



**LEARNING UDI  
COMMUNITY**



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Association for Healthcare  
Resource & Materials Management

***Advancing the Healthcare Supply Chain***

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American Hospital Association

# FMOL Health System UDI Capture Work Group Case Study



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# LEARNING UDI COMMUNITY CASE STUDY

## WORK GROUP TITLE:

UDI Capture Work Group

## CASE STUDY PARTICIPANTS

James Phillips, Consulting Manager, DSI, the Office of Data Standards and Interoperability, Franciscan Missionaries of Our Lady Health System (FMOLHS)

## CASE STUDY ORGANIZATION

Franciscan Missionaries of Our Lady Health System (FMOLHS) is the leading healthcare innovator in Louisiana. FMOLHS brings together outstanding clinicians, the most advanced technology and leading research to ensure that its patients receive the highest quality and safest care possible. With hospitals, clinics, and physicians located throughout our state, FMOLHS is the largest in Louisiana. As a nonprofit, mission-focused Catholic healthcare ministry, FMOLHS gives special attention to its citizens who are most in need. During the most recent fiscal year, the health system provided more than \$39 million in unreimbursed care and community support to the underprivileged.

## OPENING STATEMENT

FMOLHS is a pioneer in healthcare data standards implementation, having started its implementation journey seven years ago. The health system's first work with standards was a pilot program with seven suppliers to use GS1<sup>1</sup> Global Location Numbers (GLNs) and GS1 Global Trade Item Numbers (GTINs) in electronic data transactions (EDI) to improve the efficiency and accuracy of the procure-to-pay process. Based on these pilots, FMOLHS developed a data standards implementation plan, which is a step-by-step instructional guide to implementing these data standards. Please contact James Phillips, FMOLHS Consulting Manager, for questions and clarification related to this case study. If you are interested in implementing this solution within your own organization, and James can help in any way, he can be reached at (225) 526-4526 or [james.phillips@fmolhs.org](mailto:james.phillips@fmolhs.org).

The work FMOLHS did with its supplier Cook Medical is documented in an AHRMM Cost, Quality and Outcomes Movement (CQO) case study. In addition to highlighting the collaborative efforts between FMOLHS and Cook, AHRMM will soon be publishing a CQO case study on FMOLHS' work with GS1 GLNs for organization and location identification, including identification of suppliers, the health system's facilities, and their bill-to, deliver-to, and ship-to locations.

FMOLHS is now working to use the device identifier (DI<sup>2</sup>) portion of the UDI for product identification at the point of use in the operating room (OR), alongside the U.S. Food and Drug Administration's (FDA) unique device identification (UDI) rule.

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<sup>1</sup> An FDA-accredited issuing agency (IA) is an organization that operates a system for assignment of UDIs according to the UDI Rule. FDA has accredited three issuing agencies – GS1, HIBCC and ICCBBA.

<sup>2</sup> Each issuing agency has an alternative name (aka) for the DI of UDI. The aka name used by each issuing agency is listed below:  
GS1 - Global Trade Identification Number (GTIN)  
HIBCC - Universal Product Number (UPN)  
ICCBBA – Processor Product Identification Code (PPIC)

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FMOLHS is requesting supplier DIs for all products coming into the organization, adding them to its Lawson enterprise resource planning (ERP) system, which feeds this standardized product data to a third party UDI tracking solution. FMOLHS is also exploring alternatives, including accessing DIs from suppliers through the Global Unique Device Identification Database (GUDID).

James Phillips, Consulting Manager, DSI, the Office of Data Standards and Interoperability, Franciscan Missionaries of Our Lady Health System (FMOLHS), explains how his organization's work to use UDIs is driven by patient safety, stating:

“Patient safety is the goal – that’s why we are all here. There’s always that voice that says – ‘is there a better way? Can we do this easier, faster and with less manipulation?’ UDI implementation and automation allows us to do that. We want to provide the best service to our patients – and it goes much further than that – our work can help other healthcare organizations across the country. If we could establish an encompassing system that can tell a physician if a patient has an implant and specific details about that implant – that could really make a difference to patient care in the U.S. and beyond.”

“Implementing UDIs and electronic product data capture via barcode scanning will also give our clinicians more time with their patients,” he adds. “They won’t have to find files for someone’s implant or type in product information following a surgery if it is already in the system and they can simply scan a product. Think about how much quicker and more accurate that is than manually entering data.”

## DATE INITIATIVE WAS IMPLEMENTED

February 2014 (date of initial GTIN and GLN pilots)

## CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

According to Phillips, once he and his team gained buy-in from the required parties, the greatest challenge was organizing tasks related to the DI implementation project, assigning responsible parties and putting into place a process to ensure tasks were being completed in a timely manner.

Another challenge has been accessing the DIs themselves. The FDA’s deadline for medical device manufacturers to enumerate their products with UDIs and submit standardized data to the GUDID is September 24, 2018. Over 50 percent of medical devices are already required to be labeled with UDIs as progressive compliance dates, based upon medical device class, are encountered. In addition to accessing DIs through the GUDID, Phillips and his team are reaching out to individual suppliers for their DIs, as well as using the GS1 Global Data Synchronization Network (GDSN) as a source for standardized product data.

Barcode scanning has presented further challenges. Phillips found that some of the barcodes when scanned pull different information than what is printed on the label – explicitly the dates. And while some of the labels from a reputable manufacturer appeared well printed (e.g. no smudges, clear distinct lines to the eye) the information scanned is inconsistent, with some labels generating the necessary product data and others generating nothing. This inconsistency happened among labels for the same product (with some product barcodes being scannable and others not). If a barcode is unscannable, than a manual entry must be performed.

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## STAKEHOLDERS INVOLVED

- FMOLHS executive team
- VP of materials management
- Purchasing team
- Project manager
- IT team
- MMIS team
- Clinicians
- Facility leaders
- Nurses
- Physicians
- Accounts payable (AP) team
- Logistics team
- ERP system vendor (Lawson)

## SOLUTION

Phillips and his team are continuing to secure DIs for products used in patient care and entering that data into their ERP system. Alongside this work, they are implementing a point of use scanning solution that will allow clinicians to scan product barcodes at the patient bedside and capture this data in the EHR system. In March 2017, FMOLHS will begin rolling out the EPIC EHR system in some of its facilities.

The initial focus for the bedside product capture portion of FMOLHS' data standards implementation work has been tissue and biologics products. The health system recently implemented a third party UDI tracking solution, which is a system designed to track tissue, orthopedic, cardiovascular, and other implants. FMOLHS' ERP system feeds product DIs from the item master into the UDI tracking solution. Clinicians scan product barcodes to capture product usage in the UDI tracking solution, which features capabilities to support regulatory compliance, recall investigation and inventory management. The FDA is beginning to incorporate DI information into recalls.

Because FMOLHS deployed barcode scanning technology in its ORs to facilitate the use of the UDI tracking solution, they will soon be able to leverage this same technology to capture both the DIs and the PIs (the full UDI) for products in the EHR system.

## TRAINING DOCUMENTS

The FMOLHS Issuing Agency Data Standards Master Process Implementation Plan: a step-by-step instructional guide to implementing data standards. The document is accessible in the Learning UDI Community website under this case study.

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Furthermore, they are leveraging their work with DIs and GLNs for a “best unit of measure” project. FMOLHS opened its own distribution center 18 months ago, and Phillips explains that they are trying to determine the best unit of measure in which to deliver specific products to facilities. Because the FDA’s UDI rule requires manufacturers to enumerate their products with DIs at each unit of measure, FMOLHS can use this data in its work. They are also using the GLNs assigned to deliver-to and ship-to locations to facilitate more effective delivery of items used in patient care.

## TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- Lawson enterprise resource planning (ERP) system
- Champion UDITracker solution
- Honeywell barcode scanners
- Soon to be implementing EPIC electronic health record (EHR) system

## SUCCESS FACTORS

- Leadership buy-in
- Interdepartmental cooperation and collaboration
- Complete automation for product data capture
- Barcode scanner strategy
- Coordination of parallel projects, including GLN enumeration of bill-to, deliver-to, and ship-to locations, obtaining supplier DIs and loading them into the ERP system, use of DIs and GS1 GLNs in EDI transactions with suppliers, UDITracker implementation, connecting to the GDSN

## LESSONS LEARNED

- Document tasks and assign priority levels for each task of the project, including names of responsible parties for each task so that someone is held accountable - use checklists
- Create a procedure for following up with the responsible parties to ensure task completion and prevent delays

## NEXT STEPS

Once FMOLHS has deployed the EHR system in its facilities (starting in March 2017), they will configure the system to feed standardized product data to the UDI tracking solution. Following the EHR go-live, Phillips and his team plan to conduct a system integration whereby products are tracked via barcode from receiving all the way through to the patient bedside and the information captured in the ERP system, EHR system and UDI tracking solution.

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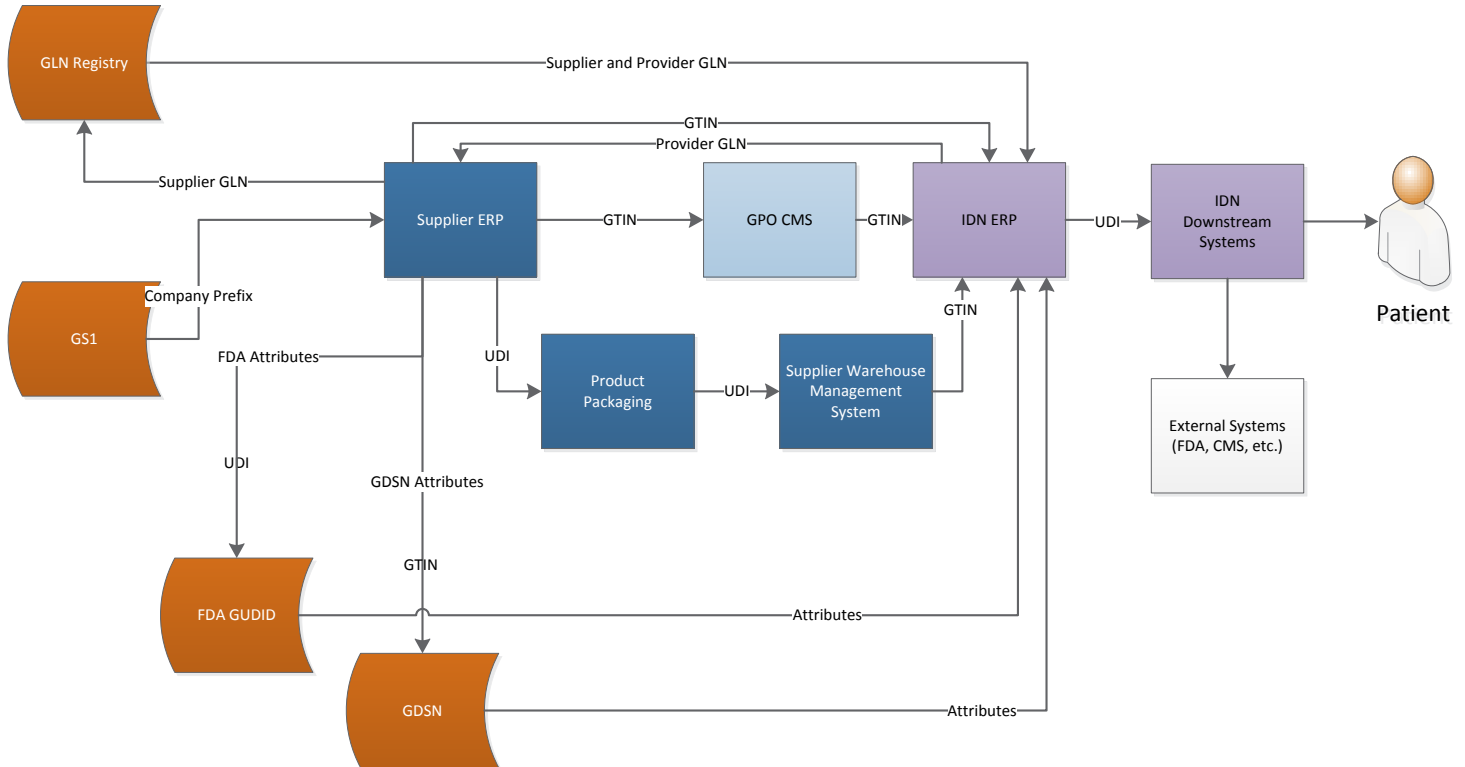
“It is still something that needs to be designed but my ultimate goal is to electronically track everything we can possibly track,” said Phillips.

Phillips and his team provide continuous training on DIs for FMOLHS staff, and work continues on GLN implementation for purchasing and logistics. They are also continuing to implement the GDSN as a source of standardized product data from suppliers using GUDID as source of core data for GDSN.

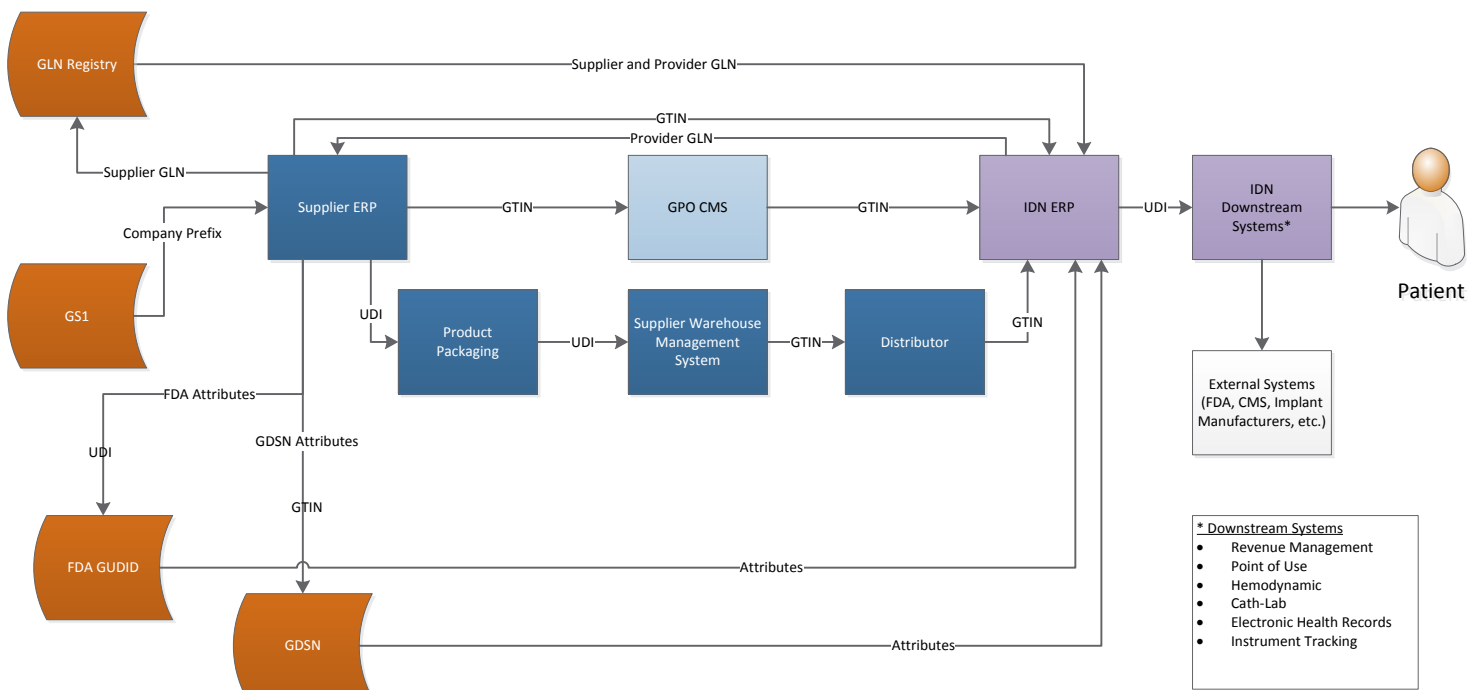
A team of approximately 80 healthcare experts came together at FMOLHS in Baton Rouge, Louisiana, to create the tools need to implement the Touchless Order using automation from product requisition to check generation (Req to Check). This team included an elite group of FMOLHS staff, a data standards organization, software companies and manufacturers. This Network Diagram below was designed as a result of collaboration between all parties present.

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FINAL-FMOLHS-GS1 DATA STANDARDS  
NETWORK DIAGRAM - DIRECT



FINAL FMOLHS-GS1 DATA STANDARDS  
NETWORK DIAGRAM - DISTRIBUTED



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## APPENDIX 1: GS1 UDI Label Example



# UDI Components



UDI = Device Identifier (DI) + Production Identifiers (PI)  
GTIN® + Application Identifiers (AI)



\*Another Production Identifier is Manufacture Date

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## APPENDIX 2: HIBCC UDI Label Example



Health Industry Business  
Communications Council

2525 E. Arizona Biltmore Cir.  
Suite 127  
Phoenix, AZ 85016  
602-381-1091  
FAX 602-381-1093  
www.hibcc.org



## HIBCC UDI Label Example

### DataMatrix

**CompuHyper GlobalMed®**  
Ultra Implantable™  
Fictitious Medical Device  
2.25 mm x 8 mm

<b>CAT</b> 123ABC	<b>USE BY:</b> 2019-05-15	<b>MANUFACTURED ON:</b> 2015-10-01	<b>SN</b> 5678EDFG
<b>LOT</b> 1234AB			QTY: 1 EA
<b>2</b> SINGLE USE	DO NOT USE IF PACKAGE IS DAMAGED	40°C UPPER LIMIT OF TEMPERATURE	KEEP DRY
<b>Manufacturer</b>			
CompuHyper GlobalMed® 123 Technology Dr Somewhere, XX 00000			
MedDevFront UK Somewhereshire XX12 3XX UK			
800.555.1234 (USA) 555.555.1234 (All Others) www.chgm.com		www.mdfco.uk	
*X999123ABC0\$\$\$31905151234AB/S5678EDFG/16D20151001J*			

HIBCC DI  
(Fixed Product Data)

HIBCC PI  
(Variable Production Data)

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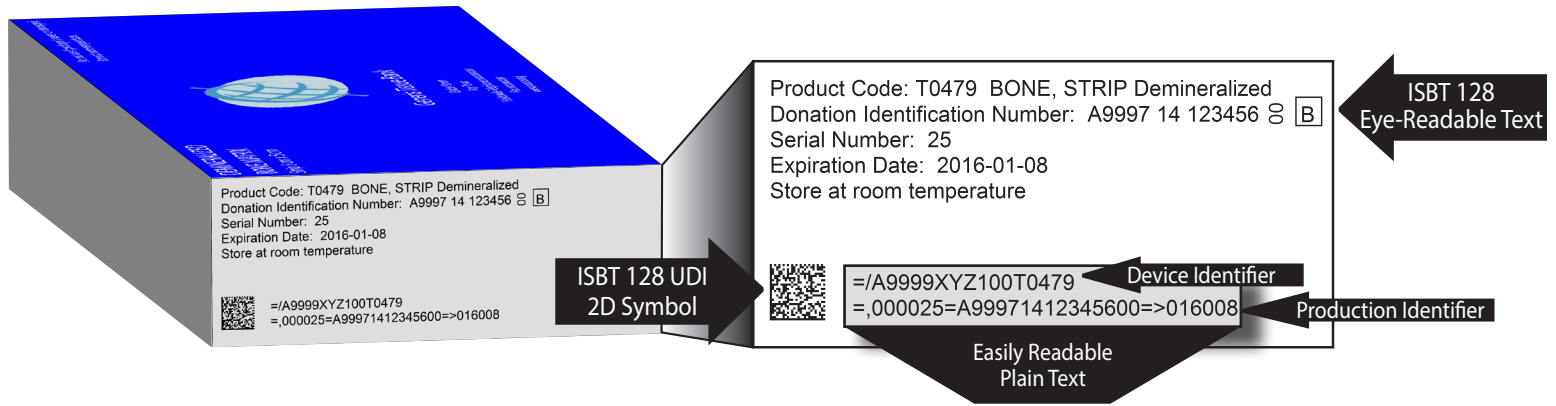
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## APPENDIX 3: ICCBBA UDI Label Example

# USING ISBT 128 UNIQUE DEVICE IDENTIFIER ON MEDICAL DEVICES THAT CONTAIN HUMAN TISSUE



Medical devices containing Human Cells, Tissues, or Cellular and Tissue-Based Products (HCT/P) labeled using ISBT 128 will provide UDI information, including the Donation Identification Number, in a standardized electronically-readable format and in eye-readable text. These illustrations show examples of how the information may be presented. The two-dimensional symbol contains the critical tracking information. Receiving systems should be programmed to scan and interpret this symbol to provide optimal efficiency and accuracy.



Item	Recommended Abbreviation(s)	What it Identifies
Donation Identification Number	DIN	This identifier links the product to its donor (the Distinct Identification Code as required by 21 CFR 1271.290(c)).
Product Code	Prod Code or PC	This code identifies the type of product (e.g., bone powder or a pre-sutured tendon).
Pack Number or Serial Number	Pack or SN	This code uniquely identifies a specific product for a given DIN and Product Code.
Expiration Date	Exp or Exp Date	The date on which the product should no longer be used.
Manufacturing or Production Date	Mnf Date or Prod Date	The date on which the product was made.
Lot Number	Lot No. or LN	This identifier links to a production record of the process or the tissue.
Device Identifier	DI	The FDA UDI Device Identifier (identifies the specific version or model of a device and the labeler of the device).
Production Identifier	PI	The FDA UDI Production Identifier (information that more precisely identifies the device).

**DEMINERALIZED BONE MATRIX**  
Strip 5 cm x 5 cm

**Generis Tissue Bank**  
Global Street  
Any Town  
Worldwide Telephone: xxxxxxxxxx  
Fax: xxxxxxxxxx  
www.xxxxxxx.org

Do not use if package is open or damaged.  
Store at room temperature.

PC: T0479 BONE, STRIP Demineralized  
 DIN: A9997 14 123456 [B]  
 SN: 25  
 Exp Date: 2016-01-08  
 Store at room temperature

ISBT 128 UDI 2D Symbol

Device Identifier  
 =/A9999XYZ100T0479

Production Identifier  
 =,000025=A99971412345600=>016008