Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification
Webinar #3 – 17 August 2021

Challenges and considerations on the journey to a global UDI system

Michelle van Wijk

UDI Project Manager
Therapeutic Goods Administration

17 August 2021

TGA Health Safety Regulation

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Today's presentation

Guest speaker – Dennis Black from Becton Dickinson

Progress update

Demonstration – 'sandpit' Australian UDI database

Questions and answers

Guest presenter – Dennis Black

UDI Program Director - Global Regulatory Affairs, Becton Dickinson

- Global manufacturer perspective on UDI
- Experience in designing and implementing UDI in multiple countries, including the USA and EU
- Deeply involved with the US Association for Health Care Resources and Materials Management (AHRMM) Learning UDI Community, and other committees and boards
- Involved in UDI pilots and projects in hospitals
- Author and co-author of numerous papers

We are a leading global medical technology company uniquely positioned to improve both the treatment of disease and the process of care.

- Global position: One of the top 5 medical technology companies in the world with ~$17 billion annual revenues
- Founded in 1897: A legacy of health impact
- Global reach: Serving 190+ countries
- Employees: 70,000+
- Annual investment in innovation: $1+ billion

BD

Challenges and Considerations on the Journey to a Global UDI System

- UDI Benefits
- Vison of globally harmonized UDI requirements
- How suppliers are organizing and investing to implement UDI
- Challenges related to non-harmonized UDI regulations
- Aligning UDI regulations with Clinical & Supply Chain needs
- UDI User Group: AHRMM Learning UDI Community
- What does UDI Success look like from a Manufacturer's perspective?

Benefits of using Data Standards

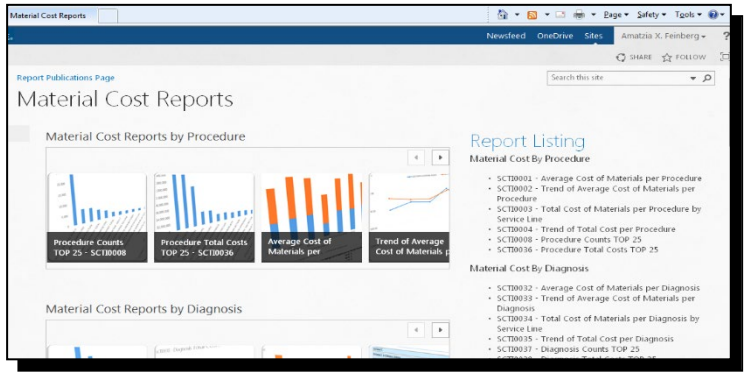
Supply Chain Benefits Include:

- Accurate Shipments
- Supply Chain Efficiency
- Product Tracking
- Common Business Language

BD began using GS1 Standards to enhance our supply chain processes over two decades ago. Extracting additional value from UDI will require greater adoption by Healthcare Providers and Distributors.

Value Propositions 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.



Courtesy of Kaiser Permanente.

The UDI Value Proposition may vary by user.

Successful UDI Implementation: Mercy Health

Clinical Integration of UDI:

- Identified the systems ability to improve inventory management and tracking supplies
- Benefits cited included:
  - Preventing procedure delays,
  - Lowering costs,
  - Increasing revenue
  - Determining system is extensible to all implanted device

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Case Reports

The Mercy unique device identifier demonstration project: Implementing point of use product identification in the cardiac catheterization laboratories of a regional health system

Joseph P. Drozda Jr.*, Curtis Dudley, Paul Helmering, James Roach, Lisa Hutchison

Mercy Health

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ABSTRACT

Mercy, a 4 state health system, conducted an FDA-sponsored demonstration whereby prototype unique device identifiers (UDIs) of coronary stents were implemented in its electronic information systems for safety surveillance and research. To accomplish this, a multi-disciplinary team implemented a point of use barcode scanning inventory management system in all 5 Mercy cardiac catheterization laboratories. The system's potential for improving inventory management and tracking Cath Lab supplies was felt to be sufficiently compelling for system deployment outside of the context of the demonstration. Further, it was felt to be useful for all Cath Lab renewable supplies and not just coronary stents. Benefits included preventing procedure delays, lowering costs, and increasing revenue. Finally, the system is extensible to all implanted medical devices and generalizable to most hospitals.

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1. Background

Implanted medical devices are arguably among the most important and effective health care advances of the last 50 years. Artificial joints have relieved pain and prevented disability; implanted cardioverter defibrillators have saved lives; and coronary stents have relieved pain and revolutionized the care of patients with acute myocardial infarction. At the same time implanted devices are not without their downsides as evidenced by the widely publicized failures of Riata implantable cardioverter defibrillator leads and metal-on-metal hip implants [1,2]. In 2011 the Institute of Medicine called for significant improvements in the medical device approval process and in post-market safety surveillance [3]. The United States Food and Drug Administration (FDA) published its strategy for strengthening post-market surveillance of medical devices in 2012 [4] and followed that report with an update in 2013 [5].

The FDA's strategy is composed of 4 parts; establish a unique device identification (UDI) system; promote device registries for selected products; modernize adverse event reporting; and develop new methods for generating, synthesizing, and analyzing evidence. In 2013, the FDA published the final rule that establishes the UDI system and that calls for UDIs on all Class III (high risk) devices effective September 24, 2014 [6]. The FDA is working on the other aims by means of public/private partnerships under the umbrella of the Medical Device Epidemiology Network (MDEpiNet) [7]. MDEpiNet has established the National Postmarket Surveillance System. Planning Board under the leadership of the Brookings Institution [8] and the Medical Device National Registry Task Force through the MDEpiNet coordinating center at the Duke Clinical Research Institute [9]. The MDEpiNet Infrastructure Center at Weill Cornell Medical College has already implemented an approach to registries through the International Consortium of Orthopaedic Registries [10] and the International Consortium of Cardiovascular Registries [11]. The MDEpiNet Methodology Center in the Department of Healthcare Policy at Harvard Medical School is leading the effort to develop the new methodologies for analyzing device data emanating from a variety of sources [7].

MDEpiNet's work extends beyond safety surveillance and includes the creation of a conceptual framework for comparative effectiveness research involving medical treatments and devices that will analyze patient outcomes and develop novel study designs and analytic methods for both pre-market and post-market assessment of medical devices in support of FDA regulatory decision making. This strategy will also serve patients and healthcare providers by providing information on device performance necessary for therapeutic decision making and by answering basic questions regarding device value.

In 2012, Mercy contracted with the MDEpiNet Methodology Center to perform a Demonstration Project whereby UDIs would be incorporated into its electronic information systems with coronary stents being chosen as the medical device exemplar for the

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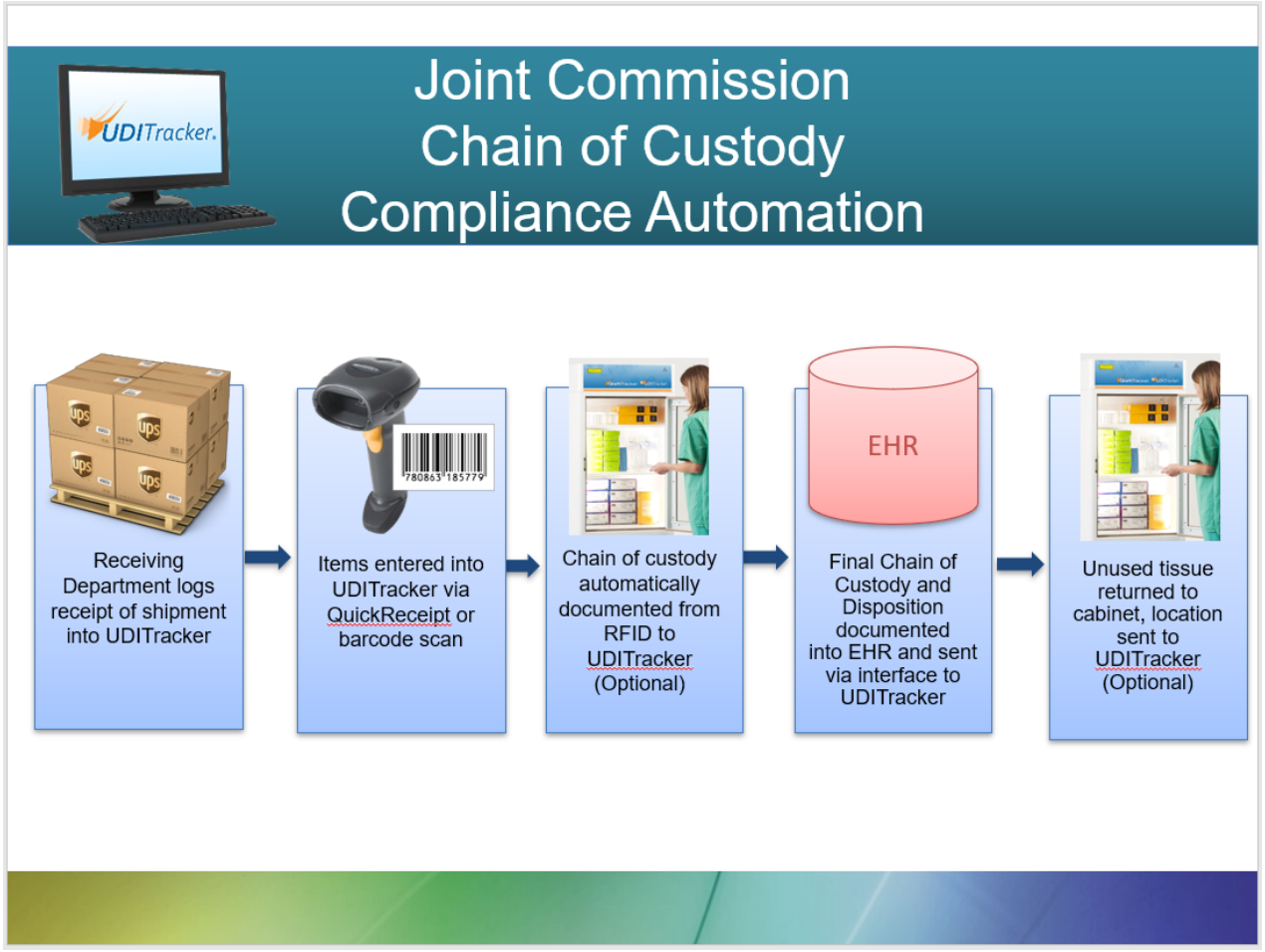
Mercy has published articles on their use of UDI for clinical purposes.

Successful UDI Implementation: FMOL



Courtesy of Sandi Michel, FMOL

FMOL has leveraged UDI for Joint Commission Chain of Custody Compliance Automation and other purposes.

High Spots: Regulator/Industry Engagement on UDI

Rule Making Period

- Industry outreach and engagement
- Leverage existing efforts
- Recognition of existing regulations
- Alignment with Issuing Agencies (expectation of training, support, etc.)

Implementation

- Clarity on Data Definitions
- Machine-to-Machine Data upload
- Help Desk Support
- Data error “amnesty” versus locked fields (with the expectation that data changes can be viewed)
- IT Solution Provider enablement
- Usage requirements (an example is the EU requirement for Class 3 Products)
- Guidance documents, updates, and exceptions as needed

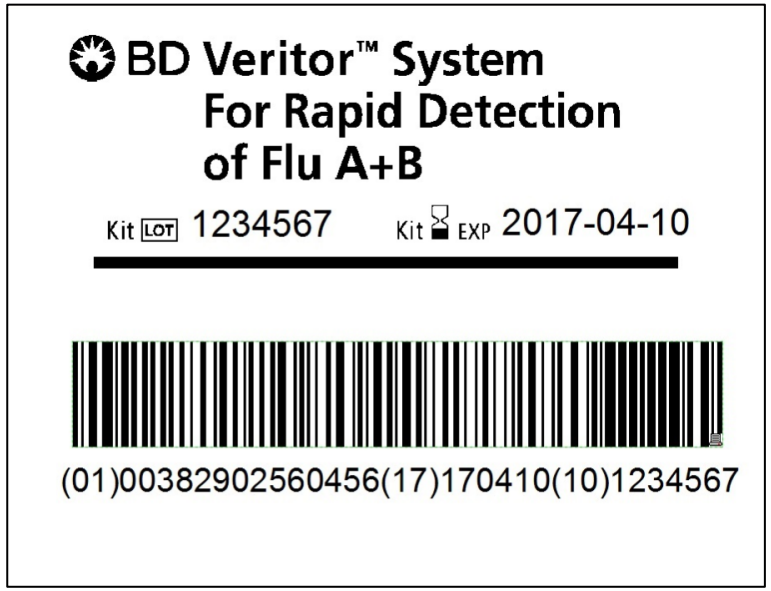
Post Implementation

- Post Rule Community Engagement

UDI: More than Device Identifiers and Bar Codes

UDI-DI = 00382902560456

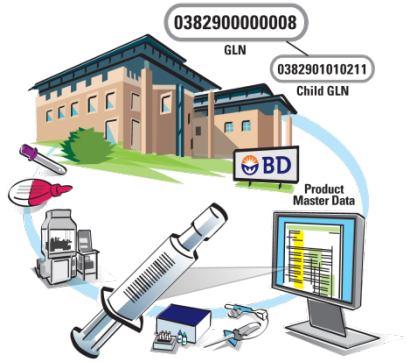
UDI Device Identifier



UDI Bar Code

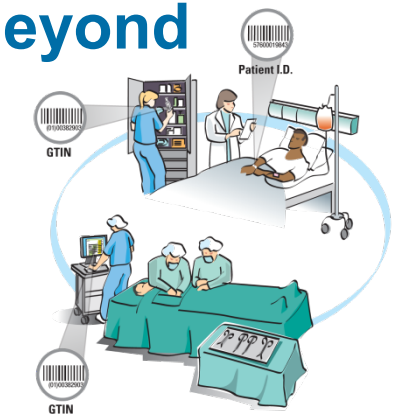
UDI: More than Bar Codes and Device Identifiers

Product Design



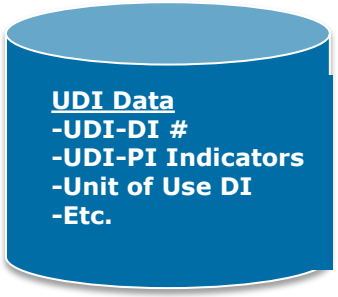
- Device Identification
- Placing UDI on device and/or label
- UDI Data Creation & Publication
- Add to Applicable Processes
- Maintain System

Product Usage & Beyond



Vision of Globally Harmonized UDI Requirements

- One label and one set of data used globally*



**Supplemental labeling additions and some country-specific data may be necessary to comply.*

UDI Data Attributes: Growing Demand with each Regulation

Current State: ~125 Data Fields

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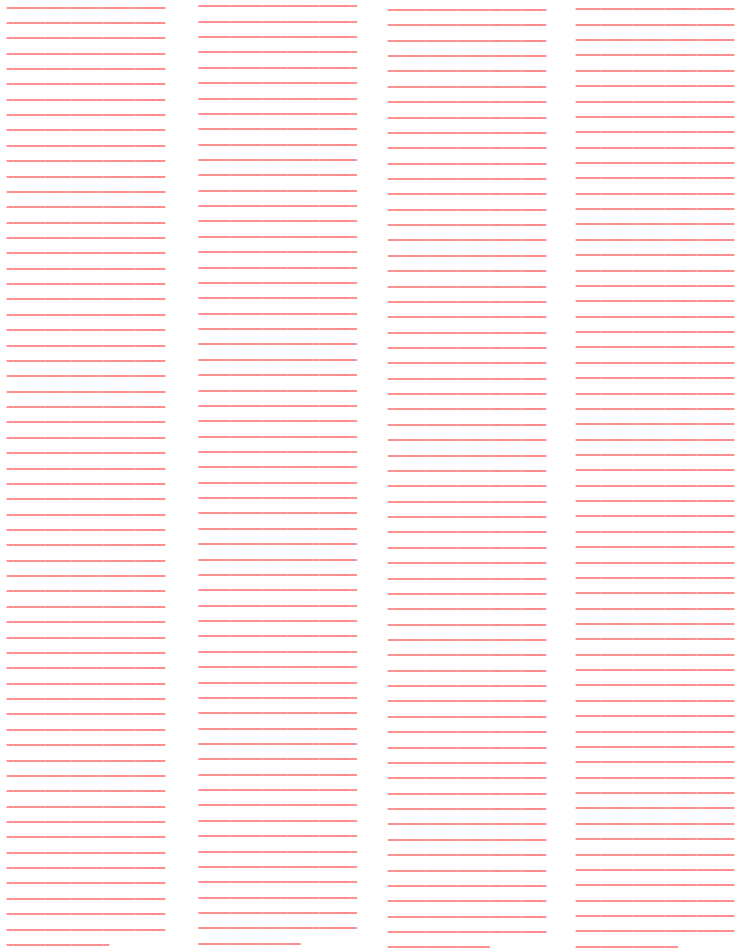
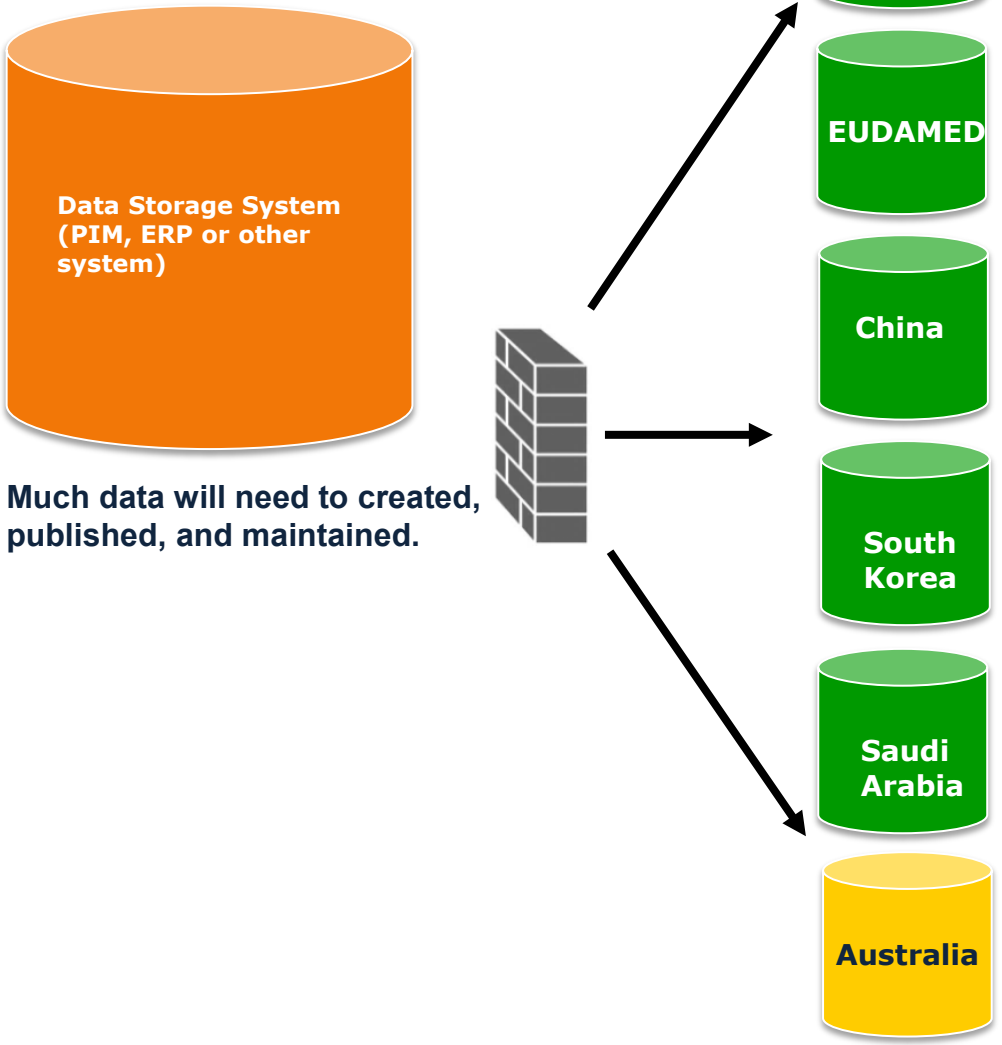
Future State: 400+ Data Fields for each device sold globally.



Current Location

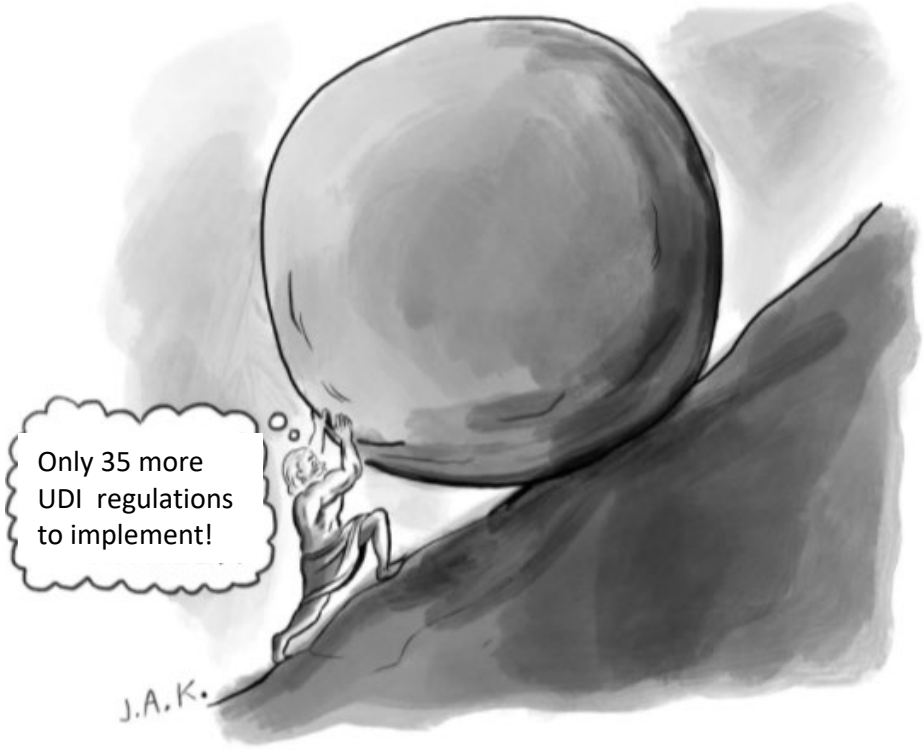
- Paper Files
- ERP
- Tech Files
- E-Catalog
- WMS
- Product Labels
- TrackWise
- Other
- Other
- Other



Much data will need to created, published, and maintained.

Challenges Related to Non-Harmonized UDI Regulations

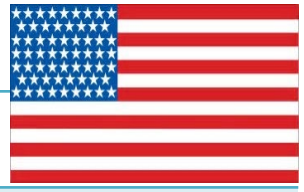
1) Disparate UDI Marking Requirements
2) Different UDI Carrier (Bar Code) Requirements
3) Different UDI Data Definitions: Same Attribute
4) Different List Values: (Clinically Relevant Size)
5) Non-Harmonized Data Requirements
6) Excessive UDI-DI Triggers
7) Lack of Clarity on Requirements



UDI Comparison

	EU Medical Device Regulation	US FDA UDI Regulation
Devices in Scope for UDI	All Medical Devices, with the exception of custom or investigational. Contact lenses are in scope immediately.	All Medical Devices, with the exception of custom or investigational. Contact lenses are in scope but on hold indefinitely.
Label Requirements	UDI will include a device identifier (DI) and a product identifier (PI), e.g., serial numbers, lot/batch numbers, manufacturing and/or expiration dates.	UDI includes a device identifier (DI) and a product identifier (P), e.g., serial numbers, lot/batch numbers, manufacturing and/or expiration dates.
Classes	Applies to all classes of medical devices	Applies to all classes of medical devices
Data Submission Required?	YES – EUDAMED will make core data about the products accessible at no charge to the public and enable uploads and downloads of data. The database will support languages required by the European Union member states where the product is sold.	YES – GUDID will make core data about the products accessible at no charge to the public and enable uploads and downloads of data.
Storage of UDI for Class III devices	MDR includes requirements that health institutions store, ideally electronically, the full UDIs (device and production identifiers) for all Class III implantable devices that they have received.	
Basic UDI-DI	Non-transactional data element in EUDAMED. Used for regulatory purposes as a bridge between the different databases.	Not part of the US Regulation.

UDI Comparison (2)



	EU Medical Device Regulation	US FDA UDI Regulation
Exempt Devices	• Custom devices • Investigational devices For single-use devices of classes I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging, e.g. a carton containing several individually packaged devices. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging of the individual device. Devices for other than human use (e.g., veterinary devices) Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself. Exemptions: (a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier; (b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.	• Custom device within the meaning of CFR 812.3(b), • Investigational device within the meaning of CFR 812, • 3-year existing inventory, • GMP-exempt Class I devices, • Devices intended for export, • Clinical/research/teaching/chemical analysis, • Individual single-use devices, distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution or sale, • Veterinary device, • Device within a combination product or a convenience kit, • Device held by the Strategic National Stockpile and granted an exception, • FDA exception in a performance standard

UDI Comparison (3)

	EU Medical Device Regulation	US FDA UDI Regulation
Label space constraints:	• Space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level • AIDC (professional use) • HRI (home use)	No exceptions; can request exception per 21 CFR 801.55
Software:	Software identification = manufacturing control mechanism	Lot/Batch PI= Software Version
Label UDI-PI	If a lot number, serial number, **software identification** or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.	A lot or batch number, a serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by 1271.290(c) of this chapter. (May request an exception.)
Other Information in Data Carrier	UDI data carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data	FDA *Draft* Guidance on Form and Content* (2016) – FDA recommends UDI information should precede any non-UDI elements. *has not been finalized
UDI Updates	EUDAMED updates to existing UDI records: within 30 days of a change being made to an element, which does not require a new UDI-DI. New devices must be registered prior to placing the product on the market.	US GUDID updates to existing UDI records: within 10 business days of the change if the information does not appear on label; no later than the date a device is first labeled with the changed information.
Retail:	Retail/POS Exemption is for all classes	Class 1 only
Multiple Parts	In the case of single finished devices made up of multiple parts that must be assembled before their first use, it shall be sufficient to place the UDI carrier on only one part of each device.	

Different UDI Carrier (Bar Code) Requirements

China NMPA: Announcement No. 66

"Article 12 Registrants/filers shall select the data carrier standard suitable for the unique device identification it has created, assign the unique identification data carrier to the minimum sales unit and higher-grade packaging of medical devices marketed under its name, and ensure that the unique identification data carrier is firm, clear and readable during the operation and use of medical devices."

Other Countries

Saudi Food & Drug Administration: MDS-G34

If linear barcodes are used, the entire UDI shall be concatenated into a single barcode. However, If the UDI information is available through a 2D barcode as well, then either concatenated or stacked barcodes are acceptable."

(We applaud the Saudi Regulator's goal of market adoption and intent to enable scanning systems and processes.)

Saudi Arabia Only

Market Selects UDI Carrier ⟷ **Regulator Selects UDI Carrier**

Market Driven Requirements provide harmonization opportunities and allow for evolution of standards. (Requires collaboration and convergence on the part of Device Manufacturers, Healthcare Providers, and Issuing Agencies)

Different Data Definition: Same Attribute Name

Primary DI

1) 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) The UDI - DI of the lowest salable unit.

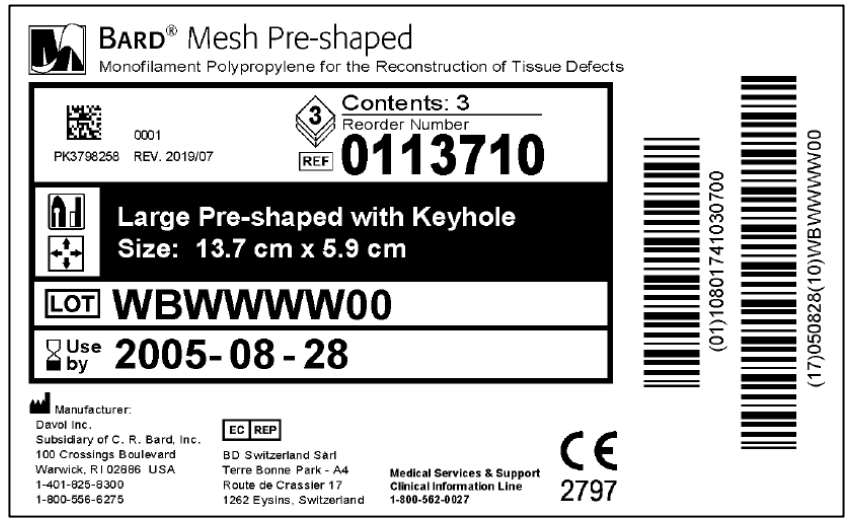
Device manufacturers must be careful with UDI data requirements.

Different List Values: Clinically Relevant Size

- Some of the UDI Data Bases as for Clinically Relevant Size as a distinguishing characteristic.
  - Syringe Size
  - Stent Dimensions
  - IV Catheters

- Regulators haven't aligned on a single set of measurements and values.
  - US: Specific US List of values
  - EU: Specific EU List of values
  - Saudi Arabia: Free text

- The lack of harmonization will result in some device having different size measurements in different counties



13.7 cm x 5.9 cm
All Clinically Relevant Sizes should be harmonized

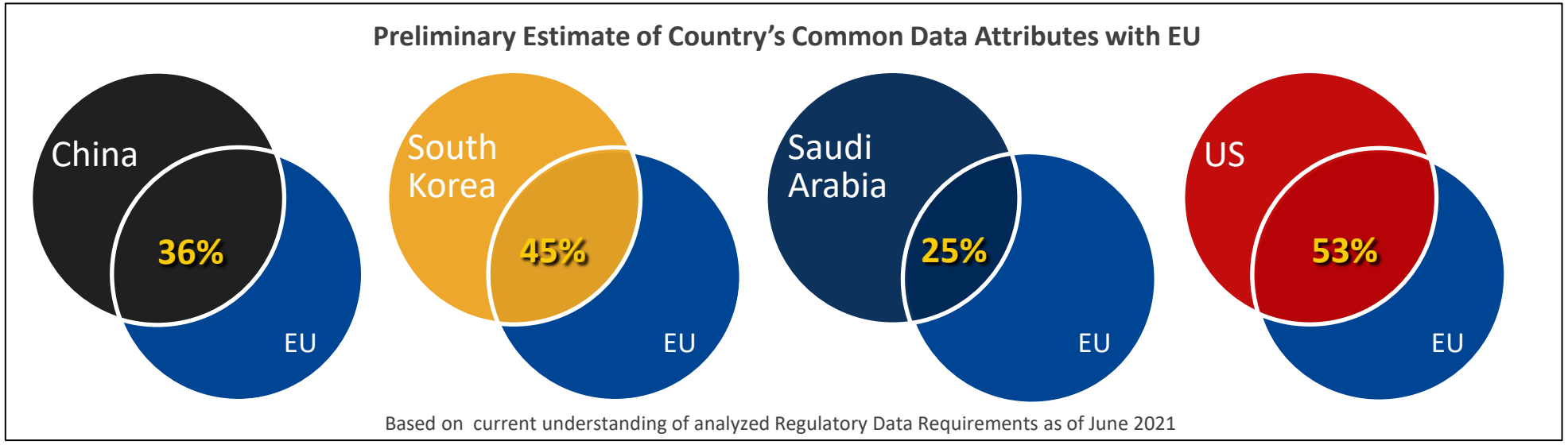
Disparate size data to describe devices will impact the healthcare system.

Different List Values: 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

It would benefit the industry if we could align values.

Non-Harmonized Data Attributes: EU Comparison



Country	Approximate # Internal Data Attributes	Approximate # Attributes Common with EU
China	81	29
South Korea	53	24
Saudi Arabia	48	12
US	68	36

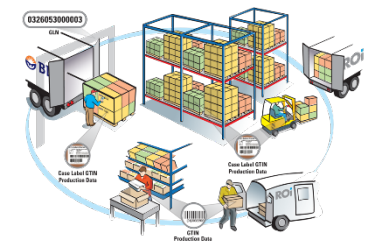
Key Points:

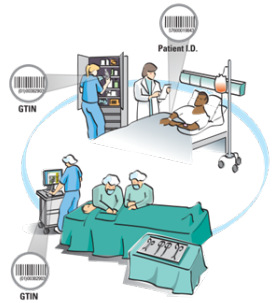
- A similar analysis must be conducted for each country
- Our system needs to be programed
- Policies, Procedures, and Processes are impacted
- Extensive training is required

Each globally harmonized attribute is a victory the industry.

Aligning UDI Regulations with Clinical & Supply Chain Needs

- To provide clinical value, UDI must be adopted and embraced by Healthcare Providers
- Existing practices and future needs of Healthcare Providers, Distributors, Payors, and other participants should be considered.





Supply Chain

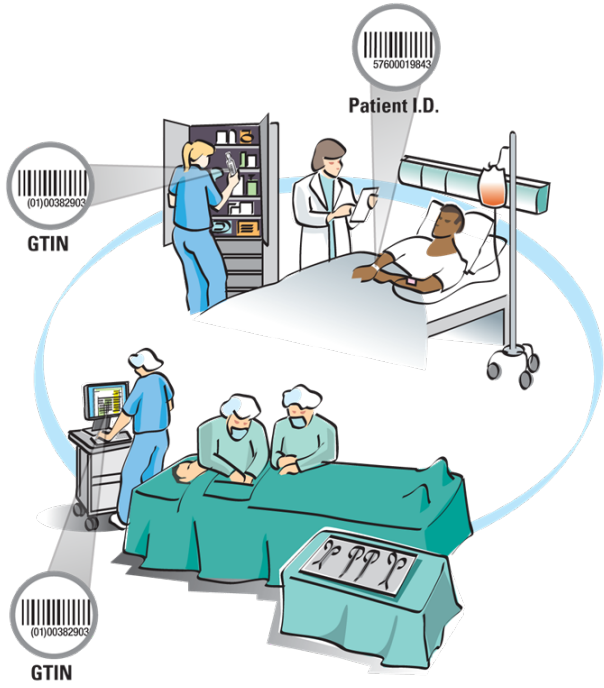
TGA
UDI Regulation

Clinical

Clinical Usage of UDI

- UDI Needs Include:
  - Clarity on which Bar Code(s) to scan
  - Desire for 1:1 relationship between catalog numbers & UDI-DI
  - Stability and logic on UDI-DI assignments
  - Transparency and communication on UDI-DI updates
  - Accurate Master Data
  - Clarity on “Unit of Use”
  - Easy access to UDI Data

- Challenges Include:
  - Gaps in IT (Aligning clinical systems and scanning technology)
  - Funding for implementation programs
  - “C-Suite” support

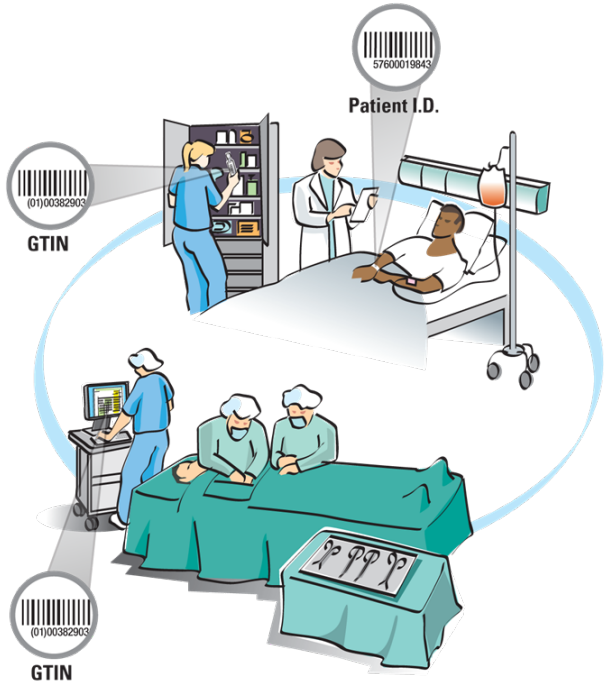


Healthcare Providers

Supply Chain Usage of UDI (Includes Distributors)

- UDI Needs Include:
  - Ability to use UDI in ERP and other systems
  - Must work on conveyors and/or automated scanning systems
  - Big bold Bar Codes for processing speed and distance
  - Clarity on UDI related to multiple levels of packaging
  - Ability to absorb, process, and use “UDI Data”

- Challenges Include:
  - Migrating to newer Bar Code formats
  - Modifying ERP and/or WMS data fields
  - Understanding which PI elements to use



Healthcare Providers

Example of New Data Requirement: Pack Level Identification

This is one example of a seemingly simple challenge that will need to be sorted out.

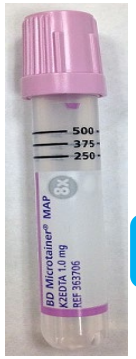
Example of Pack Level Identification

Pack Levels

- Level 1 (Each or Base Unit)
- Level 2 (Shelf Pack, Box)
- Level 3 (Case)
- Level 4 (Pallet)

UNIT/EACH/BASE

- Unit UDI-DI is a “Virtual” UDI as the UDI-DI is not printed on the product.
- This may be referred to a **Unit of Use** DI.



“Virtual” UDI-DI:
00382903637065

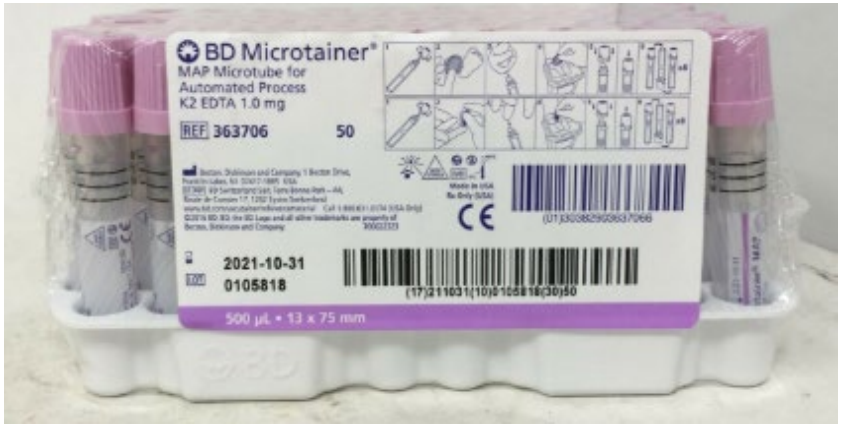
Level 1

Material 363706 UBE MICRO K2 EDTA LAV MAP

Units of measure/EANs/dimensions

X	AUn	Measure...	<...	Y	BUn	Measure...	EAN/UPC
1	EA	each	<=>	1	EA	each	00382903637065
1	SP	Shelfpack	<=>	50	EA	each	30382903637066
1	CAS	Case	<=>	200	EA	each	50382903637060
1	APL	US pallet	<=>	39.600	EA	each	

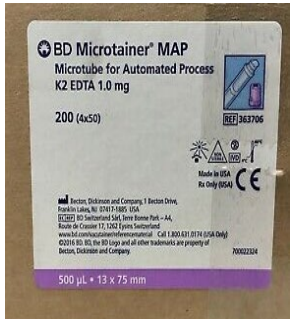
SHELF PACK



UDI-DI:
30382903637066

Level 2

CASE



UDI-DI:
50382903637060

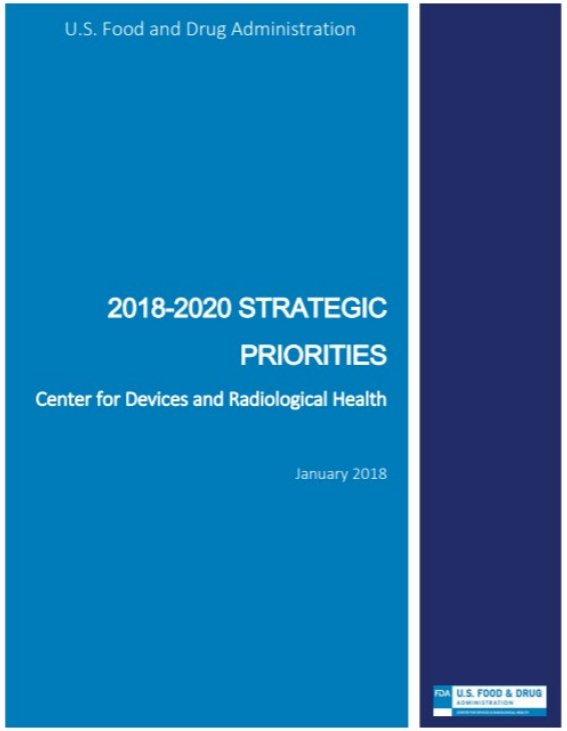
Level 3

UDI in the US: Current Status

- ✓ **UDI Regulation in place**
- ✓ **UDI Implementation by US Device Manufacturers**
- ✓ **Health Care Provider interest in implementation**
- ✓ **Support and Engagement from the US FDA**
- ✗ **Widespread UDI adoption by hospitals** (Adoption isn't ubiquitous.)

UDI User Group: AHRMM Learning UDI Community

- The Association for Health Care Resource & Materials Management (AHRMM) is the premier membership group for health care supply chain professionals.
- FDA identified the (AHRMM) Learning UDI Community (LUC) as an example of a coordinated, action-oriented early adopter collaborative community.
- The AHRMM Learning UDI Community is a health care collaborative effort designed to address issues impacting the implementation and use of unique device identifiers by developing a **common understanding** and approach to UDI adoption within the health care setting.
- A memorandum of understanding signed by AHRMM and the FDA formally demonstrates both parties' collaborative support of the LUC.



Other User Groups Include: GS1, AdvaMed, and HTG.

What does UDI Success look like from a Manufacturer's perspective?

1) Globally harmonized requirements.

2) An uneventful implementation process with ample planning time.

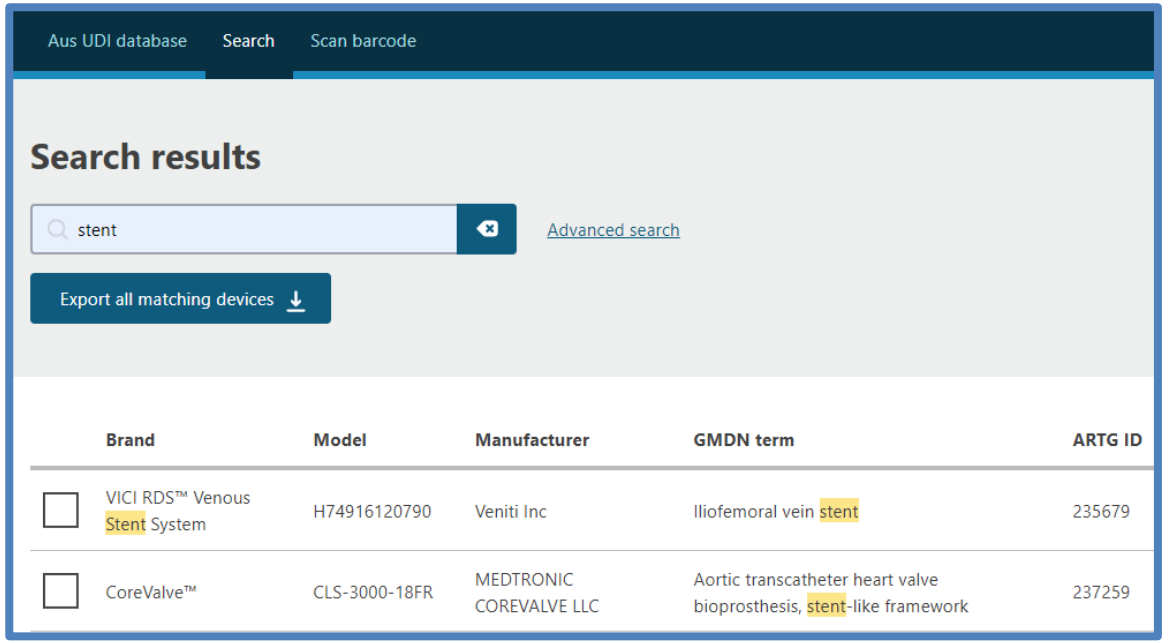
3) Widespread adoption by healthcare providers and the overall healthcare eco-system leading to enhanced patient safety and the achievement of associated goals and objectives.

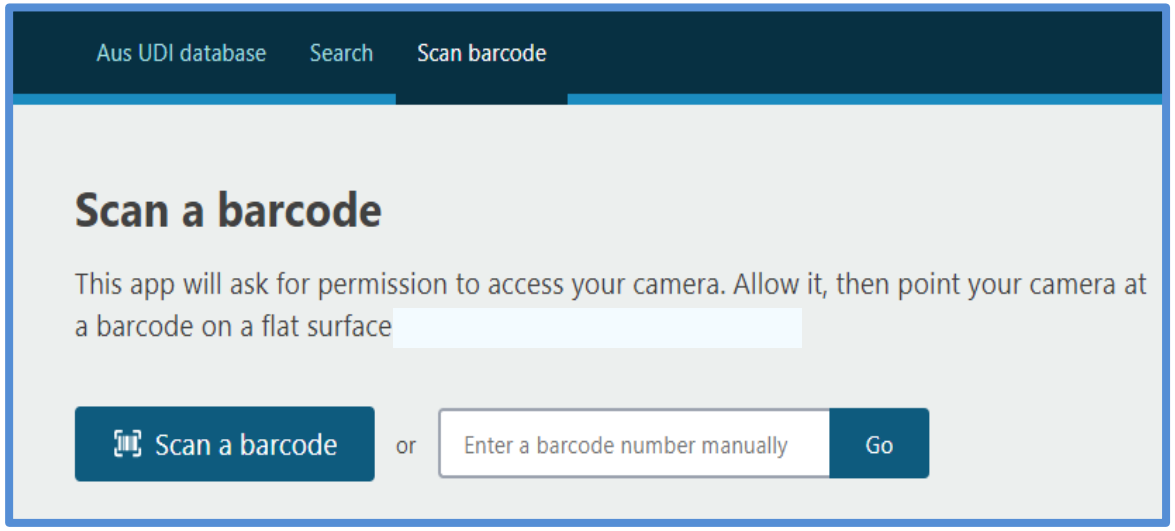
Unique Device Identification webinar

- Guest speaker
- **Progress update**
- Demonstration
- Questions and answers

Progress update

- ✓ Scoping continues on Qld early adopter project
- ✓ Work has started to build on the foundational version of the Australian UDI database
- ✓ Discussions with the Australian Digital Health Agency on including UDI in the new digital experience centre, to facilitate co-design and collaboration





UDI Working Group 1 - Triggers

Mission

- To provide advice to the TGA on the framework to define the scenarios under which a new device identifier is required

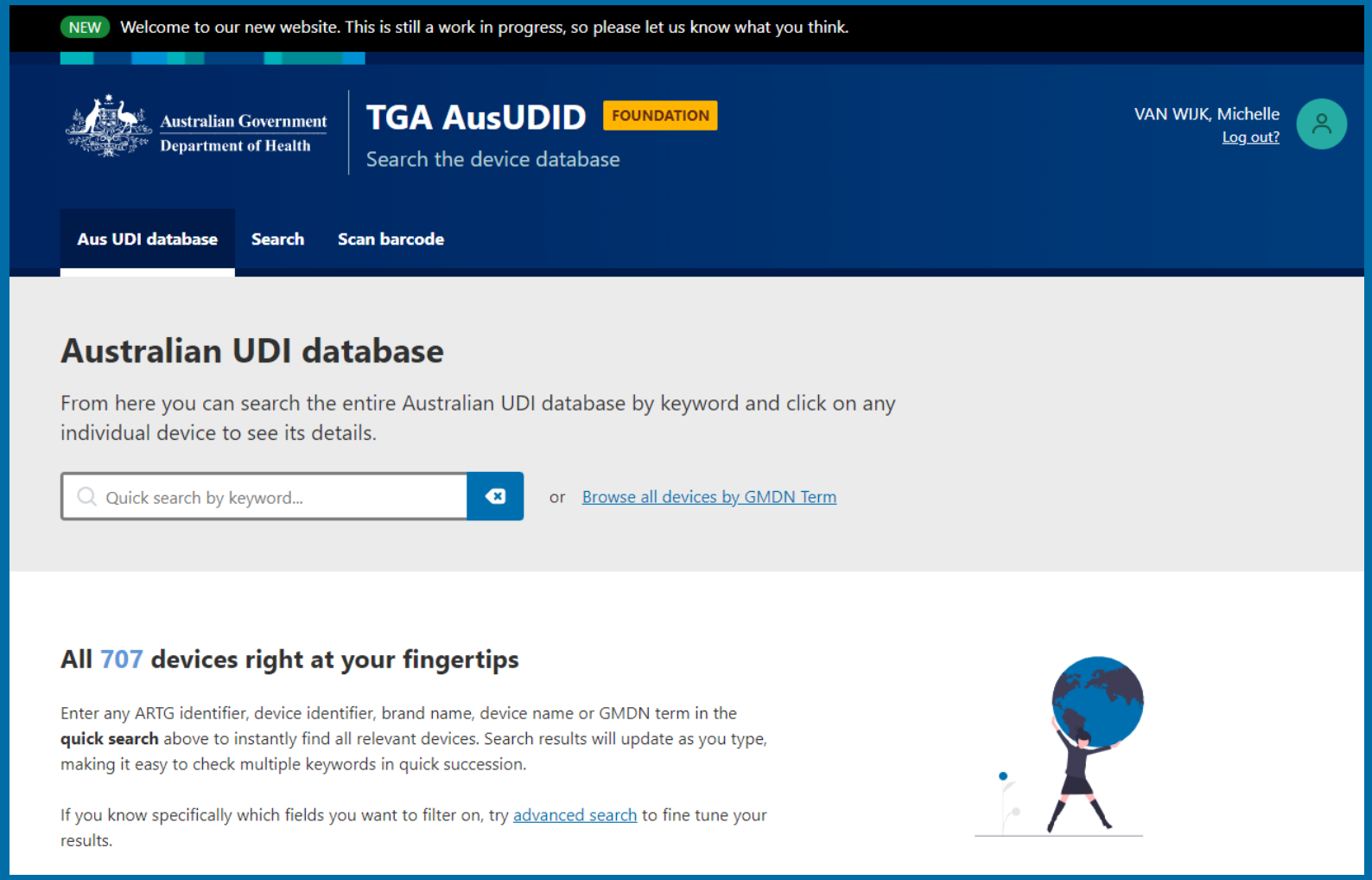
- Define the problem and deliverables
- Recommendations
- Use cases

September to November

? Manufacturers, issuing agencies, healthcare organisations

udi@health.gov.au

Demonstration - ‘Sandpit’ UDI database



How did we go?

LIVE POLL

Michelle and Dennis are currently reading over your submitted questions.

We'll be back shortly for Q&A

Contact us

UDI Project

udi@health.gov.au

Questions?

Website and link references

New UDI hub ★	https://www.tga.gov.au/unique-device-identification-system
Second UDI consultation paper	https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system
First UDI consultation paper	https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia

Contact us

UDI Project

udi@health.gov.au

More information

TGA website	https://www.tga.gov.au
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TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
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Australian Government

Department of Health

Therapeutic Goods Administration

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