



MDSCC UDI Meeting

October 22, 2009
Orlando, FL

Dennis Harrison

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President, GS1 Healthcare US

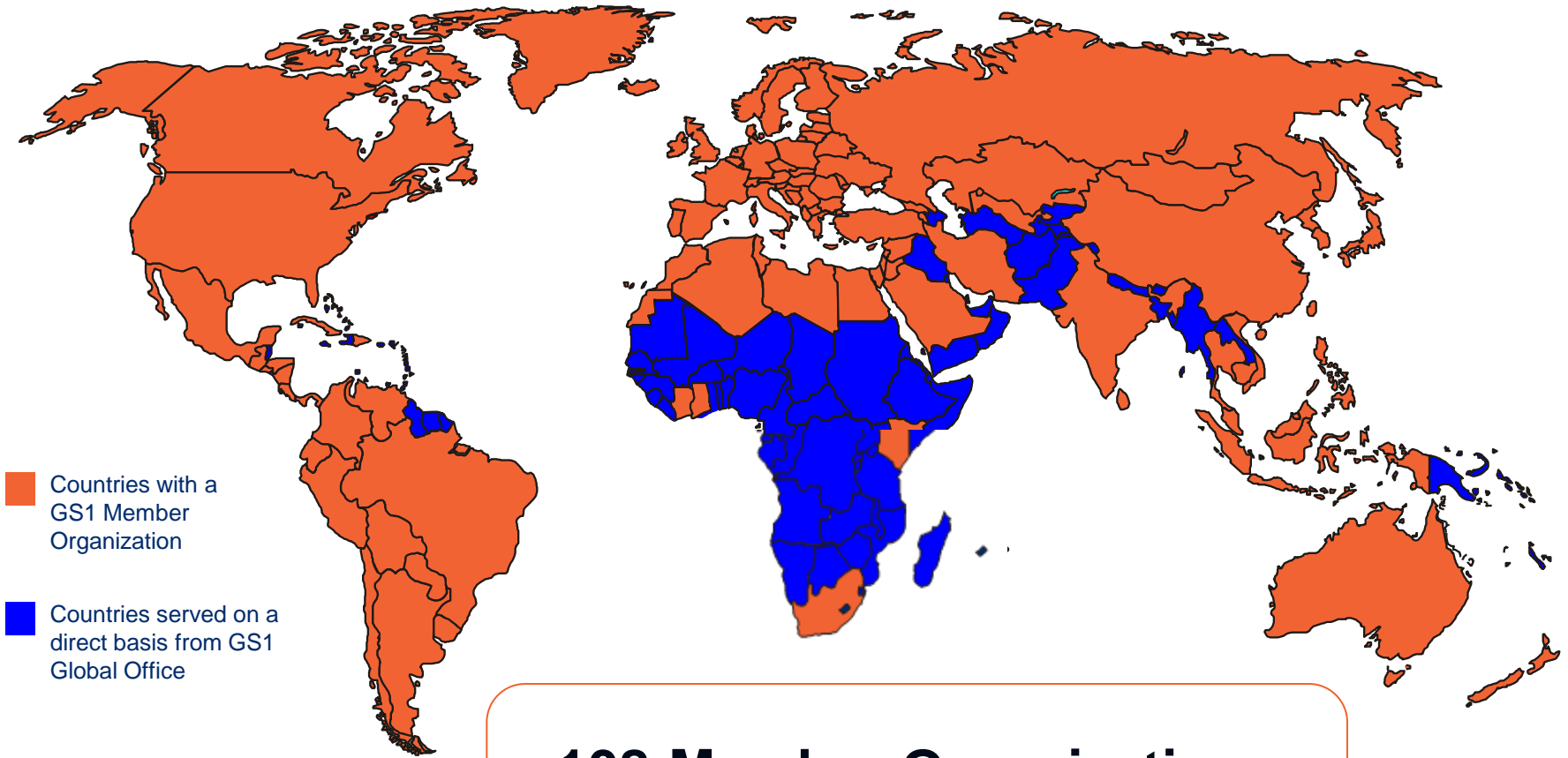


Agenda

- About GS1/GS1 US
- Implementation Activities
- Implementation Tools

About GS1/GS1 US

GS1 Around the World



108 Member Organizations
150 Countries Served

Local Healthcare user groups driving adoption



Advancing global standards in Healthcare



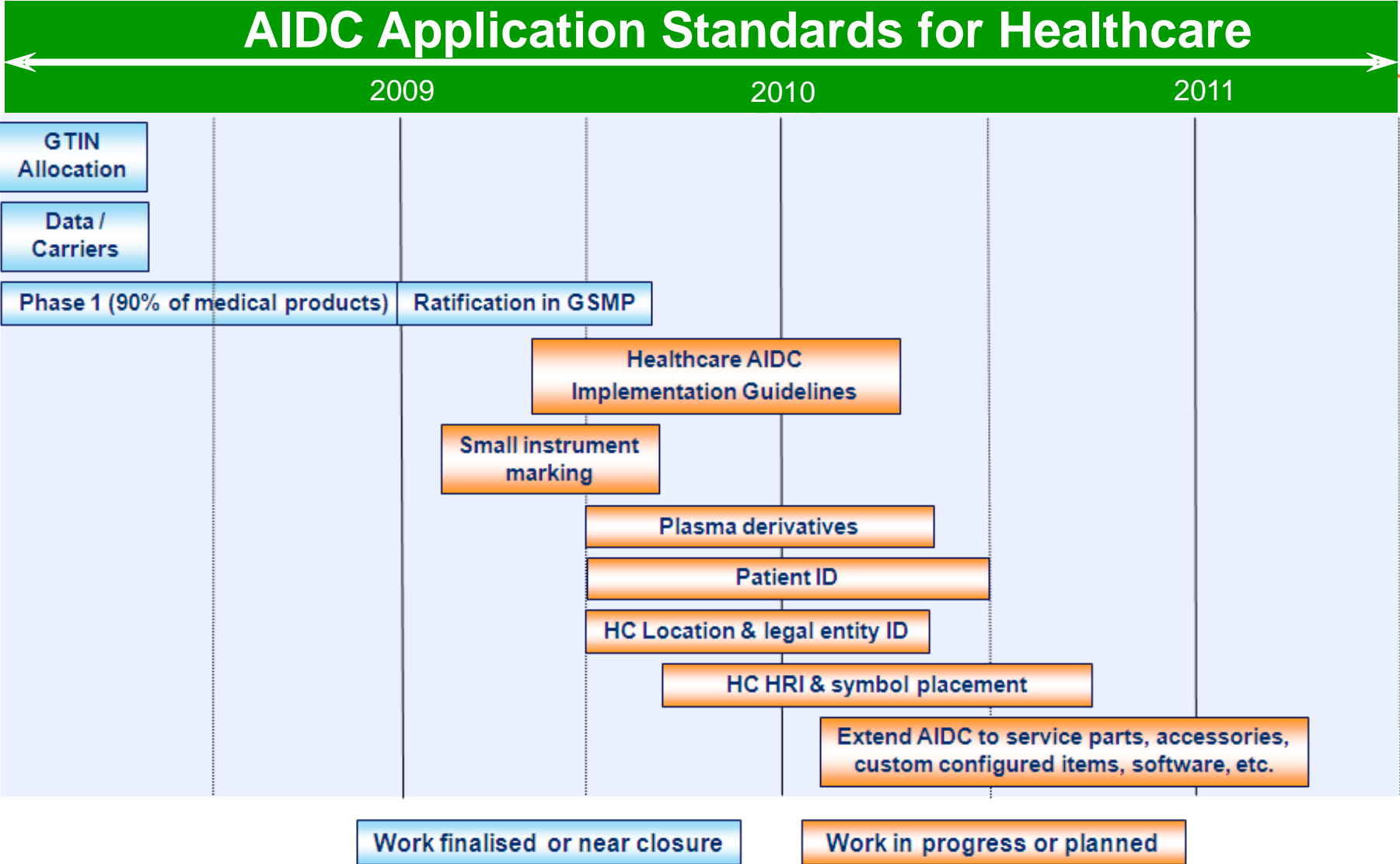
- **Global Healthcare User Group**
 - Develop global healthcare standards
 - Drive global harmonization
- **Local Healthcare User Groups**
 - Drive adoption & implementation of GS1 Standards
 - Help develop global healthcare standards

Implementation Activities

Global Healthcare Standards Activities

- **AIDC Application Standards**
 - GTIN allocation rules
 - Product marking standards
 - Small instrument marking
 - Plasma derivatives
 - Patient ID
 - GLN standards
- **GDSN Standards**
 - Healthcare product attributes
 - Product classification
- **Traceability**
 - Global traceability standard for healthcare
 - Healthcare traceability implementation guideline

Roadmap towards Global Standards



108 Member Companies

Industry Associations (17)

- AAP - American Academy of Pediatrics
- AHA - American Hospital Association
- AHRMM - Association for Healthcare Resource and Materials Management
- ASHP - American Society of Health-System Pharmacists
- CHPSO - California Hospital Patient Safety Organization
- CHSCR - Center for Healthcare Supply Chain Research
- Dental Trade Alliance
- GHVRHIO - Greater Hudson Valley Regional Health Information Organization
- GPhA - Generic Pharmaceutical Association
- HDMA - Healthcare Distribution Management Association
- HIDA - Health Industry Distributors Association
- Medical Device Supply Chain Council
- MITA - Medical Imaging & Technology Alliance
- NACDS - National Association of Chain Drug Stores
- NCPD - National Coalition of Pharmaceutical Distributors
- NCPDP - National Council for Prescription Drug Programs
- SMI - Strategic Marketplace Initiative

Manufacturers (20)

- Abbott Laboratories, Inc.
- Baxter International, Inc.
- Becton Dickinson
- Boehringer Ingelheim USA
- Bristol-Myers Squibb Company
- Covidien
- C.R. Bard
- GE Healthcare
- Genzyme Corporation
- GlaxoSmithKline
- Johnson & Johnson
- Kimberly-Clark Corporation
- Medical Action Industries
- Medline
- Medtronic, Inc.
- Merck & Company, Inc.
- Novartis Pharmaceuticals Corporation
- Pfizer, Inc.
- Sage Products, Inc.
- Talecris Biotherapeutics, Inc.

108 Member Companies

Solution Providers (24)

- Accenture
- Acsis, Inc.
- AXWAY
- BravoSolutions
- Clarkston Consulting
- Craneware, Inc.
- D2 Pharma Consulting LLC
- DataPros for Healthcare
- Deloitte Consulting
- ECRI Institute
- GHX
- Lansa, Inc.
- Lawson Software
- Loftware, Inc.
- MediClick, Inc.
- Noblis
- PharmTech, Inc.
- Product Identification & Processing Systems, Inc.
- rfXcel Corporation
- SAP AG
- Supplyscape Corporation
- Systech International
- Tecsys, Inc.
- Vendormate, Inc.

Retailers (1)

- CVS Pharmacy

Distributors (4)

- AmerisourceBergen Drug Corporation
- Cardinal Health
- McKesson
- Owens & Minor

Academic Institutions (2)

- CIHL - Center for Innovation on Healthcare Logistics
- Wright State Research Institute

Government Agencies (4)

- DMSB - Defense Medical Standardization Board
- DoD/DMLSS - Defense Medical Logistics Standard Support
- Dept. of Veteran Affairs
- FDA - US Food and Drug Administration

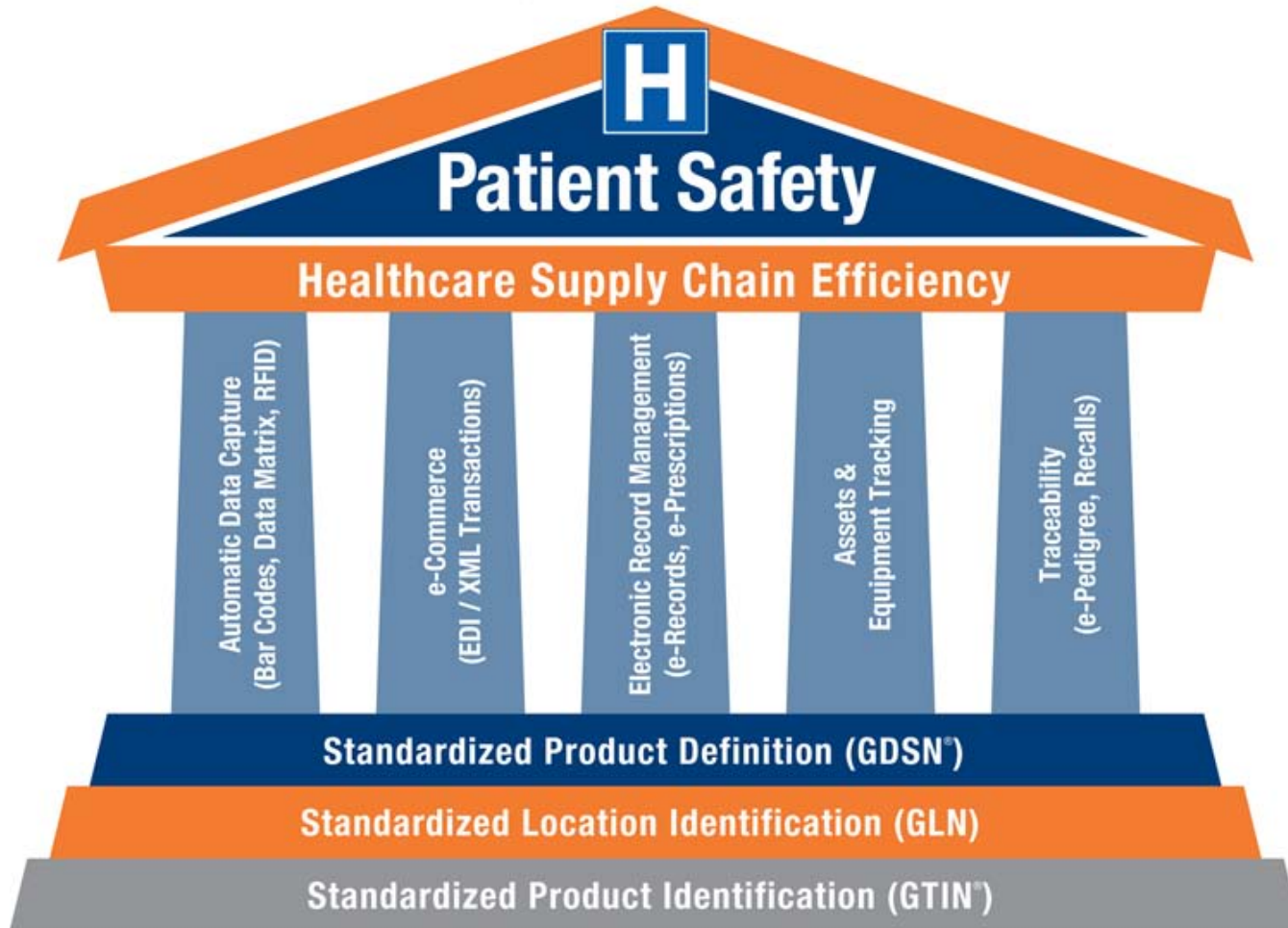
Group Purchasing Organizations (7)

- Amerinet
- Consorta
- GNYHA Services
- HealthTrust Purchasing Group
- MedAssets
- Novation LLC
- Premier, Inc.

Hospitals/IDNs (29)

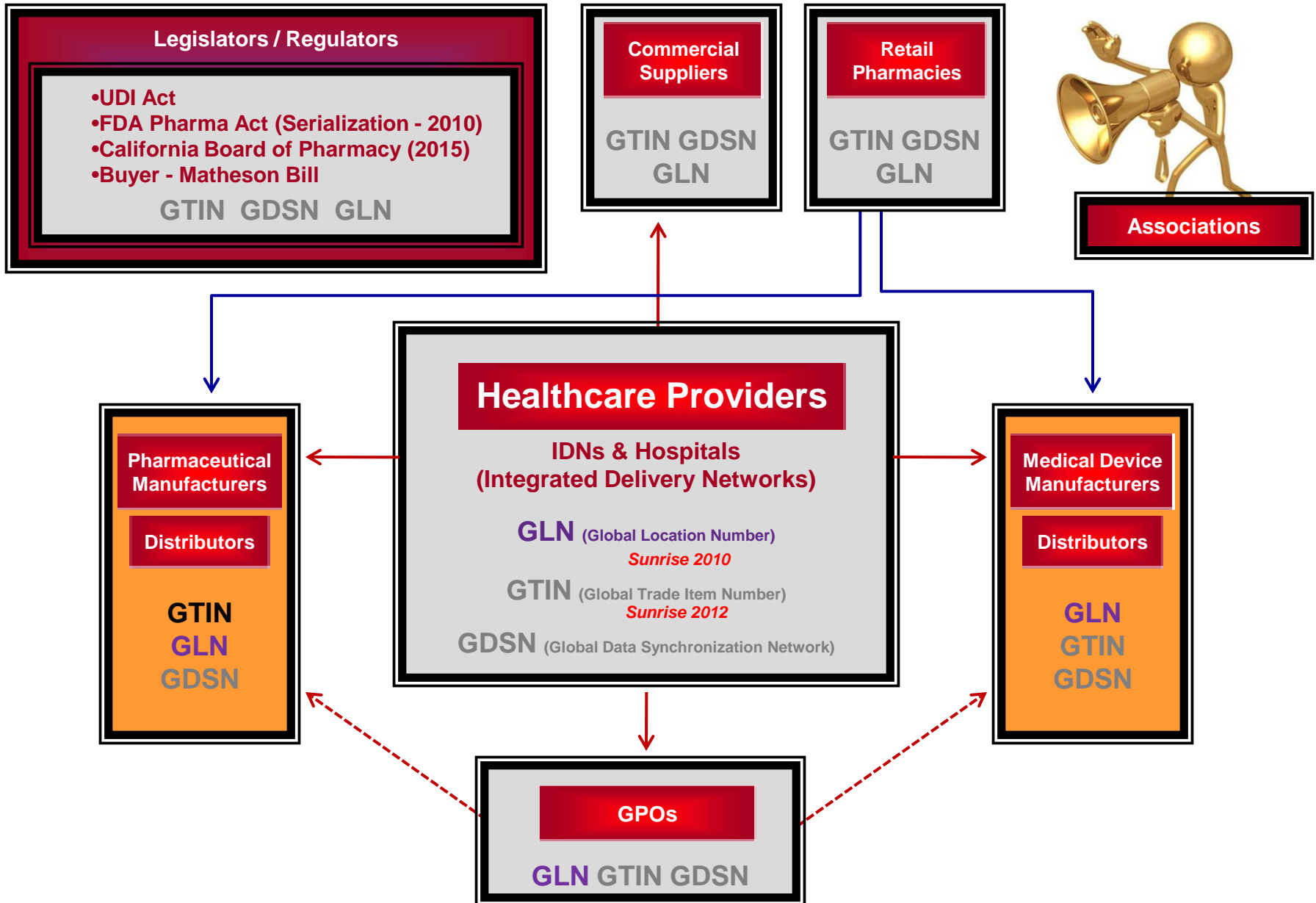
- Ascension Health
- Atlantic Health
- BJC Healthcare
- Carolinas Healthcare System
- Catholic Health Initiatives
- Geisinger Health System
- Intermountain Healthcare
- Johns Hopkins Health Systems
- Kettering Health Network
- Louisiana State University Health Sciences Center
- Mayo Clinic
- Ministry Health Care Inc.
- Munroe Regional Medical Center
- New York Presbyterian Hospital
- OSF Healthcare System
- PeaceHealth
- Premier Health Partners
- Ridgeview Medical Center
- Sentara Healthcare
- Sisters of Mercy ROI
- SSM Healthcare
- Surgical Care Affiliates
- The Ohio State University Medical Center
- UK Healthcare
- University of Mississippi Medical Center
- University of Virginia Medical Center
- University of Wisconsin Medical Foundation
- University Southern California Health Sciences
- Wellspan Health

“Building Patient Safety”



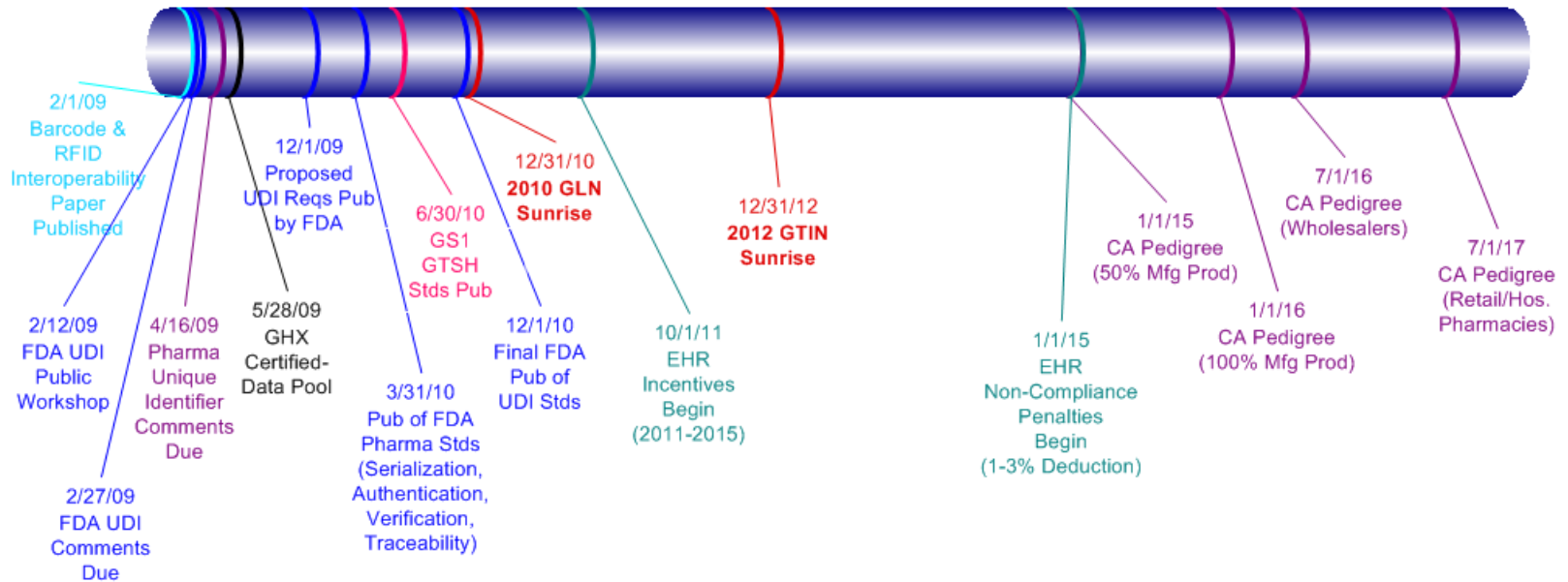
Standardization → Interoperability

GS1 Standards: U.S. Healthcare Adoption Strategy



U.S. Healthcare Community Initiatives

6/23/2009



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Implementation Tools

Available GS1 Standards Tools and Resources

Location ID: Global Location Number (GLN)

1. [Healthcare Provider Tool Kit: GLN](#)
2. [Healthcare Supplier Tool Kit: GLN](#)
3. [GLN Registry for Healthcare®](#)
4. [GS1 GLN Allocation Rules](#)
5. [GS1 US Minnesota GLN Pilot Report Phase 1: Lessons Learned](#)
6. [GS1 US Minnesota GLN Pilot Report Phase 2: Process Map](#)
7. [GLN GPO Roster Pilot Report](#)
8. [GLN/GLN Registry for Healthcare web seminar](#)
9. [2010 GLN Sunrise web seminar – Starts in November 2009](#)
10. [2010 GLN Sunrise Resources web page](#)

Product ID: Global Trade Item Number® (GTIN®), Bar Coding, EPC/RFID

1. [Healthcare Provider Tool Kit: GTIN](#)
2. [Healthcare Supplier Tool Kit: GTIN](#)
3. [GTIN Allocation Rules for the Healthcare Sector](#)
4. [GS1 US Data Driver®](#)
5. ["North American Guideline for Application of GS1 Bar Codes to Very Small Healthcare Items"](#)
6. [2012 GTIN Sunrise web seminar – Starts in November 2009](#)
7. [GTIN 101 web seminar – Starts in November 2009](#)

Global Data Synchronization Network® (GDSN®)

1. [Healthcare Provider Tool Kit: GDSN](#)
2. [Healthcare Provider Tool Kit: UNSPSC](#)
3. [Healthcare Supplier Tool Kit: GDSN](#)
4. [GTIN Attributes for Healthcare Products – Interactive Spreadsheet](#)
5. [GDSN Implementation Guides \(GS1 Standards Knowledge Center\)](#)
6. [“GS1 Data Quality Framework Including the Data Quality Protocol”](#)
7. [GS1 US data pool services: 1SYNC™](#)
8. [“U.S. DOD Pilot Report: Creating a Source of Truth in Healthcare: Testing the GDSN as a Platform for the Healthcare Product Data Utility”](#)
9. [“Synchronising Product Data in Healthcare - Global GDSN Healthcare Pilot Report”](#)
10. [GDSN Package Measurement Standards](#)
11. [GS1 US Measurement Services](#)

Traceability Adoption

1. [Global Traceability Standard for Healthcare \(GTSH\)](#)
2. [EPCglobal Pedigree Messaging Standard](#)
3. [EPC Information Services \(EPCIS\) Standard](#)
4. [EPCglobal Architectural Framework](#)
5. [“EPCglobal Healthcare and Life Sciences Industry Adoption Roadmap”](#)
6. [“Multi-Sourcing EPC Assignment \(MEA\) Work stream Recommendation Document v1.0”](#)
7. [EPCglobal Transportation and Logistics Phase 3 Pilot Program documents](#)
8. [Technology, Standards and Real-World Deployments of the EPC Network White Paper](#)
9. [EPCIS Validation Portal](#)
10. [EPCIS Open Source RFID Software Platform \(Fosstrak\)](#)

Available GS1 Standards Tools and Resources

General Tools and Resources

1. [Online Healthcare Document Library](#)
2. [Basics of GS1 Standards in Healthcare web seminar – *posted as scheduled*](#)
3. [GS1 US Partner Connections On Demand Web Seminars](#)
4. [GS1 US Product Catalog: Technical guidelines for GS1 ID standards, marking, and e-commerce](#)
5. [GS1 US Solutions Center \(GS1 General Specification and Technical Guidelines\)](#)
6. [GS1 US Glossary](#)
7. [GS1 Check Digit Calculator](#)
8. [Application Identifier \(AI\) Wizard](#)
9. [Calibrated Conformance Standard Test Cards \(linear symbols\) and other bar code symbol tools](#)
10. [GS1 US Bar Code Verification Services](#)
11. [GS1 EPCglobal US Knowledgebase \(GS1 EPCglobal Standards including Object Naming Service \(ONS\) Standard\)](#)
12. [GS1 EPCglobal Glossary](#)
13. [Accredited Test Centers \(EPCglobal\)](#)
14. [GS1 GEPIR](#)
15. [GS1 Global Data Dictionary \(GDD\)](#)
16. [Certified solution providers \(hardware/software/consultants\)](#)

Future: Tools and Resources in Development

1. [Healthcare Provider GLN Quick Start Guide – *Coming Soon*](#)
2. [Healthcare Supplier GLN Quick Start Guide – *Coming Soon*](#)
3. [Healthcare Supplier GTIN Quick Start Guide – *Coming Soon*](#)
4. [“Simplified Guide for U.S. Healthcare Bar Code Scanner Acquisition Criteria” – *Coming Soon*](#)
5. [“Procedure for Responding to Troublesome Bar Codes” – *Coming Soon*](#)
6. [2010 GLN Sunrise Implementation Plan](#)
7. [2012 GTIN Sunrise Implementation Plan](#)
8. [GDSN Early Adoption Group Report and GDSN Implementation Plan](#)
9. [Global Traceability Standard for Healthcare \(GTSH\) Implementation Guide](#)
10. [GS1 Healthcare US Traceability Tool Kit: U.S. Pharmaceutical Supply Chain](#)
11. [Calibrated Conformance Standard Test Cards \(2D symbols\)](#)
12. [New Industry Use Cases](#)
 - a. [Mid size manufacturer: GLN implementation](#)
 - b. [Mid size pharmaceutical manufacturer: traceability program with 2D & serialization](#)
 - c. [Large pharmaceutical manufacturer: returnable asset tracking with GRAI](#)



Available GS1 Standards Tools and Resources

Additional Marketing Tools

1. [Awareness Video: Standardization ...Stat!](#)
2. Healthcare Provider C-Level brochure: *Universal Data Standards – The New Paradigm in Healthcare*
3. Healthcare Provider and Supplier Tool Kits CDs
4. GS1 Standards in the Healthcare Supply Chain brochure
5. [GS1 Healthcare Reference Book 2009/2010](#)
6. Industry Use Cases
 - a. [Mayo Clinic / Cardinal Health GLN Implementation white paper](#)
 - b. [GS1 Healthcare US Success Story: Seton Family Hospitals/ BD](#)
 - c. [GS1 Healthcare US Success Story: Purdue Pharma Success Story](#)

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Questions?

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Questions We've Heard From Manufacturers

1. Will GTINs be required on all medical devices or only on certain (Class 1, 2, or 3) medical devices per FDA UDI regulations?
2. Will lot numbers or serial numbers be required, by the FDA, on devices in addition to GTINs?
3. When will the FDA UDI regulations be published?
4. Will multiple data carriers be accepted by the FDA (e.g. linear bar codes, data matrix, RFID)?
5. What percentage of my products need GTINs on them to declare compliance with the 2012 GTIN Sunrise date?
6. What happens if I don't meet the 2010 GLN Sunrise or 2012 GTIN Sunrise dates?
7. Will GDSN support the FDA UDI database and vice versa?
8. Will the FDA UDI regulation require expiry dates?
9. What trading partners are ready to use GLNs and GTINs?
10. What is the ROI of implementing GS1 standards? (e.g. GTIN, GLN and GDSN)