logistical Managers Group hosted by GS1 France
- **Participated** in international work groups to understand manufacturers issues and raise providers requirements
- **Implementing marking** of surgical instruments based on GS1 Standards
- **Implemented traceability pilot** for surgical instruments



Traceability pilot at our hospital

Pharmacy

Reception
Implantable
Medical Device

GS1

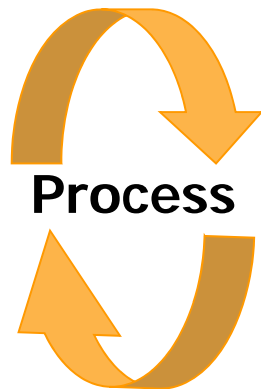


Distribution



Sterilization unit

Distribution of a
sterile medical
device

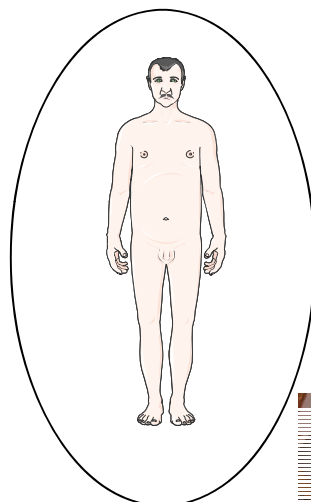


Process

GS1



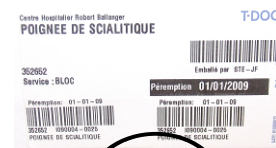
Operating room



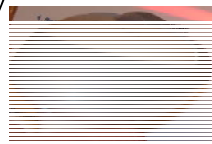
Surgery
intervention



GS1



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IT Prescription

Patient
traceability

Patient record



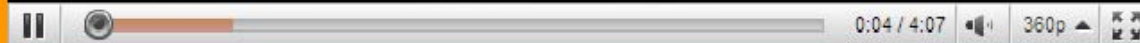
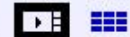
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Traceability at Robert Ballanger Hospital (France)

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Traceability project at the Robert Ballanger Hospital in France based on GS1 Standards

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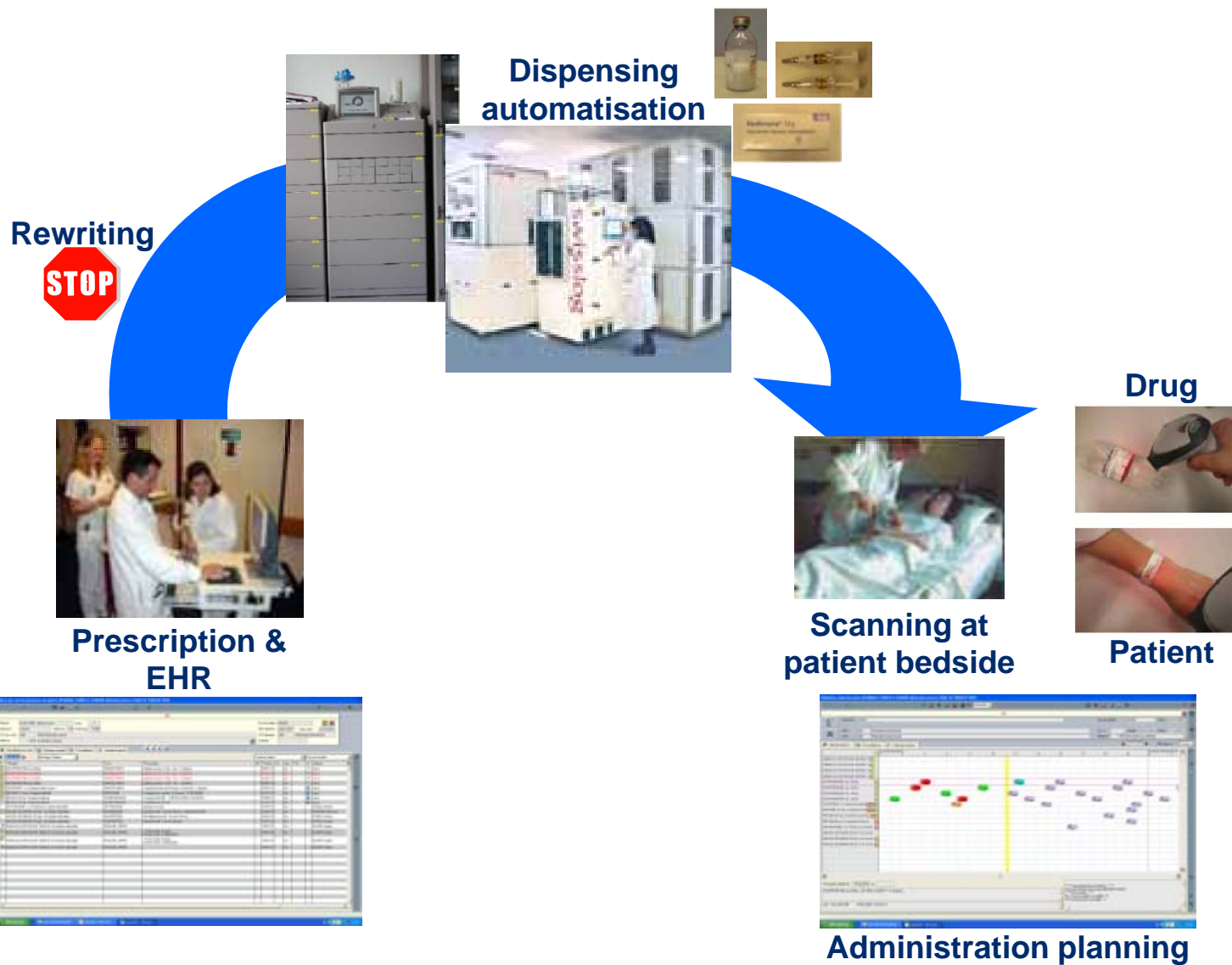
Healthcare **How our hospital got started** (cont'd)

- **Leveraged “Good Pharma Practice” contract** mandatory for Pharmacists
 - Traceability of Medical Devices
 - Implementation of GS1 DataMatrix compliant marking on drugs beginning 1st January 2011





Healthcare Drug traceability in a hospital



Healthcare How our hospital got started (cont'd)

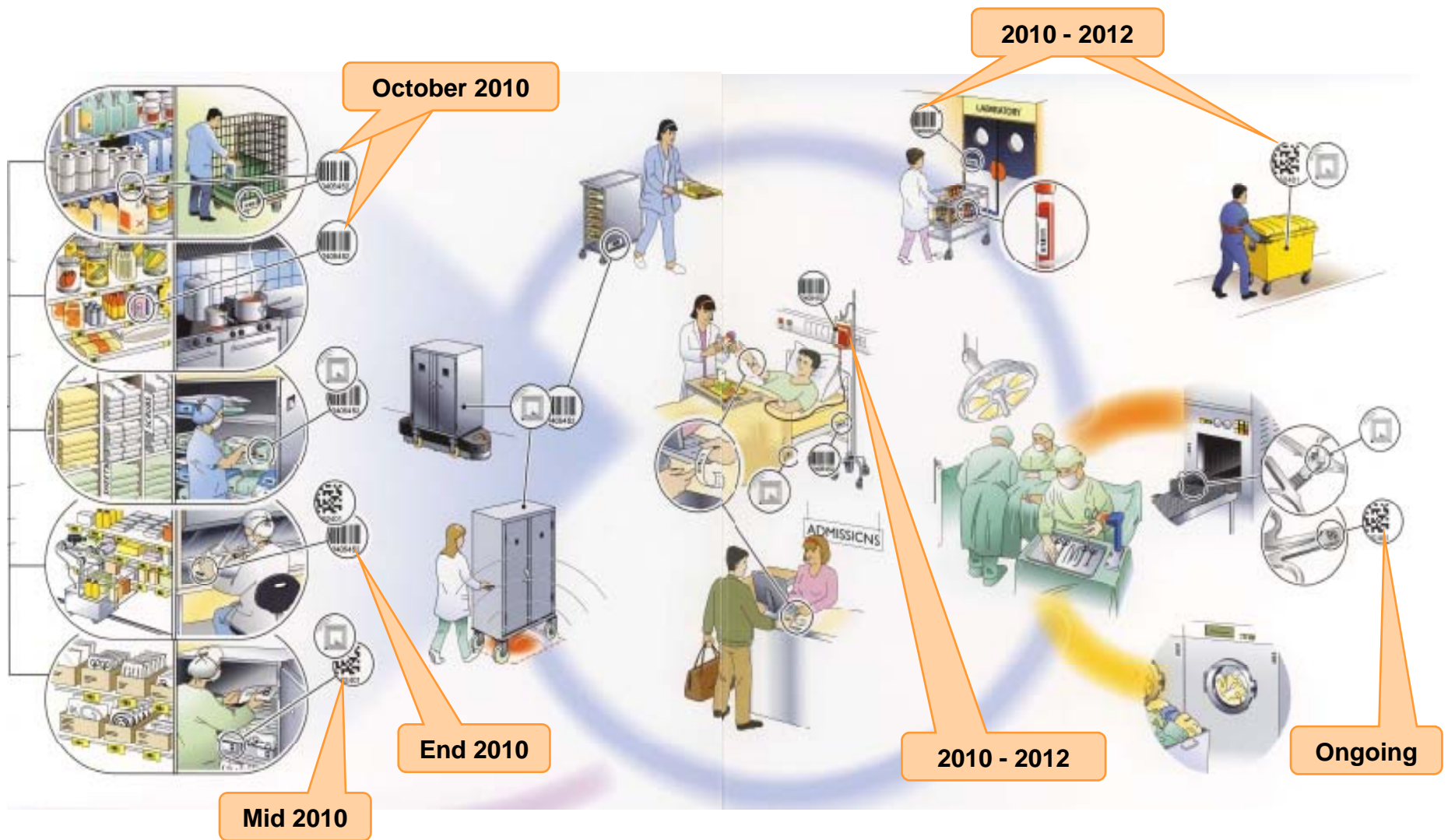
- **Leveraged traceability pilot** to promote GS1 Standards throughout the hospital
- **Action plan** to expand use of GS1 Standards
 - Common warehouse (pharmaceutical and common goods)
 - Locations and investments identification
 - Waiting for Patient and Care Giver ID

Improving patient safety...

ONE step at a time...but in a gradual way



GS1 Healthcare Our next GS1 projects



Healthcare How YOU can get started

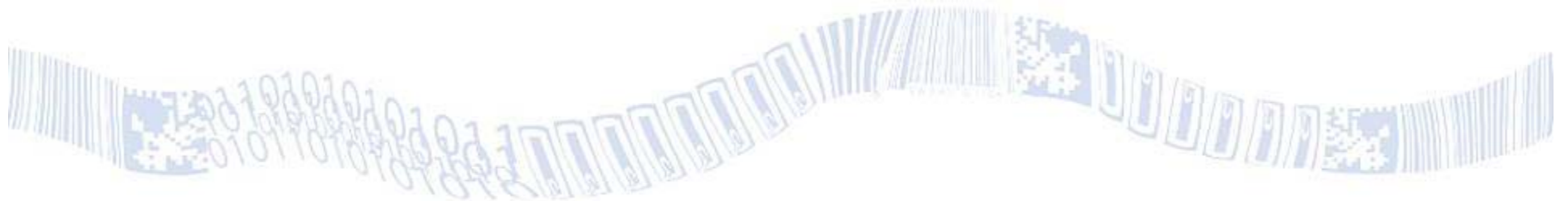


1. Contact your local **GS1 Member Organisation** for guidance
2. **Get familiar** with the standards / guidelines
 - Attend breakout session this week!
 - Participate on GS1 implementation projects / team
3. Do a **gap analysis** vs. GS1 Standards
 - Focus on key items and facilities...don't 'boil the 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, 11:00 – 12:30 (breakout session)
 - Introduction: Traceability in Healthcare Work Group



Healthcare Join us!!!

Global teams

- Global TH-II Team - Product Identifier Authentication

Local teams

- Contact your local Member Organisation representative

Join Us!

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