UDIs & GTINs: Finding Value in the Real World

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Connected. Intelligent. Healthcare.

Alphabet Soup

Some Basic Definitions

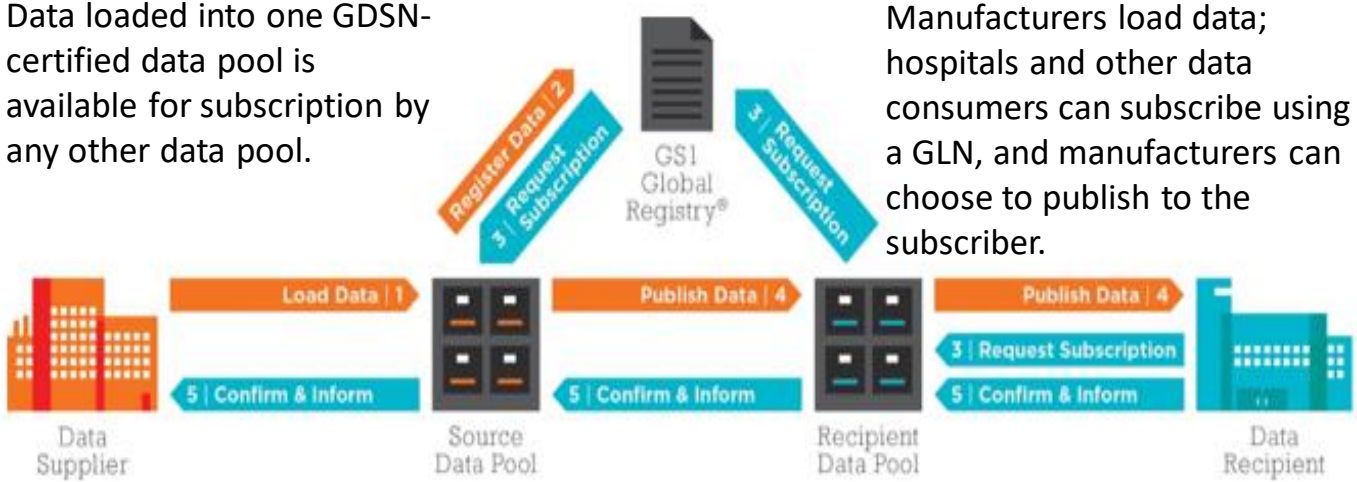
- **Global Trade Item Number (GTIN) – *Commercial identifier***
  - Globally unique 14-digit number used to identify trade items, products or services
  - Issued by the standards body GS1
  - Embedded in a barcode

- **Unique Device Identifier (UDI)- *Regulated identifier***
  - An identifier mandated by the U.S. FDA designed to adequately identify medical devices through their distribution and use.
  - UDI compliant codes provided by issuing agencies authorized by the FDA (GS1, HIBCC, ICCBBA)
  - Includes a static device identifier, (e.g., a GTIN, a HIBC-LIC, or an ISBT 128 code) and a dynamic production identifier, (e.g., lot, serial number, expiration date, etc.)
  - Part of the U.S. FDA UDI regulation published in 2013 and being implemented now
  - Being regulated globally

Some Basic Definitions

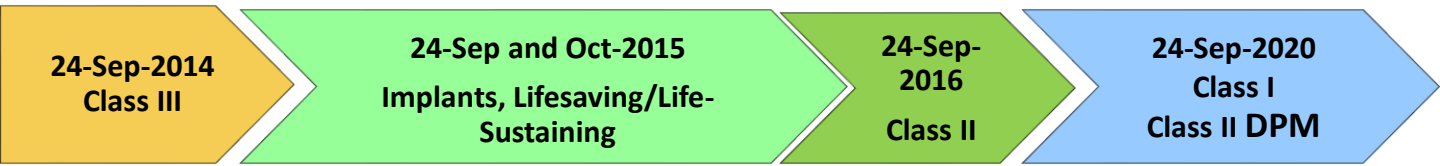
Global Data Synchronization Network (GDSN) - an internet-based, interconnected network of interoperable data pools and a global registry that enables companies around the globe to exchange standardized and synchronized supply chain data with their trading partners.

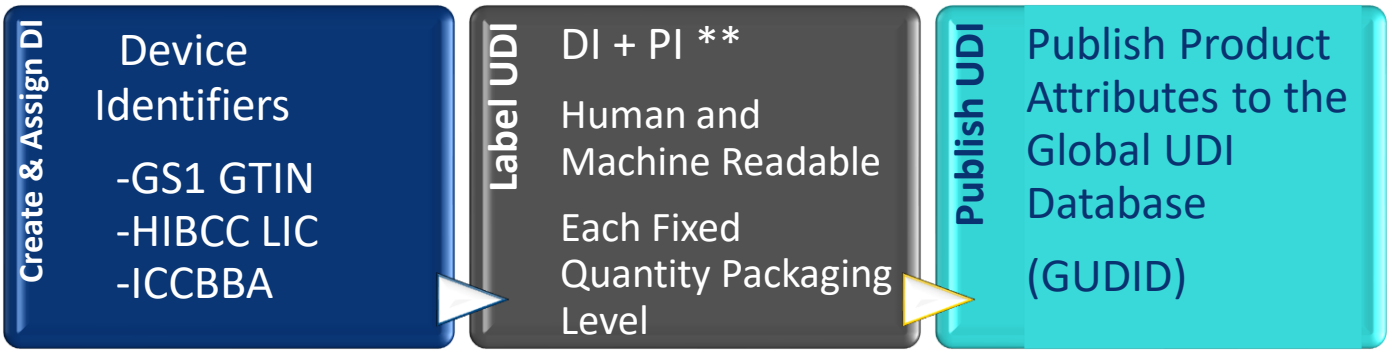
Data loaded into one GDSN-certified data pool is available for subscription by any other data pool.



Manufacturers load data; hospitals and other data consumers can subscribe using a GLN, and manufacturers can choose to publish to the subscriber.

The U.S. FDA UDI Rule for Manufacturers





**** UDI = DI + PI**

DI = Device Identifier (static – industry standard product identifier

PI = Production Identifier (dynamic data, e.g. lot, batch, serial number, expiry date)

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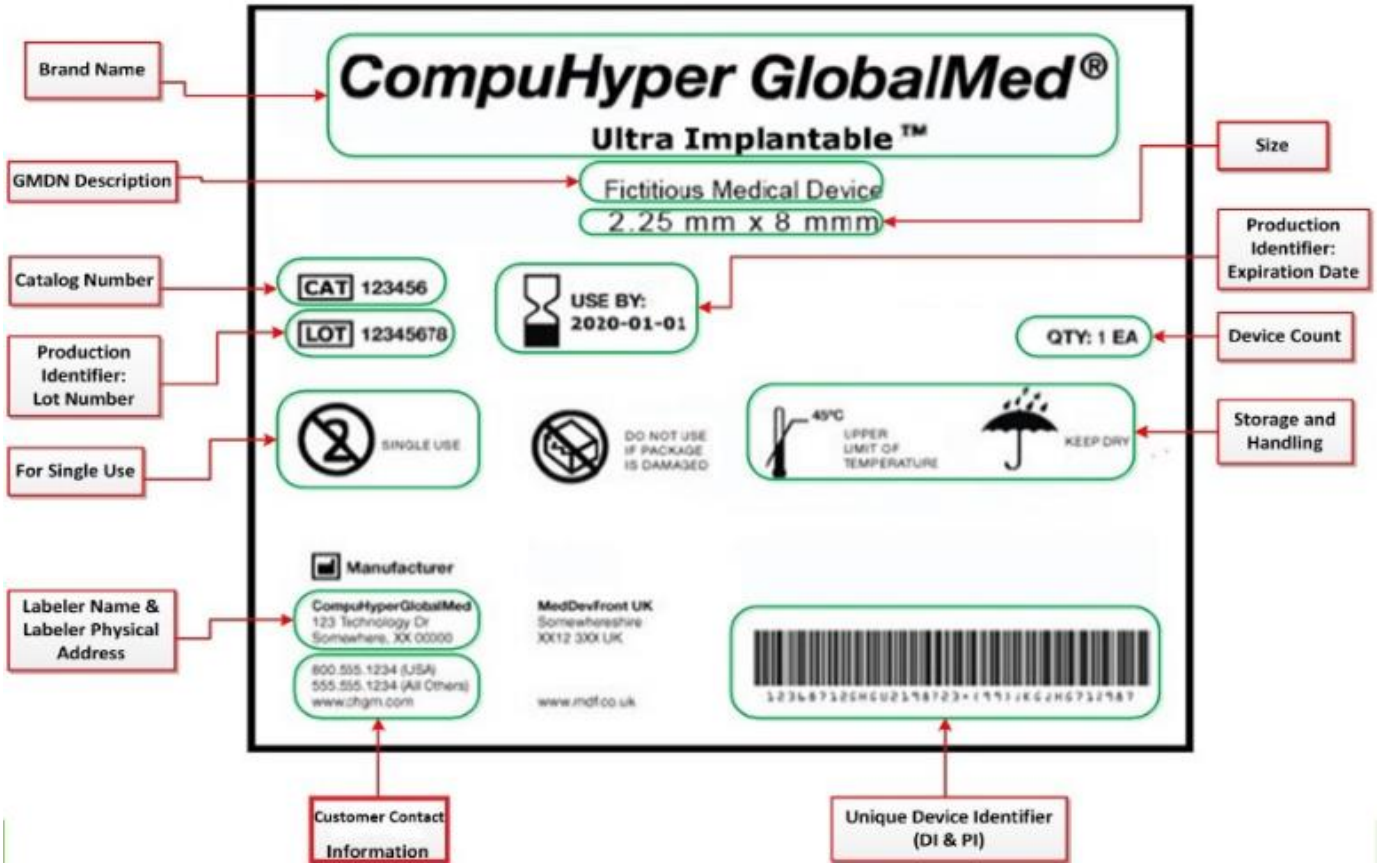
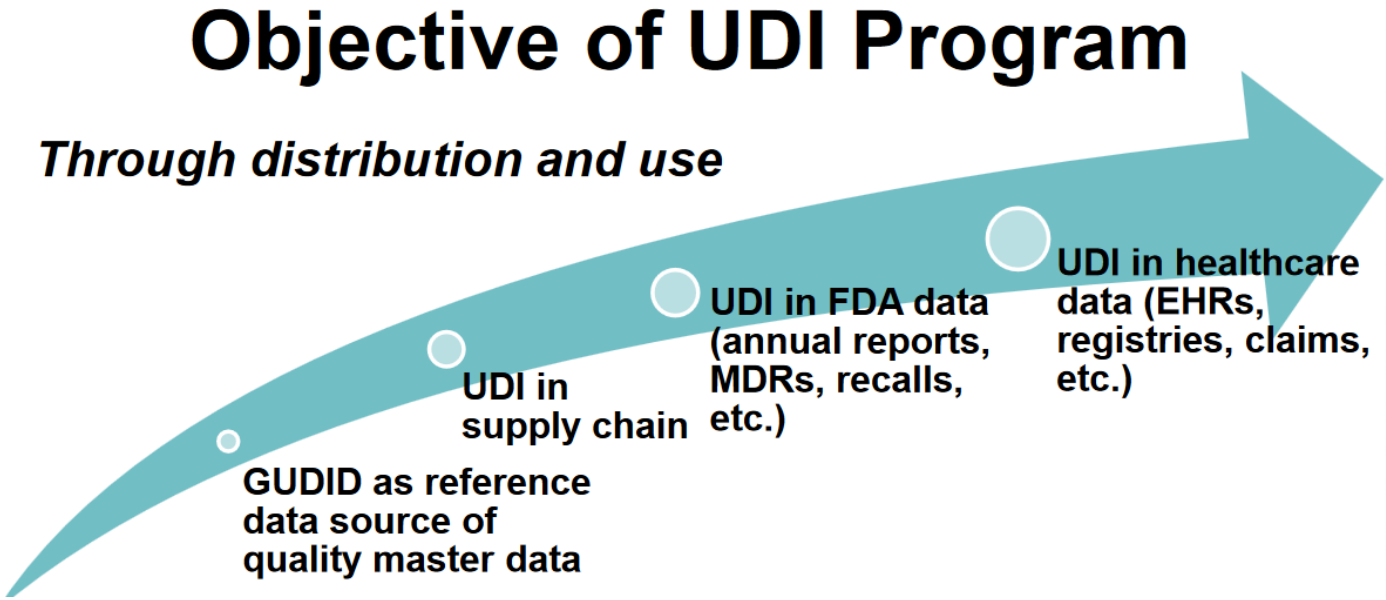
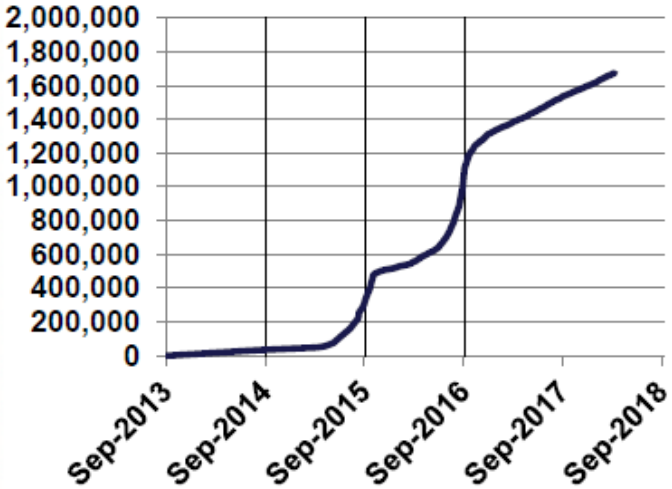
Sample UDI compliant label with GUDID elements

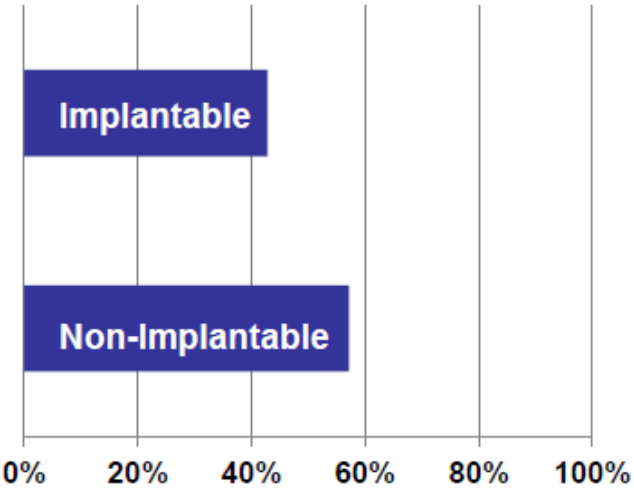


FDA Objective: UDI is *the* Item Identifier



Records in the GUDID

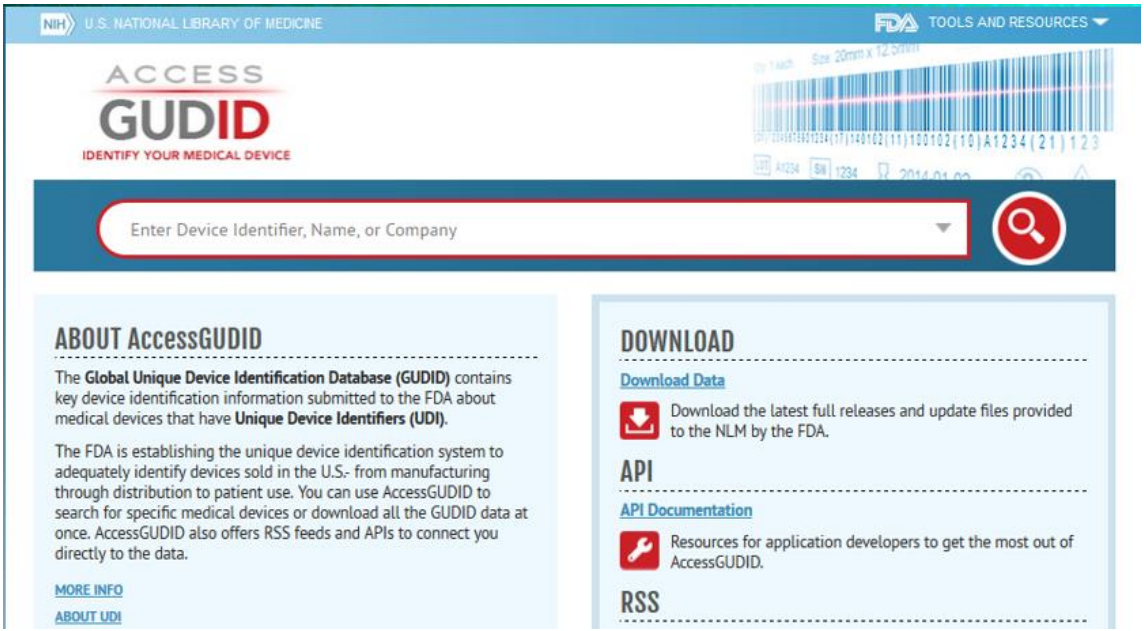




Includes different device identifiers for same product at different packaging levels.

Some Basic Definitions

Global UDI Database (GUDID) - a database administered by the US FDA that will serve as a reference catalog for every device with a UDI.

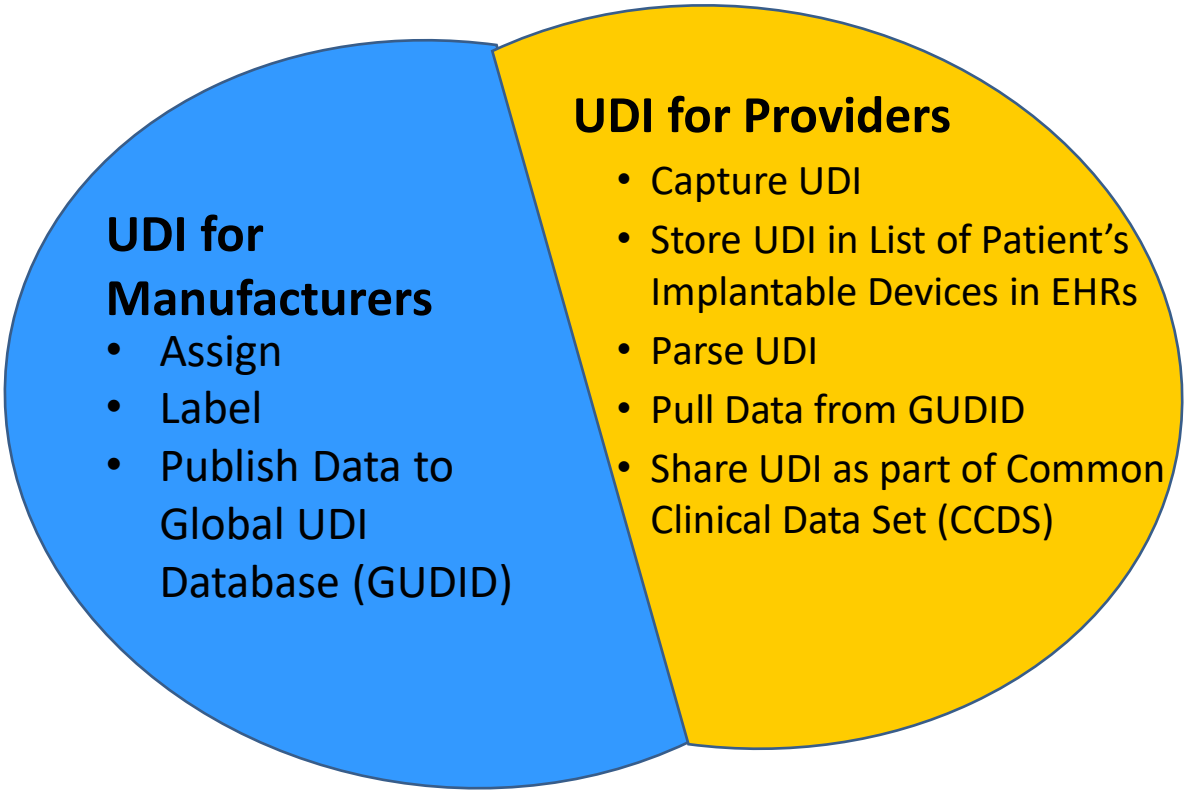


The public can access information contained in the GUDID through [AccessGUDID](AccessGUDID.nlm.nih.gov) (AccessGUDID.nlm.nih.gov)

GUDID Device Attributes (Majority)

GUDID Device Attributes (Majority)	FDA Product Code
Secondary DI number (and issuing agency)	GMDN Code
Brand Name	DM DI different from primary DI (and DM DI number)
Catalog Number (optional)	Device subject to direct marketing but exempt
Device description (optional)	For single use (Y/N)
Production identifier(s) (Y/N)	Device count (for primary DI)
Labeler company name and physical address	Package type
Labeler DUNS number	Package DI number
Customer contact - phone and email	Quantity per package
Commerical distribution end date	Contains DI package
Device is also a HCT/P, kit and/or combo product	Unit of Use DI number
Device labeled as containing natural rubber latex or dry natural rubber (Y/N)	Device labeled as "Not made with natural rubber latex"
Requires sterilization before use (Y/N)	MRI safety status
Sterilization method	Storage and handling
Device packaged as sterile (Y/N)	Special storage conditions
Clinically relevant size	Prescription use (Rx) and/or Over the counter (OTC)

UDI: It's a Requirement for Providers, Too



ONC EHR Certification Required GUDID Elements

Data elements required in the implantable device list as part of electronic health records per the ONC 2015 edition Health IT certification criteria regulation 45 CFR 170.315(a)(14). The data elements are primary DI, brand name, model/version, company name, MR safety, Latex, Description (GMDN/SNOMED), and Production Identifiers (Lot, serial number, expiration date, manufacture date, and DIC (see Donation Identification Number data element).
https://www.healthit.gov/sites/default/files/2015Ed_CCG_a14-Implantable-device-list.pdf

But Why UDI?

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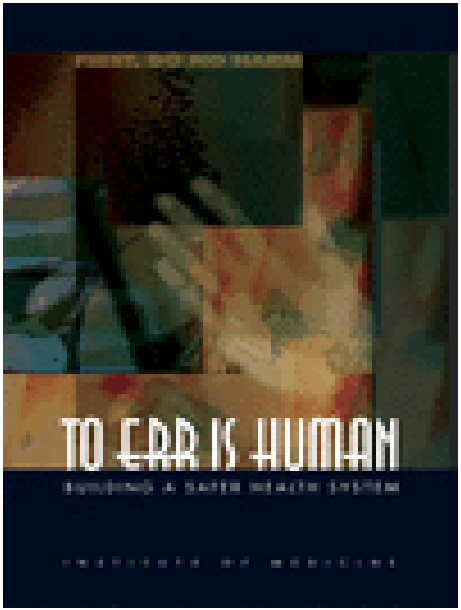
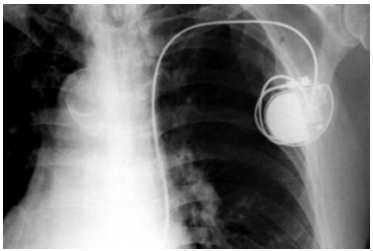
From the Regulator's Perspective





Metal on Metal

To protect patient safety…but much more…

Understanding the Benefits and Risks of Medical Devices

By promoting incorporation of UDIs into electronic health information, a vast quantity of untapped ***real-world data*** *from clinical experience with devices housed in EHRs and other electronic information sources may become available for use in* ***understanding the benefit-risk profiles of medical devices.***

Statement of Jeffrey Shuren, M.D., J.D. before the Committee on Health, Education, Labor and Pensions, April 28, 2015 http://www.help.senate.gov/imo/media/doc/Shuren3.pdf

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The Need for a Learning Healthcare System

Today's Healthcare System

Source: Institute of Medicine, Better Care at Lower Cost, 2013.

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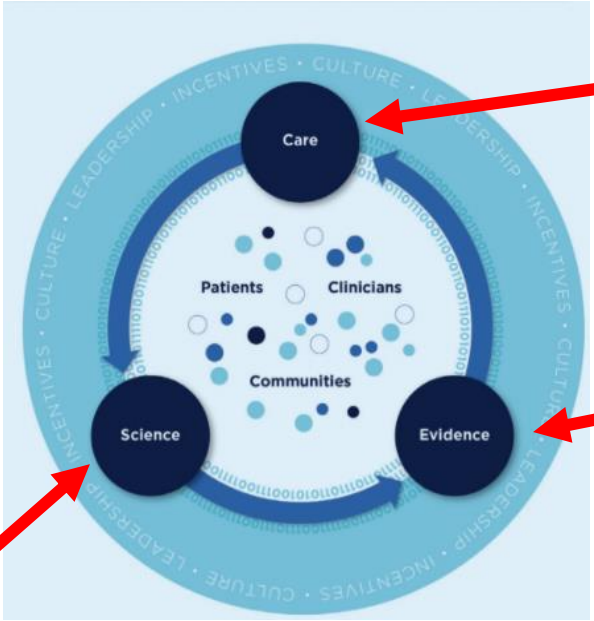
A Continuous Learning System

How UDI can help



2. But Only if It is Captured and Used Here *(in a consistent and standardized manner)*

1. UDI Key to Creating *Usable* and *Accessible* Evidence about Medical Devices *(consistent, standardized)*

3. And only if information provided by manufacturers is usable *(accurate and relevant)*

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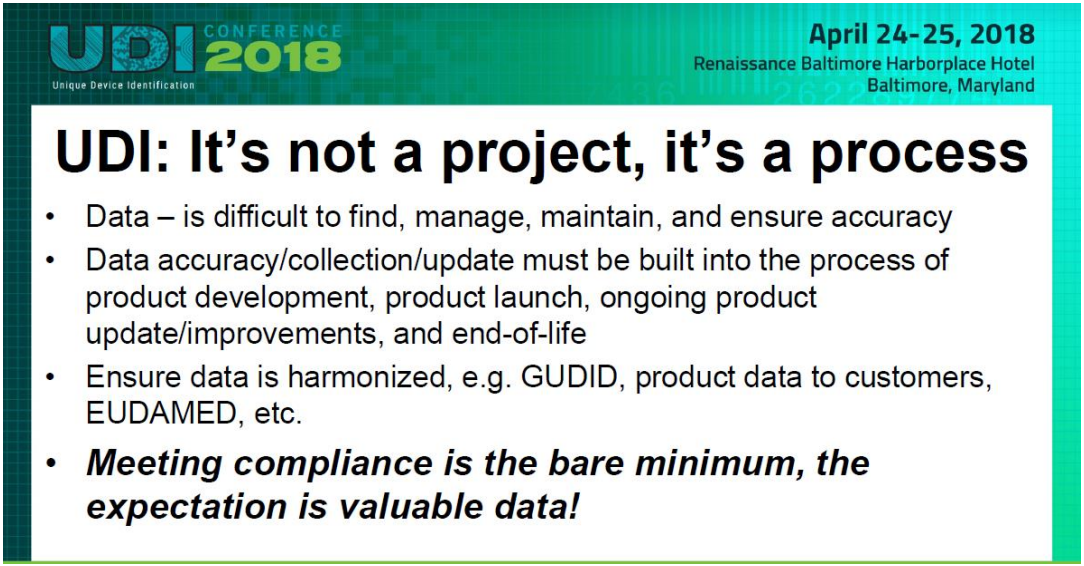
FDA Committed to Improving Data Quality



- FDA has opened up existing GUDID records for manufacturer corrections; encouraging publication of "optional" attributes
- AHRMM Learning UDI Community addressing data quality in work groups (www.ahrmm.org/luc)

AHRMM Learning UDI Community

Completed Work Groups

- UDI Capture
- Unit of Use
- Catalog Number
- Low Unit of Measure
- Benefits of UDI (Workflows)
  - Inventory management for consumable and specialty (trunk stock) product
  - Capturing device usage in EHRs *and* Registries
  - Adverse event reporting
  - Recall Management
- Human Cellular Tissue Product
- Clinically Relevant Size

Work Groups in progress

- Multiple Device Identifiers
- High risk Implants
- Bar Code at the Point of Care
- Device Categorization

Check out new white paper on the link between UDI and the AHRMM CQO Movement.

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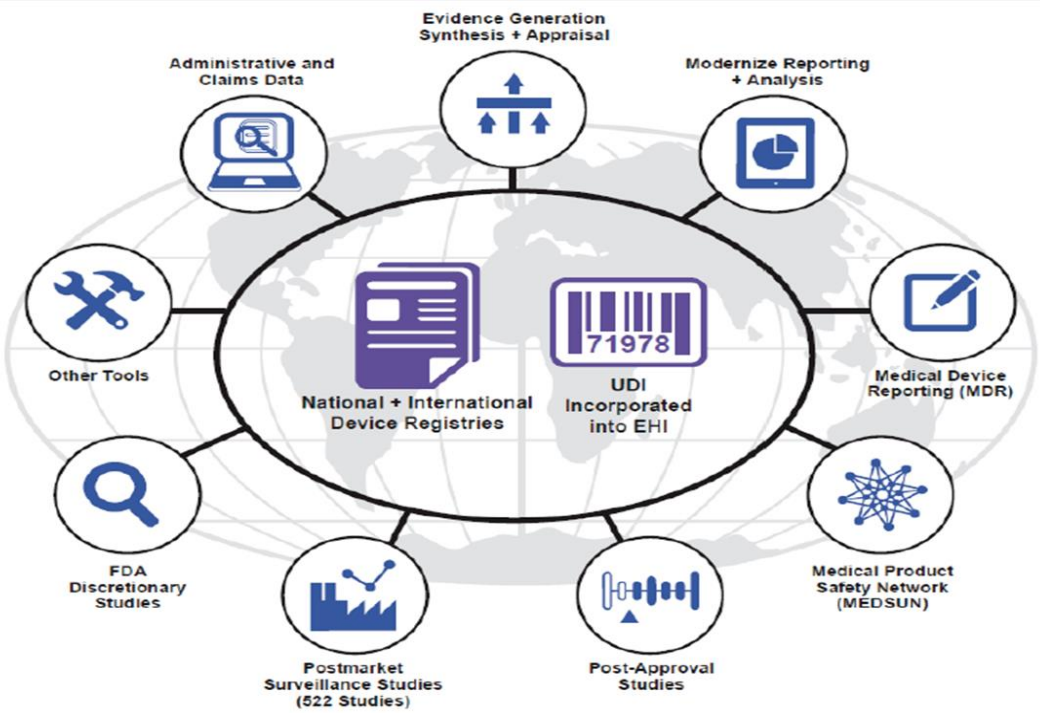
UDI: A Systems View



Source: FDA "Strengthening Our National System For Medical Device Postmarket Surveillance" April 2013

Early Adopters: > 100 Major EHRs Can Hold UDIs (Partial list)

Vendor	Software
Allscripts	Allscripts Professional EHR Allcripts TouchWorks EHR Sunrise Acute Care Sunrise Ambulatory Care
CureMD.com, Inc.	CureMD SMART Cloud
Epic Systems Corporation	EpicCare Ambulatory EHR Suite EpicCare Inpatient EHR Suite
Healthland	Centriq Centriq Clinical
GE Healthcare	Centricity EMR Centricity Practice Solution
MEDHOST	MEDHOST Enterprise MEDHOST Enterprise Clinicals
Henry Schein Medical Systems	MicroMD EMR
eMedPractice LLC	eMedicalPractice

Vendor	Software
Netsmart Technologies	myAvatar Certified Edition
NextGen Healthcare	NextGen Ambulatory EHR
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cerner Corporation	FirstNet (Clinical) PowerChart (Clinical)
SRS-Health	SRS EHR
Greenway Health, LLC	SuccessEHS
Medical Transcription Billing Corporation (MTBC)	TalkEHR
Evident	Thrive EHR Thrive Provider EHR
Bizmatics Inc	PrognoCIS
Practice Fusion	Practice Fusion EHR

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UDI in Claims?

Numerous Real World Evidence Initiatives

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Case for Quality: Product Quality Outcomes Analytics

"…information to make better purchase decisions that improve patient access to high quality medical devices."

Challenge: Lack of consistency in how data is collected and reported

Rankings by:
- Data Source
- Manufacturer
- Product

NEST
National Evaluation System for health Technology
Coordinating Center

Augmented UDI Database (AUDI)

AUDI is designed to be a resource for clinically relevant (discrete) data that is not contained in the GUDID.
- e.g., specific data in the Instructions for Use
- Specific to device type, e.g., drug eluting stent, replacement joint, etc.

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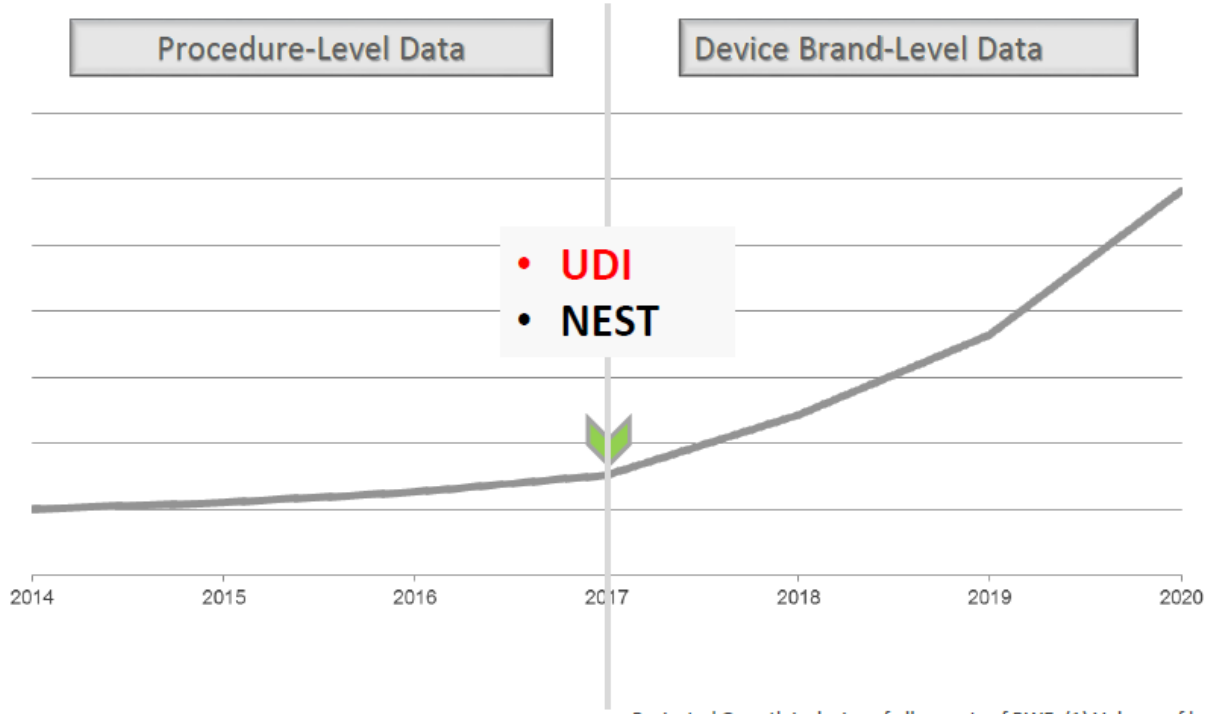
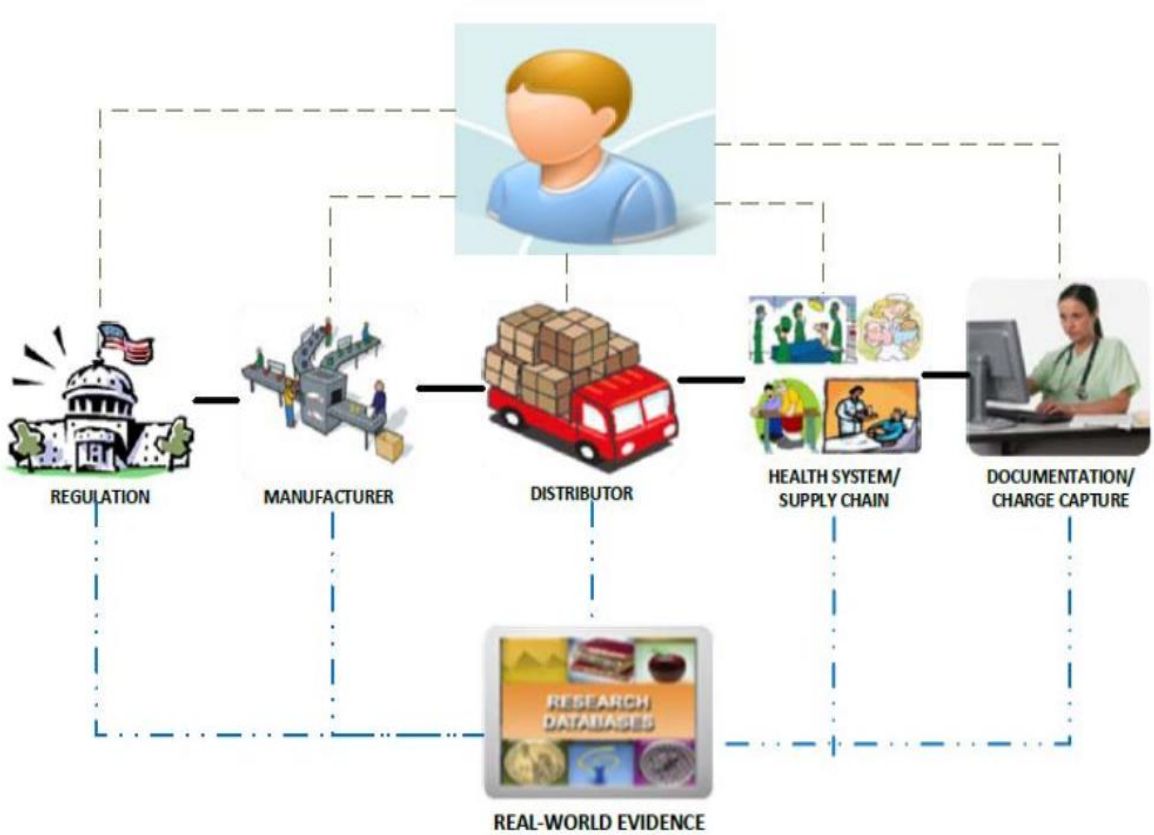
Better Visibility Into Device Performance

RWE in Med Devices is at a tipping point



Projected Growth inclusive of all aspects of RWE: (1) Volume of brand-level RWD, (2) Publications, (3) Market & regulatory expectations, (4) Overall sector spend on data & FTEs, etc.

Real World Evidence Generation Takes an Ecosystem



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How does this change your approach to item data management

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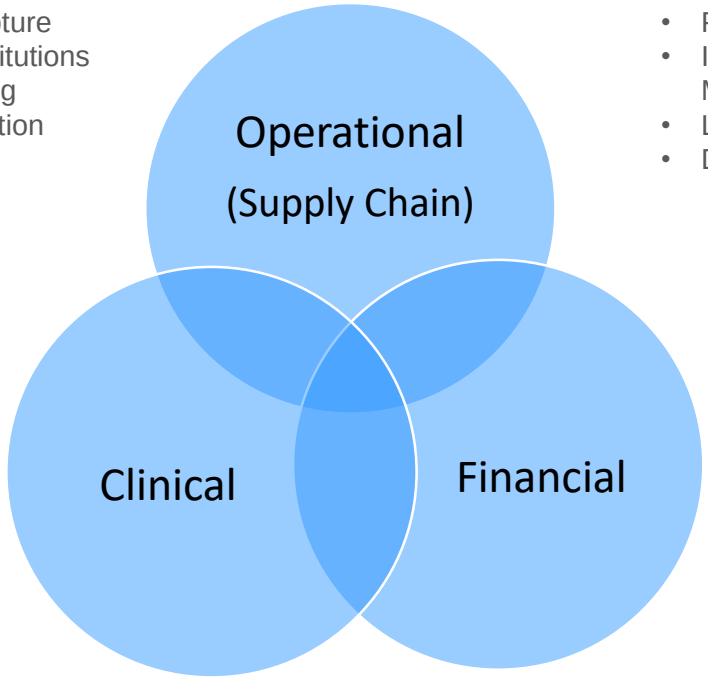
What are you trying to do with product data?

- Point of Use Capture
- Shortages/Substitutions
- Anti counterfeiting
- Disaster preparation



- Purchasing
- Inventory Management
- Logistics
- Demand Planning

- Recalls/Adverse event reporting
- Comparative Effectiveness

- Contract Compliance
- Contract Price Accuracy

- Billing
- Reimbursement

Understanding the Quality and Cost of Care

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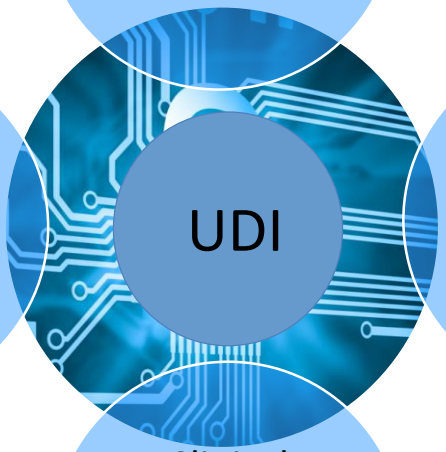
What Product Data Attributes Do You Need?



UDI

Commercial Databases, e.g., GDSN

- Manufacturer
- Device Identifier

Content and Contract Management Tools

- UNSPSC
- HCPCS
- Price

Regulatory Databases. e.g., GUDID

- Physical Size
- Clinical Size

- MRI Compatible
- Latex?
- Sterile?

Clinical Databases, e.g., Registries

- Lot #
- Serial #
- Expiration Date

- GMDN
- SNOMED
- Clinically relevant attributes

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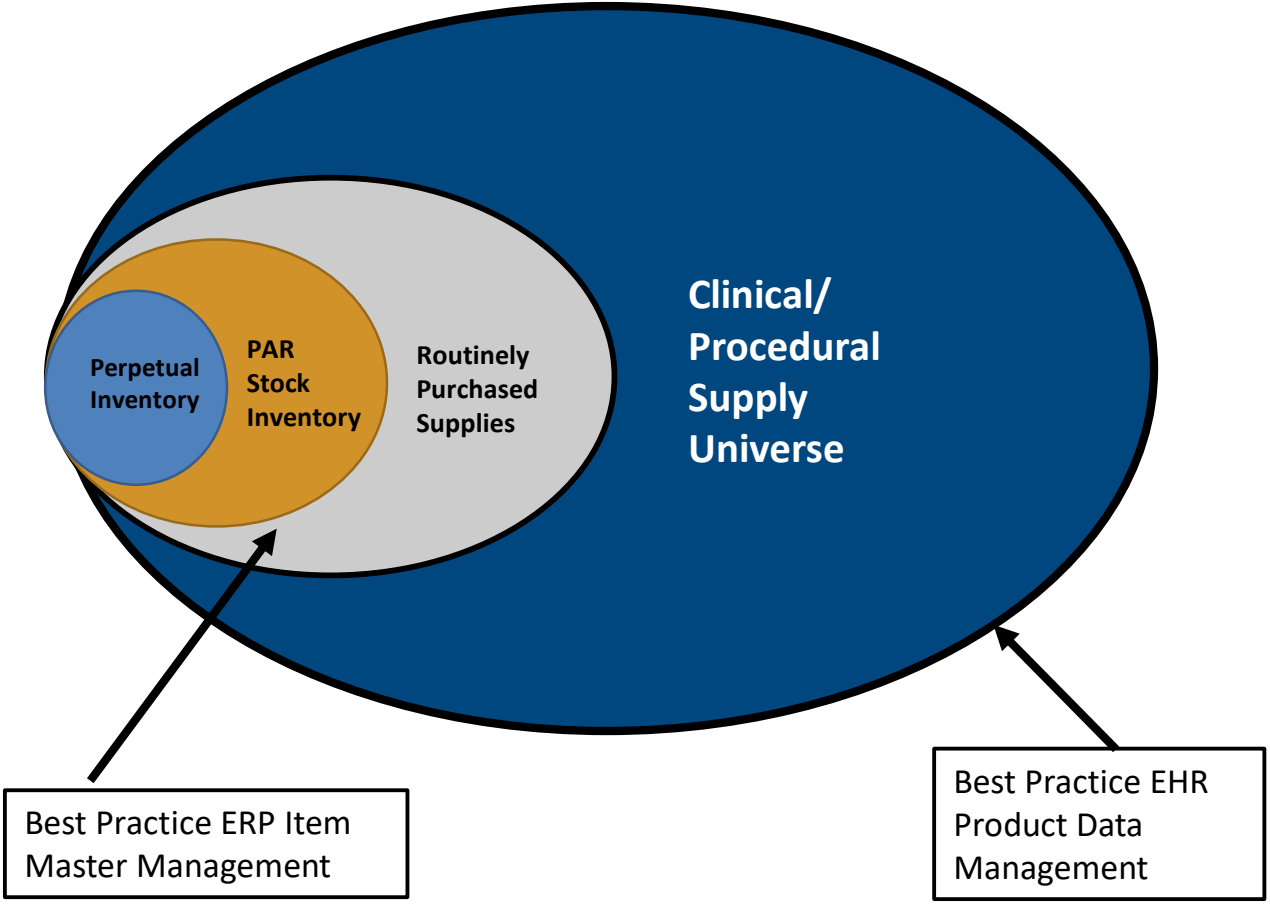
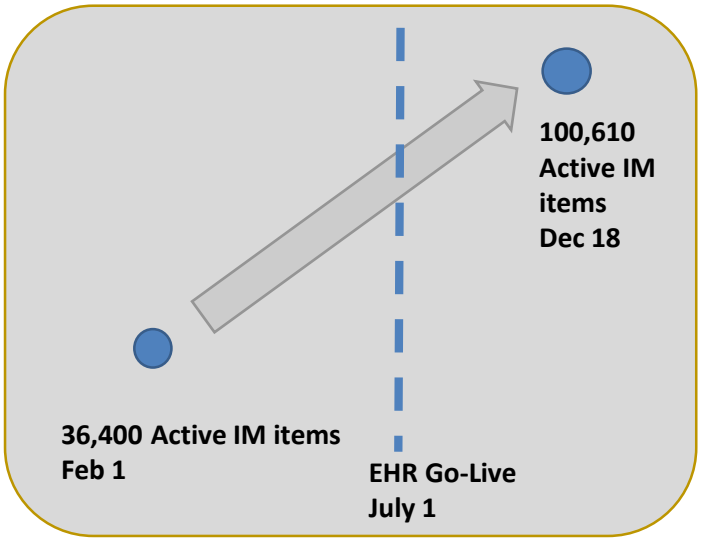

Perpetual Inventory
PAR Stock Inventory
Routinely Purchased Supplies
Clinical/ Procedural Supply Universe
Best Practice ERP Item Master Management
Best Practice EHR Product Data Management

A Tale of Two EPIC Implementations

Inaccurate data threatens patient safety and can lead to increased costs, inefficiencies, and poor financial performance.

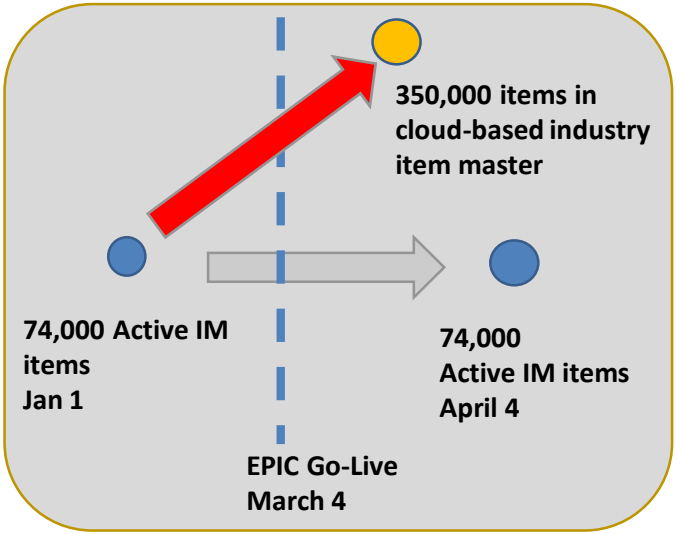
-AHIMA

ERP Item Master Approach



5 Months to Go Live

EHR/Cloud-based Item Master Approach (FMOLHS)



3 Months to Go Live

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It's What's Behind the Barcode that Matters

Clinician documents supply and implant usage during case

50%

Found in IM

- Minimal clinician time to enter supply/implant
- Charging data seamlessly passes to billing

50%

Not Found

- 29% of data needed found by research
- 21% of needed product data not found nor recorded for billing or the patient record

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Leveraging External and Internal Data Sources

…And Standard and Organization-Specific Data

CLIN|IM|13839142|6f2aeee2fd3b8d26de27616cf2f4d0d2|02.210.158|10886982053220|SCREW BONE STAINLESS STEEL L58 MM OD2.4 MM FOREFOOT MIDFOOT STARDRIVE SELF TAPPING LOCKING VARIABLE ANGLE NONSTERILE|SCREW||42321506|Bone screws||Y|1|C1713|0278|27801713|Y|0000.00|EA|DEPUY SYNTHES - A JOHNSON & JOHNSON CO|02.210.158|US|4462|A|2018-01-23 00:59:29.50861|101010411

- Provider Item Code
- Primary DI
- Description
- UNSPSC
- HCPCS
- Unit Price

  Revenue Code | Charge Code | Billable Flag
- Supplier Part Number for ordering

Manufacturer provided descriptions fall short of what clinicians and supply chain need.

Manufacturer provided description in AccessGUDID):
AccessGUDID Description = 2.4MM VA LCKNG SCREW SLF-TPNG WITH STARDRIVE RECESS 58MM

It's What's Behind the Barcode that Matters

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Challenge:

- $3-5 million in unbillable OR usage/yr. due to missing supply data

Solution:

- EHR System does real time call to virtual item master for product data
- >98 percent of products scans link to detailed data in virtual item master
- Helps provide access to data on products purchased, consumed, price paid, amount charged, reimbursement, outcomes and variation

How will I get there?
By train? By plane? By car?
Do I have a ticket?
A car that can make the trip?

How will I pay for it?

Do I have a passport?
Do I have a place to stay when I get there?
Is it safe?
Can I speak the language?
Do I have what I need to take with me?

Travel Plans

Supply Chain Can Help!

Value to Multiple Stakeholders

- Less paperwork
- Less time looking for, counting supplies

- Visibility to which products improve quality *AND* cost and for which patients

- Confidence that she knows they can find her if there is a recall.

- Understand costs of care
- Ensure accurate billing
- Optimize reimbursement

- Real world evidence (RWE) to:
  - Better market and design products
  - Achieve faster regulatory approvals
  - Improved customer business relationships

UDI at the Annual AHRMM Conference

Monday, August 13

11:00 a.m. to 12:00 p.m. - Defective Product Recalls are Now Overwhelming – the Potential Impact of UDI

1:30 p.m. to 2:30 p.m. - Everyone has a stake in a successful UDI implementation

Tuesday, August 14

1:00 p.m. to 2:00 p.m. - Manufacturers are from Jupiter; Providers from Saturn: Understanding each other's world to make UDI work

2:30 p.m. to 3:30 p.m. - Tracking UDI on Hospital-Sterilized and Manufacturer-Packaged Implants During Surgery

4:00 p.m. to 5:00 p.m. - Forward Deployed Inventory

Wednesday, August 15

8:00 a.m. to 9:00 a.m. - UDI: Finding Value in the Real World

9:30 a.m. to 10:30 a.m. - Where Do I Begin? Building a UDI Implementation Roadmap

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Your Turn!

Thank you…

For future questions, comments or to continue the discussion:

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