RFID JOURNAL LIVE!

MAY 9-11, 2023 | ORLANDO, FLORIDA

UDI Around the World

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Why is AIM Relevant to You?

AIM is the global authority that links physical, digital and regulatory worlds!

We are the unbiased and trusted global authority for technologies that automate accurate data capture and efficiency.

We provide a vehicle for global standardization adoption and scale.

We link standardized & emerging technologies to work interoperable to suppliers, manufacturers, services providers, and users.

- We verify compliance and harmonization.
- We impact digital identification and authentication regulations.
- We develop standards.
- We provide guidance and technology insight.

Through this we enable sustainable, efficient, safe, resilient, and accurate data.

Education** · **Advocacy** · **Standards** · **Community

There's Strength in Numbers

- AIM is an unbiased, global organization
- Network with like-minded individuals
- Influence the industry
- Committees to solve industry issues

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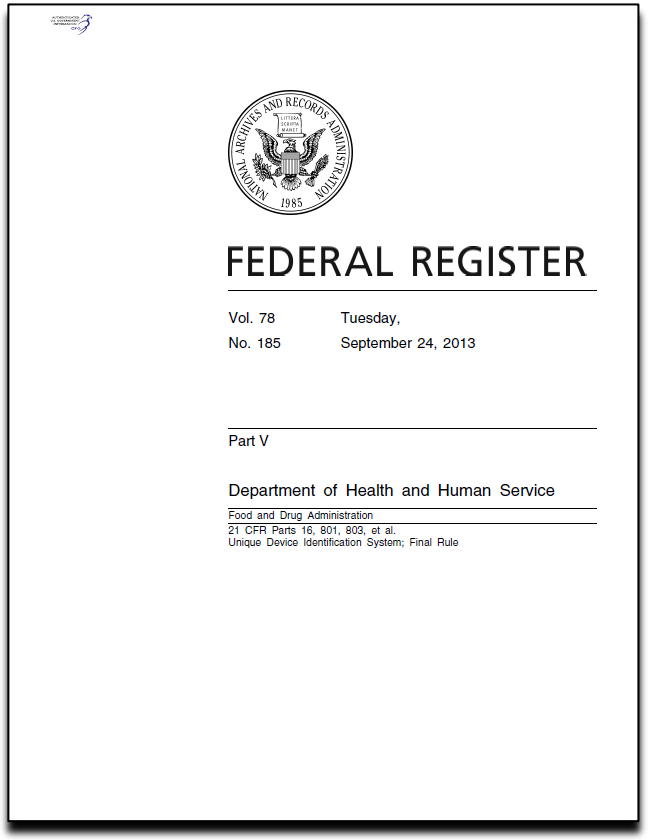
UDI 10th Anniversary: September 2023



FEDERAL REGISTER

Vol. 78 Tuesday,
No. 185 September 24, 2013

Part V

Department of Health and Human Service

Food and Drug Administration
21 CFR Parts 16, 801, 803, et al.
Unique Device Identification System; Final Rule

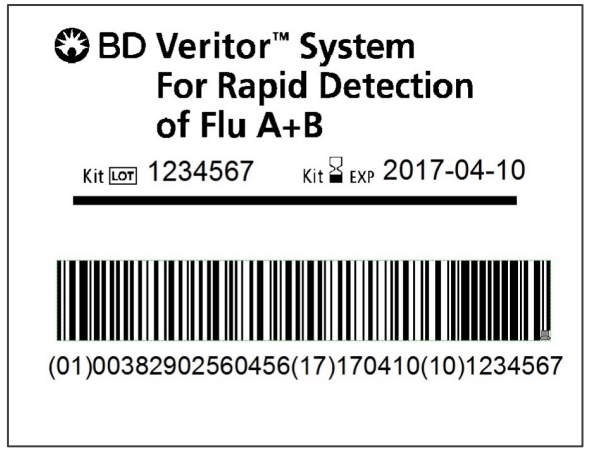
The views expressed/presented are that of the individual speaker and do not necessarily represent the views of the speakers' respective company.

UDI: Key Components

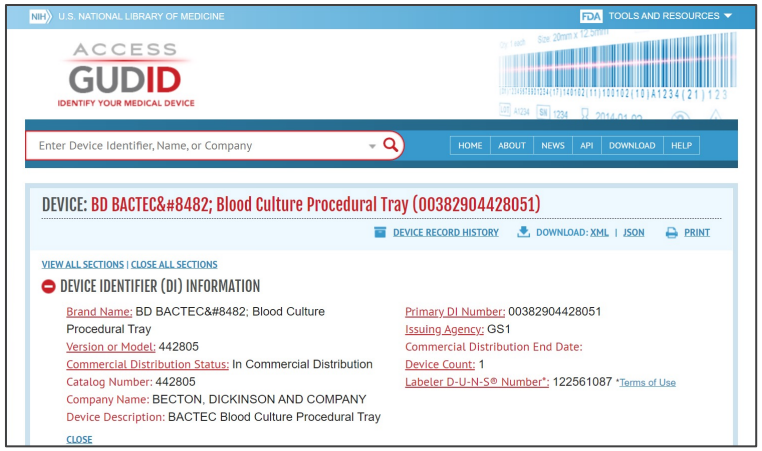
UDI Device Identifier

UDI-DI = 00382902560456

UDI Bar Code



UDI Data



*Definitions of UDI and the specific requirements vary by jurisdiction.

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Key UDI Implementation Steps

1

Device Identification

- Select an Issuing Agency
- Assigning UDI-DI
- Identifying UDI-PI

2

Placing UDI-DI and UDI-PI on Bar Codes

- Place UDI-DI and UDI-PI on labels
- Place UDI-DI and UDI-PI directly on the product (when applicable)

3

UDI Data

- Create, Gather, & Scrub Data
- Share Data with Regulator
- Maintain Data

4

Add UDI to Applicable Processes

- Complaints
- Track & Trace
- Quality Process
- Commercial
- Supply Chain
- Surveillance

5

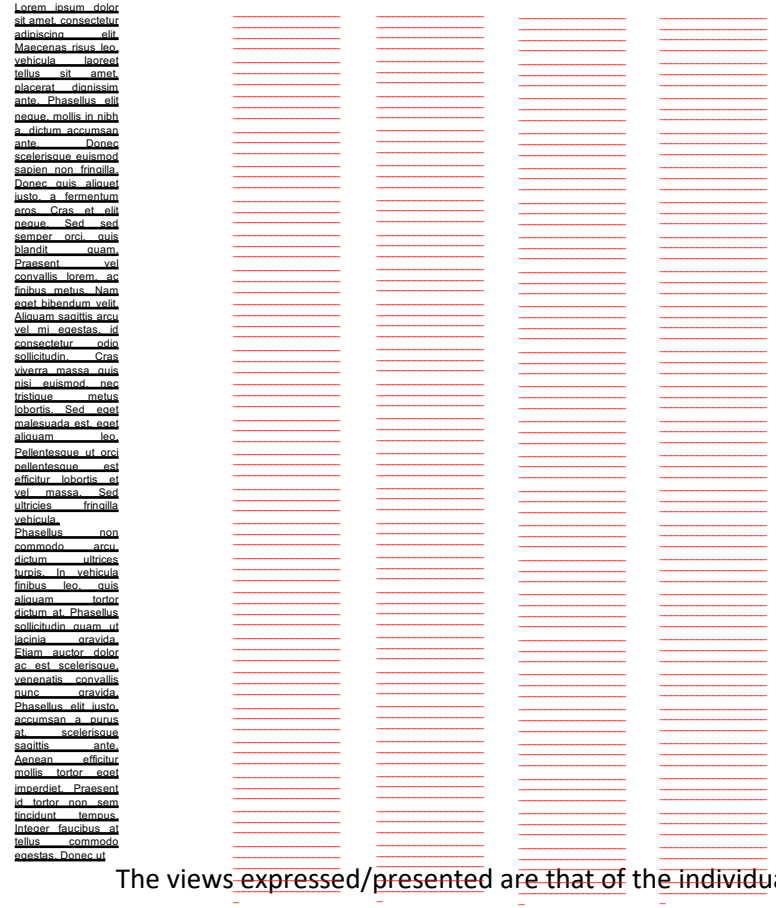
Maintain

- Updates to Data
- DI Triggers
- Policies
- SOPs
- Bar Code Formats

UDI Data Attributes: Requires Investment

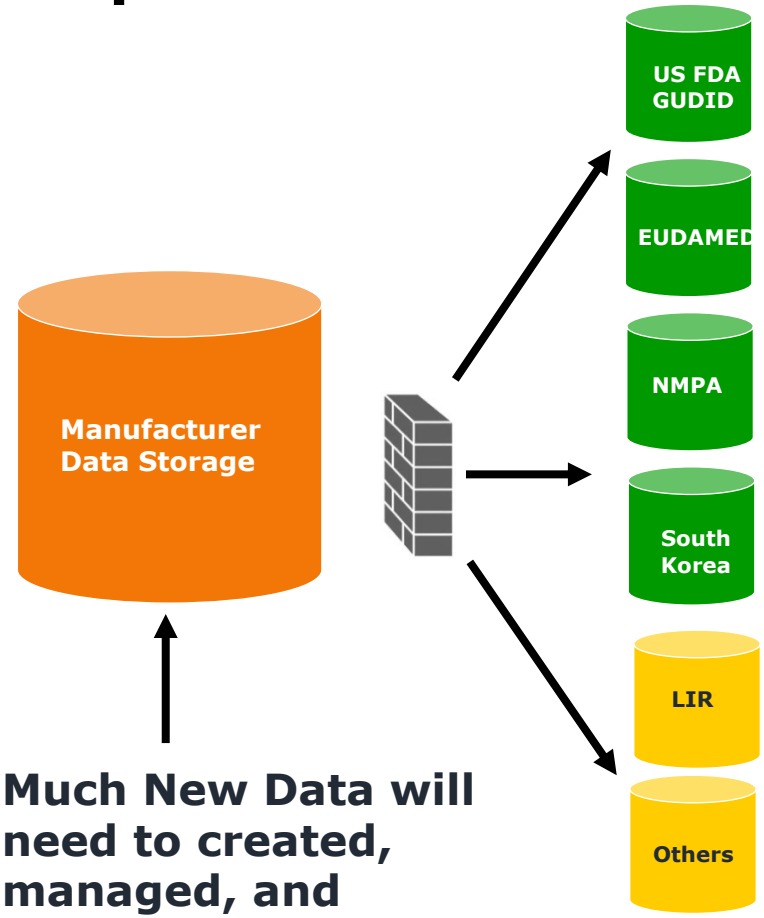
Current State: ~150 Data Fields

Future State: 400+ Data Fields for each global product.



Current Location

- Paper Files
- ERP
- Tech Files
- E-Catalog
- WMS
- Product Labels
- Other
- Other
- Other
- Other



Much New Data will need to created, managed, and distributed.

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Maintenance Example: UDI-DI Triggers

"DI Triggers" Include:

- New Brand Name
- New Version or Model #
- Change in Device Count
- Change from GS1
- Primary DI
- Kit Status
- Combination Product
- Single-Use
- Latex
- MRI Safety Information
- Packaged as Sterile
- Clinical Size
- Critical Warnings/Contraindications
- CMR/Endocrine disruptors
- Change in color coding
- Removal language
- Basic UDI-DI
- Risk Class in Europe
- Change in SRN
- Certifications such as CE Mark

=

Result

New Device Identifier (GTIN)
Modify DHF, ERP, and other records
Label Change
Product Conversion

Business Impact

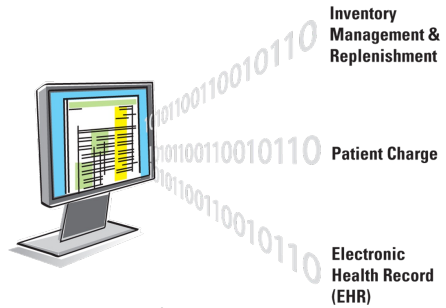
Labeling Costs
Notify Customers, Distributors, etc.
Change Contracts
Segregate and Manage Inventory
Alert Chargeback Process
Price File Notification Update
Re-Registration for some countries

Customer Impact

Change Item Master
Segregate and manage inventory
Revise Ordering Process
Clinician Communication
Patient HER

Clinician Impact

Learn new numbers
Manage Multiple Device Identifiers
Manage Registries (where applicable)



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Current and Future UDI Requirements

Existing UDI Regulations

- US FDA
- EU
- China
- Chinese Taipei
- South Korea
- Japan
- Singapore
- Saudi Arabia
- Egypt
- Brazil
- Turkey (UTS)
- Argentina (limited in scope)

Future Regulations Include:

- Australia
- Canada
- UK
- Switzerland
- Colombia
- El Salvador
- Ecuador
- Ghana

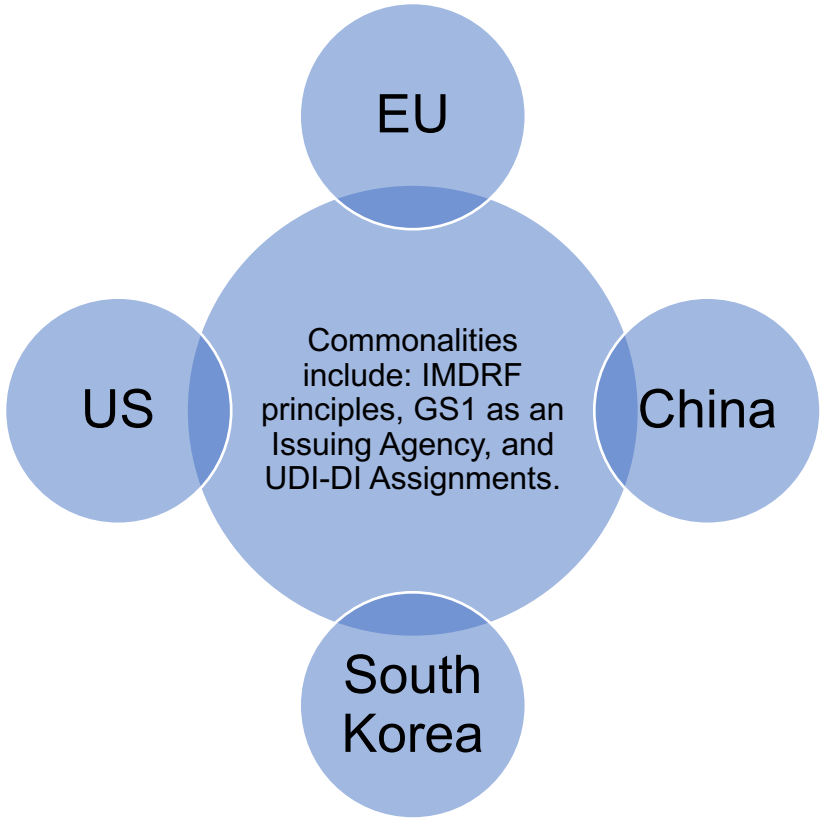
Market Requirements* Include:

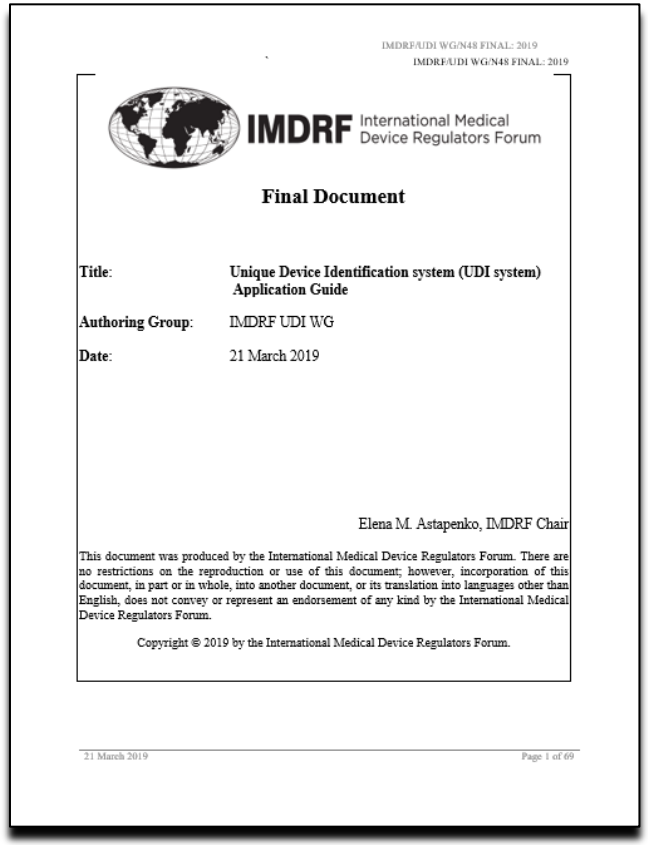
- Netherlands LIR
- PEPFAR USAID
- Cleveland Clinic UAE
- Australian National Catalog
- UNICEF
- WHO

*Market requirements may not impact all device manufacturers.

Many Common UDI Requirements

- Regulators have attempted to harmonize their requirements with the rest of the world and have agreed on several concepts including:
  - IMDRF Principles
  - GS1 as an Issuing Agency (HIBCC, ICCBBA, IFA,
  - UDI-DI assignment logic
  - Expectations on following ISO/IEC standards




IMDRF/UDI WG/N48 FINAL: 2019

IMDRF International Medical Device Regulators Forum

Final Document

Title: Unique Device Identification system (UDI system) Application Guide

Authoring Group: IMDRF UDI WG

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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Not all UDI Regulations are the same!

Differences Include:

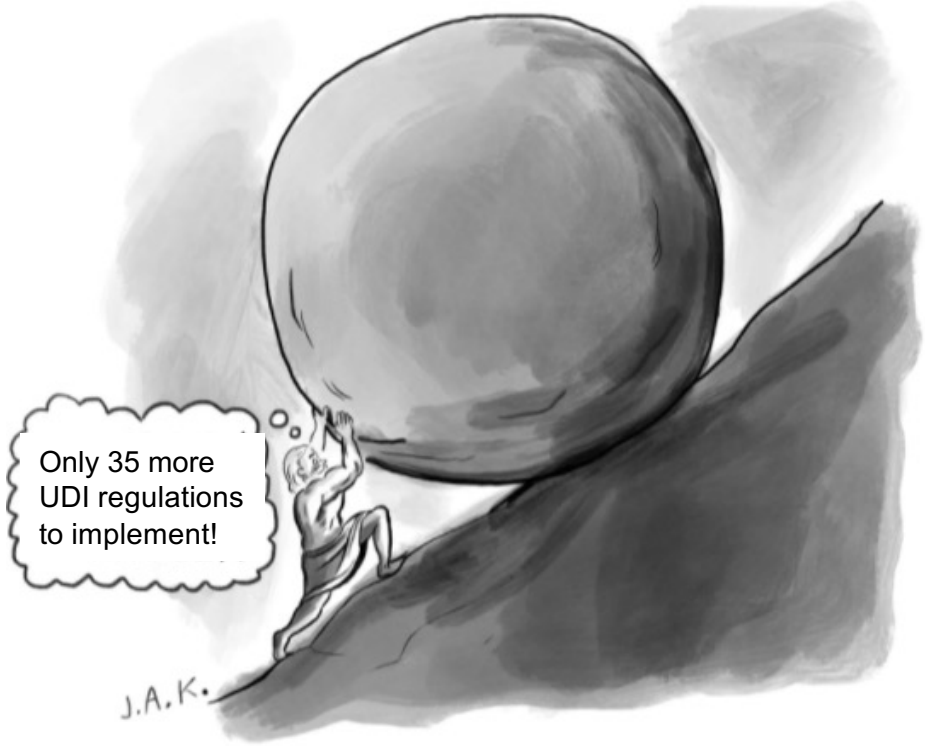
- UDI Labeling Requirements
- Data Requirements
- Exceptions
- UDI-DI Triggers
- Required use of UDI in various regulatory and clinical processes
- Entity Responsible for UDI: Labeler, (legal) Manufacturer, Market Authorization Holder or Sponsor

Also:

- The underling regulatory construct in each country and the varying definitions between Kits, Implants, IVDs, Procedure Packs, Product Risk Class, etc., by market will cause further differences in requirements.

Challenges Related to Non-Harmonized UDI Regulations

1) Disparate UDI Marking Requirements
2) Different UDI Carrier (Bar Code) Requirements
3) Different UDI Data Definitions: Same Attribute
4) Different List Values: (Clinically Relevant Size)
5) Non-Harmonized Data Requirements
6) Excessive UDI-DI Triggers
7) Lack of Clarity on Requirements



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Key Differences: EU & US Regulation

1)	**Basic UDI:**	US	US has no such concept
		EU	EU requires Basic UDI as a key component
2)	**Date Format:**	US	US date format is YYYY-MM-DD
		EU	EU does not require DD
3)	**Existing Inventory:**	US	US allows time to use existing inventory
		EU	EU does not
4)	**Responsibility for UDI:**	US	US Labeler
		EU	EU Manufacturer
5)	**SUD Packaging Exception:**	US	US Exception is for all product risk classes
		EU	EU is limited to I/IIa (Class A/B)
6)	**DPM Marking:**	US	AIDC or Human readable is sufficient
		EU	EU UDI must be both AIDC and HRI
7)	**DPM "High Level Disinfection":**	US	US makes a distinction with "high level disinfection"
		EU	EU does not differentiate with cleaning requirements
8)	**Software:**	US	Provides latitude on package and software
		EU	UDI for package and software must be the same
9)	**Class I Devices:**	US	Allows for UDI-DI only
		EU	Requires both UDI-DI and UDI-PI

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Key Differences: Data Requirements

This is an example of an attribute (Primary DI) with the same name, but a different definition.

1) **US Definition:** The Primary Device Identifier (DI) is the DI portion of the UDI placed on the lowest package level of a device that is required to meet UDI label requirements. If the device is not packaged, the UDI may be on the device itself, thereby satisfying both the UDI label and the direct mark (DM) requirement if the UDI is intended to be permanent. The Primary DI is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use.

2) **China Definition:** The UDI - DI of the lowest salable unit.

Key Differences: Data List Values

We have different List Values for some data attributes. Example: Sterilization Method

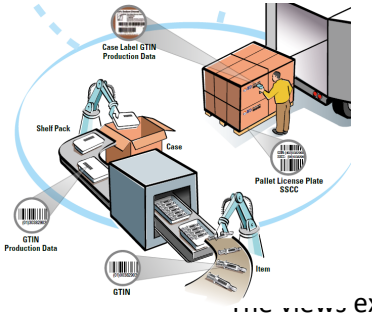
China	S. Korea	USA
Cobalt-60 Gamma Radiation Sterilization	Chloride dioxide Sterilization	Chlorine Dioxide (ClO2) Sterilization
Cobalt-60 Radiation Sterilization	Cold Fluid Sterilization	Dry Heat Sterilization
Dry heat sterilization	Dry Heat Sterilization	Ethylene Oxide Sterilization
Electron beam Irradiation Sterilization	EO gas	High Intensity Light or Pulse Light Sterilization
Ethylene Oxide Sterilization	Etc.	High-level Disinfectant Sterilization
Gamma Radiation Sterilization/ γ ray Sterilization	Formaldehyde gas	Hydrogen Peroxide (H2O2) Sterilization
Moist Heat Sterilization	Microwave Sterilization	Liquid Chemical Sterilization
Non-sterile	Plasma Sterilization	Microwave Radiation Sterilization
Radiation Sterilization		Moist Heat or Steam Sterilization
Steam Sterilization		Nitrogen Dioxide Sterilization
		Ozone (O3) Sterilization
		Peracetic Acid Sterilization
		Radiation Sterilization
		Sound Waves Sterilization
		Sterilization Method
		Supercritical Carbon Dioxide Sterilization
		Ultraviolet Light Sterilization

UDI Impact on the Healthcare Eco-System

Governments
-Product Safety
-Identify Imports

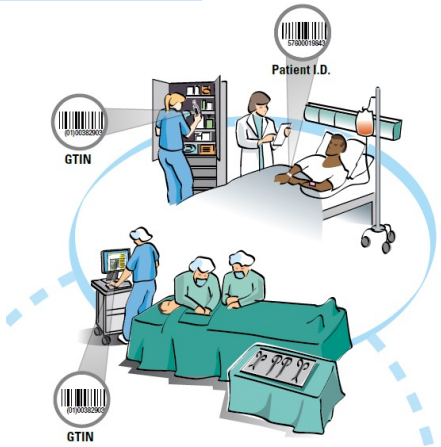
Regulators
-Product Recalls
-Safety & Surveillance
-Counterfeiting
-Enforce Product Registration

Customs
-Reduce Counterfeiting
-Tariff Enforcement



Healthcare Providers
-Cost/Quality/Outcomes
-Product Utilization
-Patient Safety
-Recall Effectiveness
-Supply Chain Efficiency

Clinicians
-Product Research
-Point-of-Care Tracking
-Product/Company Info.
-Substitutes



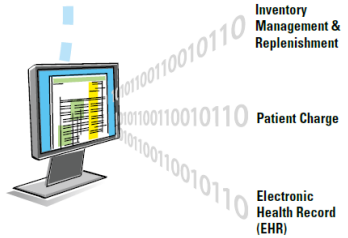
Patients
-Product Research
-Recall Effectiveness
-Product Safety

Payors
-Reduce Fraud
-Cost/Quality/Outcomes
-Reimbursement

Researchers
-Outcomes Analysis
-Implant Registries

Distributors
-Transactional Efficiency
-Managing Inventory
-Supply Chain Effectiveness

GPOs
-Price Comparison
-General Analysis



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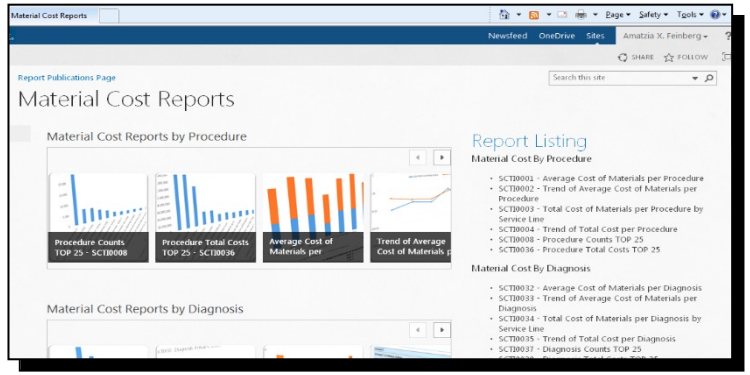
Value Proposition for UDI Include:

1) **Recalls:** Preventing use of recalled products. Enhancing surveillance opportunities.
2) **Supply Chain:** Tracking use of Product, Lot Numbers, and Expiry.
3) **Point-of-Care Scanning:** Ensuring correct product is utilized or storing data in EHR.
4) **Comparative Effectiveness Research:** Studying product and/or treatment outcomes.
5) **Comparing Clinicians:** Associating products with patient care.
6) **Reimbursement:** UDI may become a payor reimbursement requirement.
7) **Anti-Counterfeiting:** UDI may enable additional preventative measures.
8) **Commerce:** Improving accuracy in transactional, analytical, and contractual processes.



Kaiser Permanente Example

Examples of Clinical Integration of UDI

- Hospital adoption of UDI in the US
- EU Class III Implants
- Dutch Implant Registry: Landelijk Implantatenregister (LIR)
- Australia National Product Catalog

Ministerie van Volksgezondheid, Welzijn en Sport

Factsheet

Landelijk Implantatenregister voor zorgverleners en -aanbieders

Inleiding

Vanaf 1 januari 2019 is een wijziging van de Wet kwaliteit, klachten en geschillen zorg (Wkkgz) van kracht. Deze wetswijziging regelt de totstandkoming van het Landelijk ImplantatenRegister (LIR). Dat register is bedoeld om de patiëntveiligheid te verbeteren. Daarom wordt wettelijk verplicht om bepaalde gegevens over het implantaat vast te leggen in het medisch dossier van de patiënt bij wie het implantaat is ingebracht. Deze gegevens moeten daarna aangeleverd worden aan het LIR.

Het LIR is uitsluitend toegankelijk voor de Inspectie Gezondheidszorg en Jeugd in oprichting (IGJ i.o.). Als de IGJ een signaal krijgt over een veiligheidsrisico rond een bepaald implantaat, biedt het LIR voor de IGJ inzicht in het aantal betrokken patiënten en daarmee in de gevolgen voor de Nederlandse gezondheidszorg en de patiëntveiligheid. Vervolgens kunnen zorgaanbieders en, door tussenkomst van deze, patiënten geïnformeerd worden over gesignaleerde problemen met de ingebrachte implantaten. In het LIR worden geen persoonsgegevens van patiënten geregistreerd.

In het wetsvoorstel worden vier zaken geregeld:

- de minister van VWS moet het implantatenregister in stand houden;
- de zorgverlener is verplicht om een implantatie te melden in het patiëntendossier op een wijze die traceerbaarheid van het implantaat mogelijk maakt;
- de zorgaanbieder is verplicht om de gegevens over de implantatie aan te leveren aan het implantatenregister;
- de zorgverlener is verplicht om aan de betrokken patiënt de gegevens over het geïmplanteerde hulpmiddel schriftelijk te verstrekken.

Complex traject

De implementatie is een veelomvattend traject en de impact is sterk afhankelijk van de uitgangssituatie. Dit komt ten eerste, omdat meerdere afdelingen en verschillend personeel binnen de organisatie van een zorgaanbieder ermee te maken kunnen hebben. Zo moeten ICT-systemen worden geïntegreerd of aangepast en moet een logistieke procedure en/of werkafspraken worden gemaakt, waarmee door de gehele instelling implantaten kunnen worden getraceerdmet eenduidige codering.

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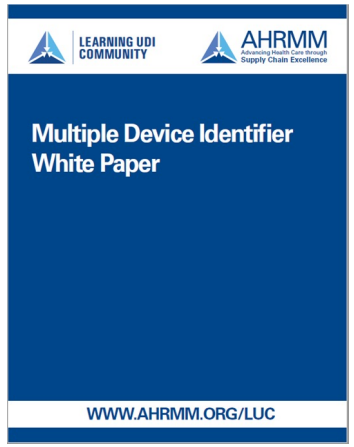
UDI-DI Trigger Impact for Providers

- Some Healthcare Providers have expressed their frustration with UDI-DI changes due to DI Triggers.
- Complaints have been received of “Same product” with two different UDI DI numbers.
- Perceptions of UDI-DI instability during UDI-DI transitions has led to:
  - Challenges in MMIS and Supply Chain processes
  - Vagueness in Electronic Health Record
  - Conversion tables or explanations required for Comparative Effectiveness Research
  - Risk of product tracking errors
  - Barriers to the adoption of POC scanning
- Conversion tables or explanations required for Comparative Effectiveness Research
- Risk of product tracking errors
- Barrier to the adoption of POC scanning



https://www.ahrmm.org/system/files/media/file/2019/12/multiple-device-identifier-work-group-report-031919.pdf

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UDI and RFID

- **US FDA:** Does not specify AIDC Technology*
- **EU:** “If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.”
- **Saudi Arabia:** “If the manufacturer is using RFID technology, a linear or 2D barcode or another type of barcode shall also be provided on the label.”

*Unique Device Identifier System: Frequently Asked Questions, Vol. 1 Guidance for Industry and Food and Drug Administration Staff. Document issued on August 20, 2014.

The AIDC version facilitates rapid and accurate identification of the device, particularly by the device user, and should be obvious to the user. While the presence of a bar code on the UDI label is visible and therefore immediately obvious, the presence of other AIDC technologies, such as RFID and near-field communication, may not be so obvious to the device user. Therefore, if the AIDC technology is not visible on the label of the device or on the device package, the device label or on the device package must provide notice of the presence of AIDC technology. No particular method for providing this notice is specified.

Implementation Guideline for RFID in Healthcare Manufacturing

- Foundational document for use of RFID in Healthcare
- Informs manufacturers how to encode GS1 EPC-enabled RFID tags for automatic data capture
- Suggests aligning RFID data with existing data
- RFID as a Secondary Data Carrier
- Further alignment with regulations would be ideal

https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Implementation-Guideline-for-RFID-in-Healthcare-Manufacturing.pdf

Questions or Comments

THANK YOU

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