



THE GLOBAL LANGUAGE OF BUSINESS

# EXPERIENCES FROM THE U.S. FDA UDID PILOT

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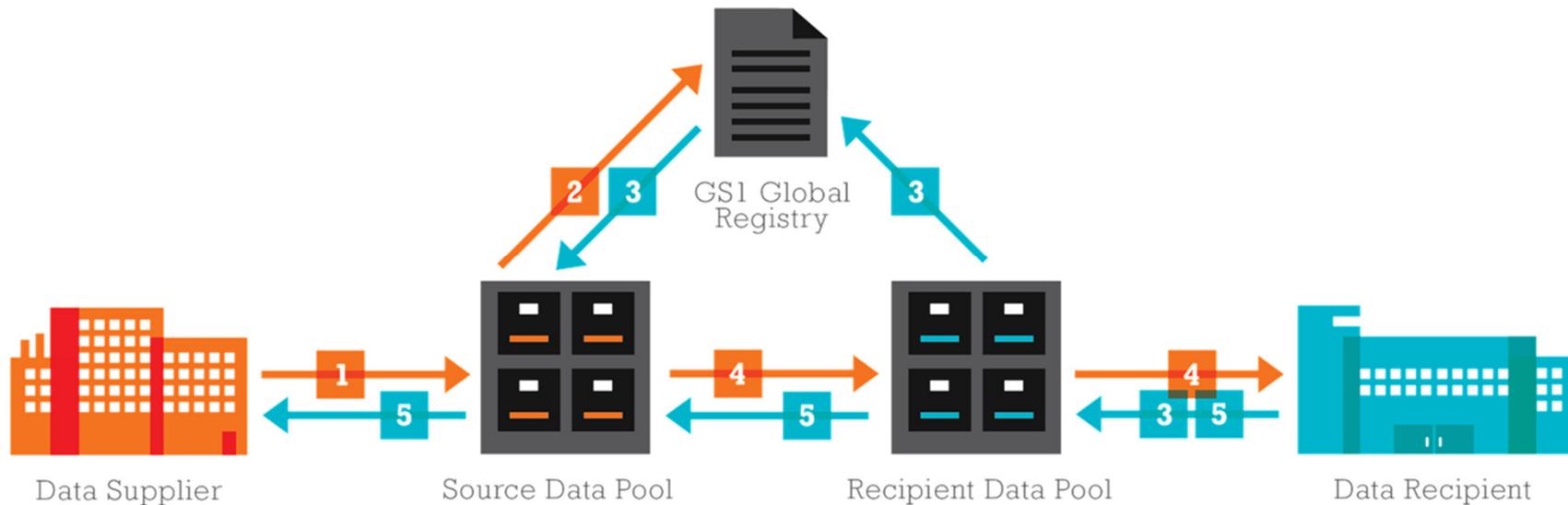
# OVERVIEW

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- What is GDSN and UDID
- Purpose of the pilot
- Work done in support of the pilot
- Pilot results
- Next steps

# WHAT IS GLOBAL DATA SYNCHRONIZATION NETWORK



The GS1 Global Data Synchronization Network™ connects customers and suppliers, via their selected GDSN-certified Data Pools, to the GS1 Global Registry® - based on the GS1 GTIN standards (unique identifier of products)

The GS1 GDSN is an automated, standards-based global environment that enables secure and continuous data synchronization, allowing all trading partners to have consistent item data in their systems at the same time.

**A Mechanism to Publish UDI to FDA GUIDID**

# UDI USING GS1 STANDARDS



## UDI (Unique Device Identification)

- DI = Device identifier = GS1 **Global Trade Item Number® (GTIN®)** allows the unambiguous identification of a specific medical device
- PI = Production Identifier = GS1 **Application Identifier (AI)** for lot/batch no., serial no., expiry date, in any combination in combination with GTIN



## UDID (Unique Device Identification Database)

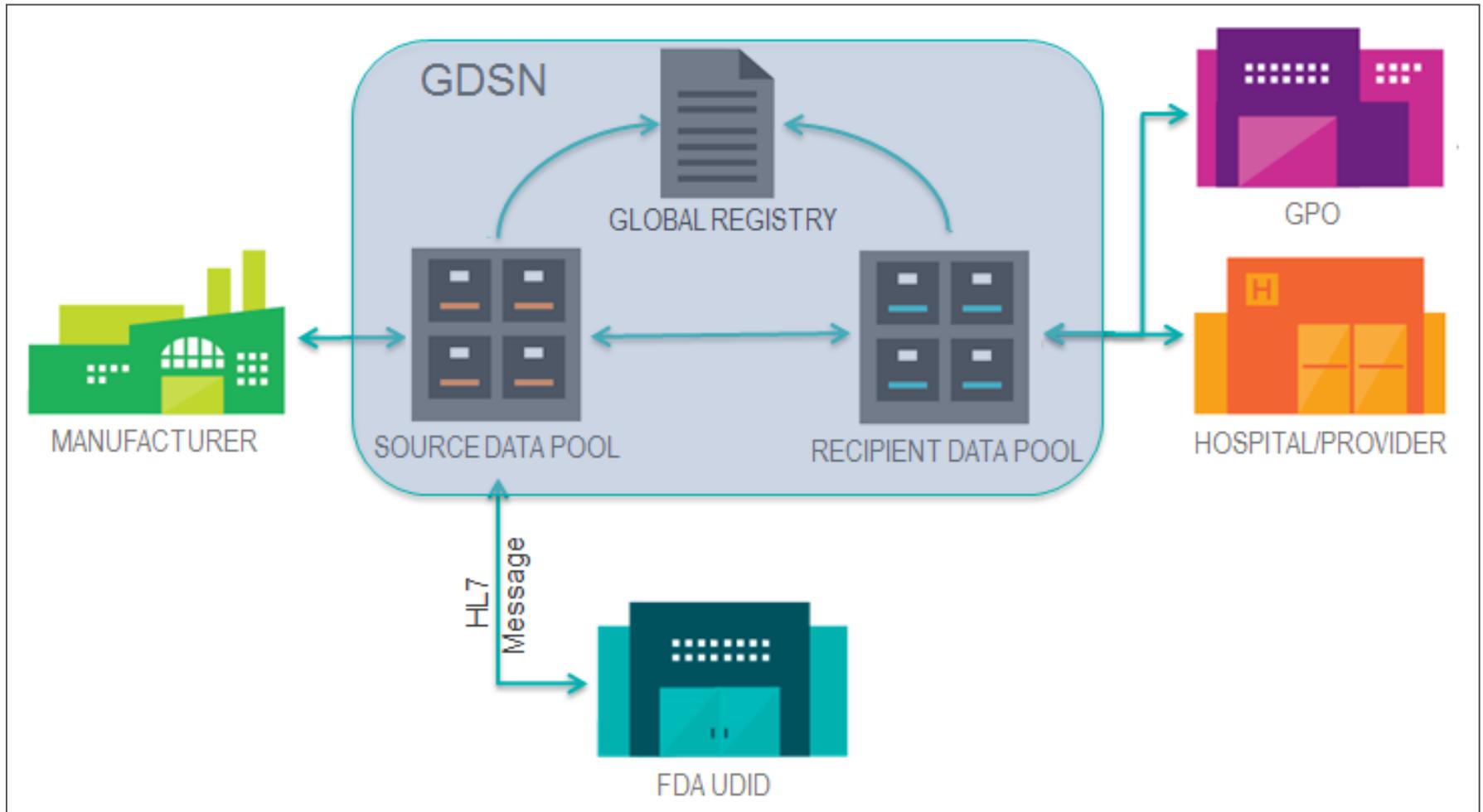
- The **Global Data Synchronization Network (GDSN)** enables feed to UDI databases via data pools across the world



## AIDC (Automatic Identification and Data Capture)

- ISO compliant machine-readable **data carrier** on the product or it's packaging, which contain the UDI: linear or 2D barcodes, RFID

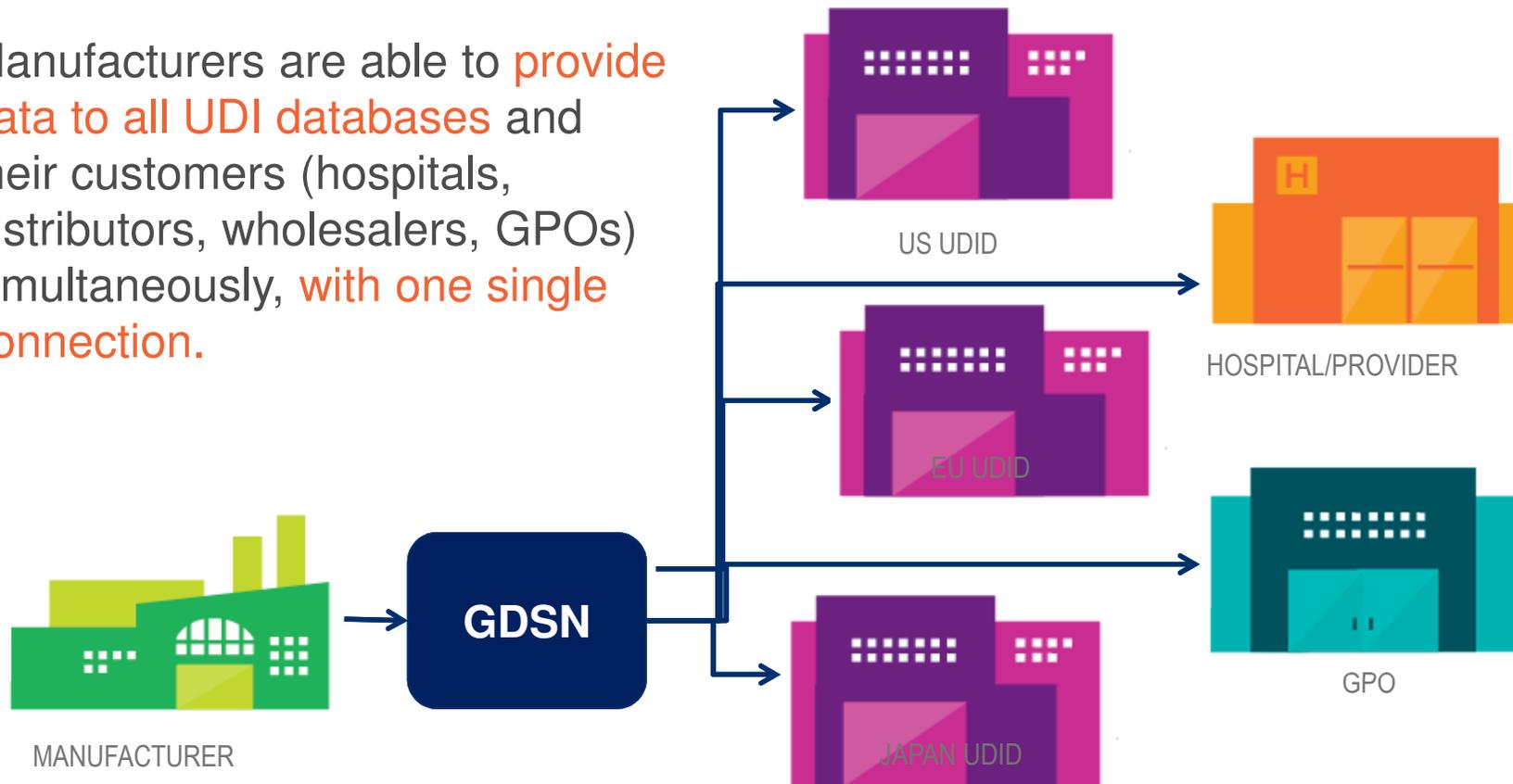
# UDID POPULATION USING GDSN



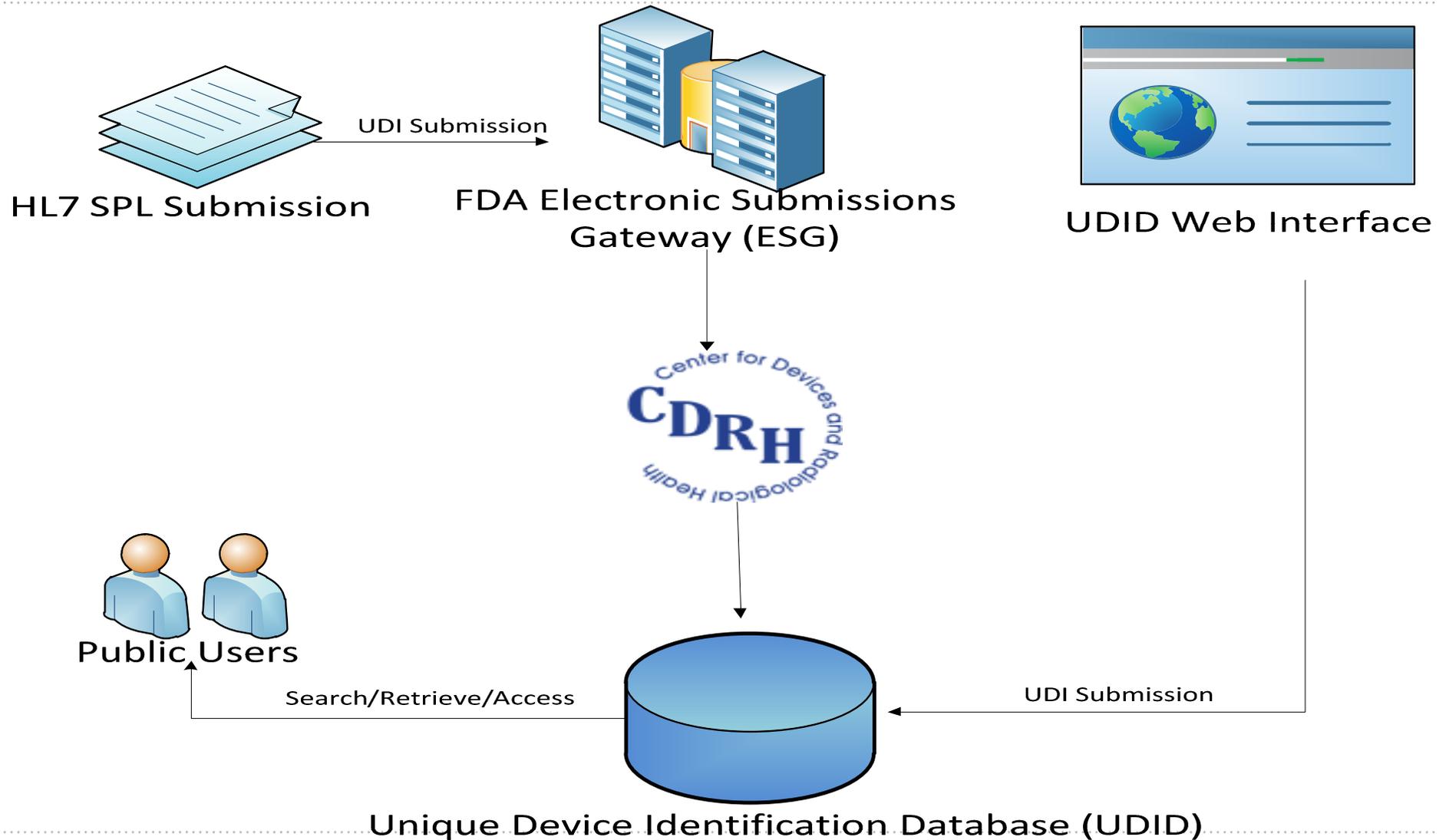
# GS1 GDSN INFORMATION FLOW



Manufacturers are able to **provide data to all UDI databases** and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, **with one single connection.**



# (G)UDID (UDI Database) Overview



# CURRENT UDI REQUESTED\* ATTRIBUTES

- Primary Device Identifier (DI) (no control information)
- Secondary Device Identifier (if applicable)
- Unit of Use DI (if different from DI)
- Manufacturer's Name, Address, and Contact Information
- GMDN
- Device Description
- Additional Product Description
- Trade Name/ Brand Name (of DI and if part of a device family)
- Model Number/Catalog Number (of DI and if part of a model family)
- Clinical Size (volume, length, gauge, etc)
- Storage Conditions
- Sterile?
- Sterilize prior to use, and method of sterilization
- Type of Control (PI) (serial number, Lot/Batch, Expiration Date, and/or manufacturing date) (not actual number or date)
- Can DI be reused?
- Contains Latex?
- Contains Human Tissue?
- FDA Numbers-
  - Product Code
  - Listing Number
  - Premarket Authorization, 510K
  - Supplement Number
- Direct Marking DI (if different from DI)
- Direct Marking Exemption Reason
- Marketing Status
- Is DI part of a Kit? Or a Combination Item?
- DI Discontinued Date (if applicable)
- Higher level information
  - Parent DI, Child DI, Child Quantity

*\*As per the UDI Proposed Rule of 2012*

# FDA UDID PILOT

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- The FDA pilot was to test loading data into the UDID Beta environment
  - 2 Data Pools participated
    - 1Worldsync
      - Abbott, Cardinal
    - GHX
      - Covidien, GE Medical, Cook Medical, J&J, Terumo, Siemens
- Data loaded by manufacturers into the UDID via GDSN
- Pilot ran September 17 to October 5

# HOW WILL IT WORK?

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- Manufacturers can use the GDSN as a single point of entry for publishing an item's master data
  - UDID data to the FDA and other similar UDI databases globally
  - Supply Chain, Market, and Public UDID data to GPOs and Providers
- Benefits to the approach
  - Single entry platform
  - Population of data one to many
  - GPOs and Providers receive public UDID data elements
- GDSN has begun modifications for UDID
  - Additional attributes needed
  - Process flow for data pools to generate and send SPL messages to the FDA

# RESULTS OF THE UDID PILOT

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- GDSN is a way to feed data into the UDID
- UDID Attributes have been mapped to GDSN
  - missing attributes have been identified and added to the GDSN
- Allows the manufacturer to enter one message and provide
  - Supply Chain data to trading partners
  - Regulatory data to the UDID
    - Only those requested elements will be sent along

# NEXT STEPS

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- Evaluation of
  - UDID implementation guides
  - Final release of the regulation
- Revisions of GDSN (if necessary)
- Driving adoption

# CONTACT INFORMATION

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