



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

# Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
  - Messages will only be visible to the moderator and speaker
  - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **‘Chat’** function
- Relevant links will be sent to you via the chat function box
- Live polls will be conducted throughout this event.



## Difficulties hearing from computer?

Check your settings located under “**Audio & Video**” tab located top of your screen:

OR

**Dial:** +61-2-9338-2221

**Access code:** 165 034 3953



Australian Government

Department of Health

Therapeutic Goods Administration

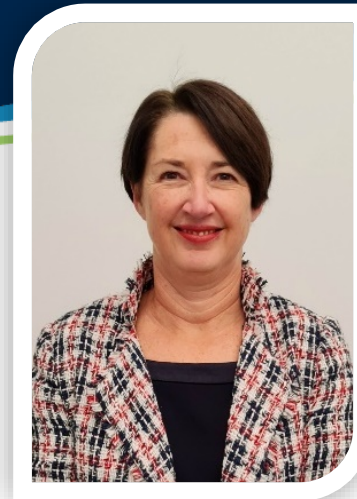
# Unique Device Identification Webinar #3 – 17 August 2021

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

# 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

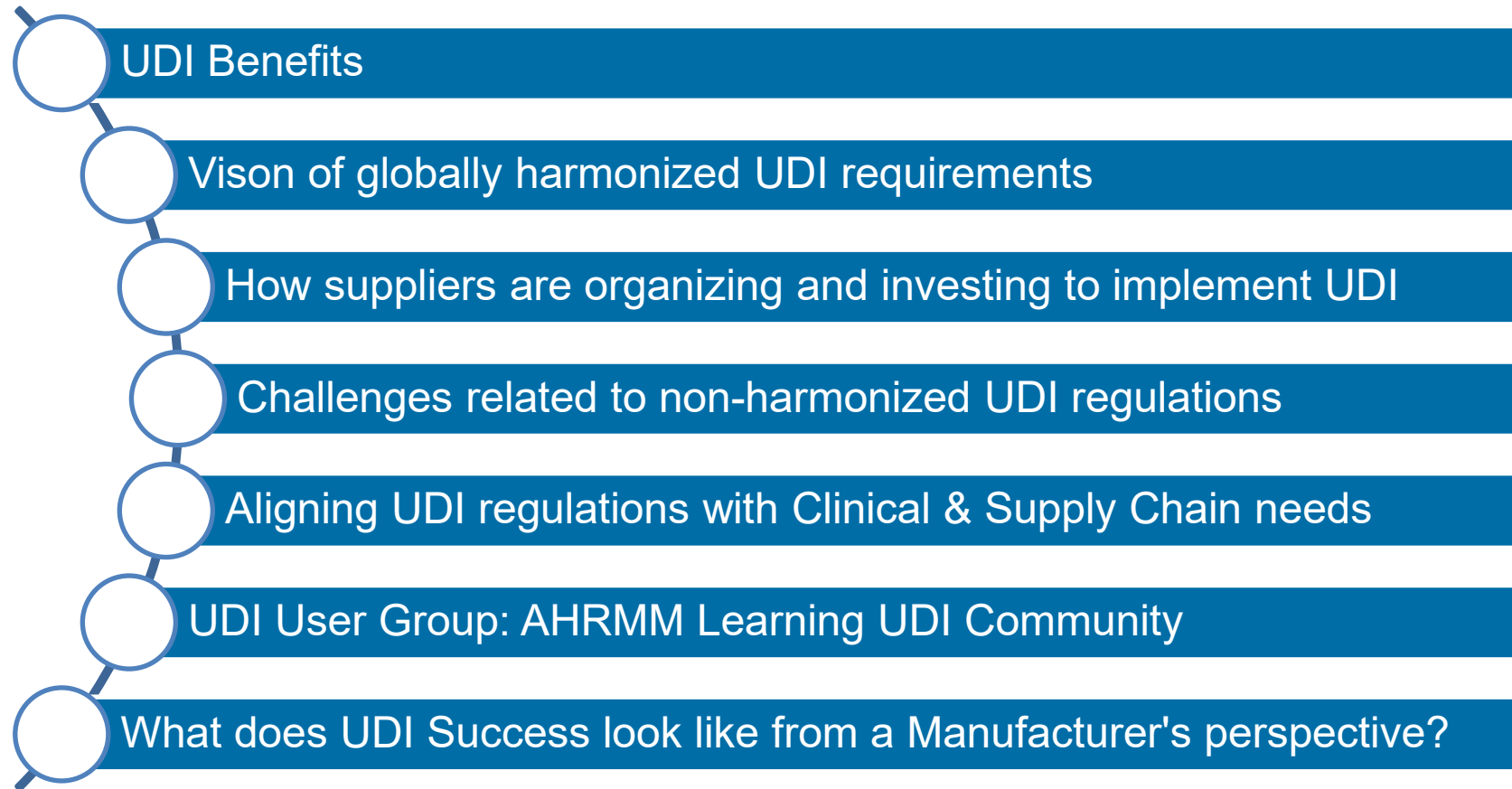


# We are a leading global medical technology company uniquely positioned to improve both the treatment of disease and the process of care.



- 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

# Challenges and Considerations on the Journey to a Global UDI System



# Benefits of using Data Standards

## Supply Chain Benefits Include:

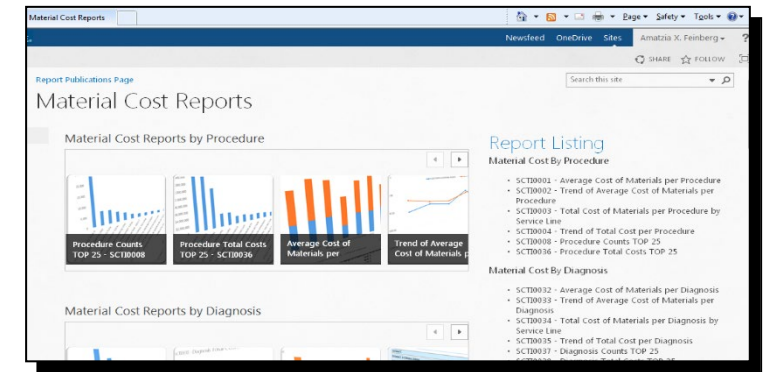
- Accurate Shipments
- Supply Chain Efficiency
- Product Tracking
- Common Business Language

*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

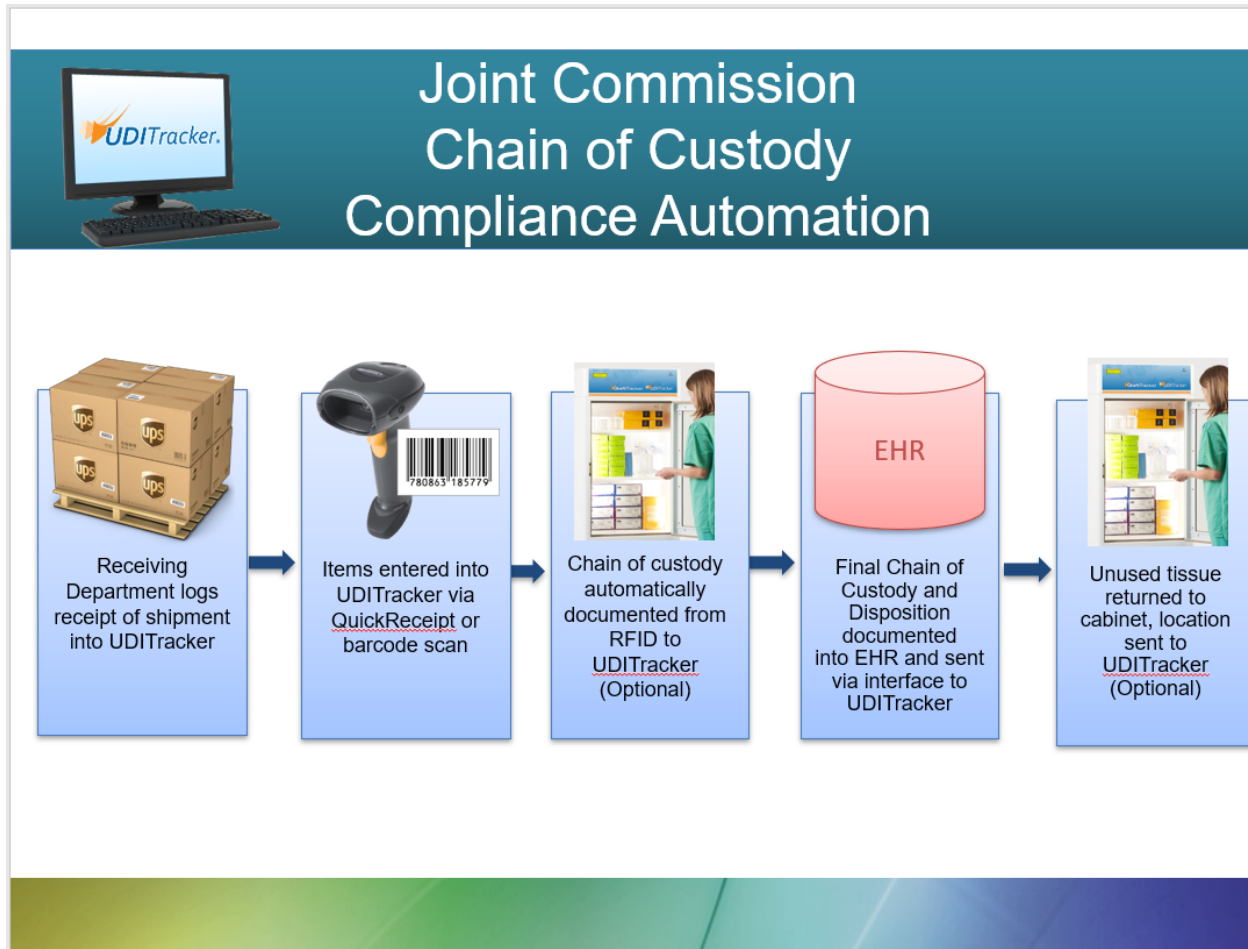
## Clinical Integration of UDI:

- 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



*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

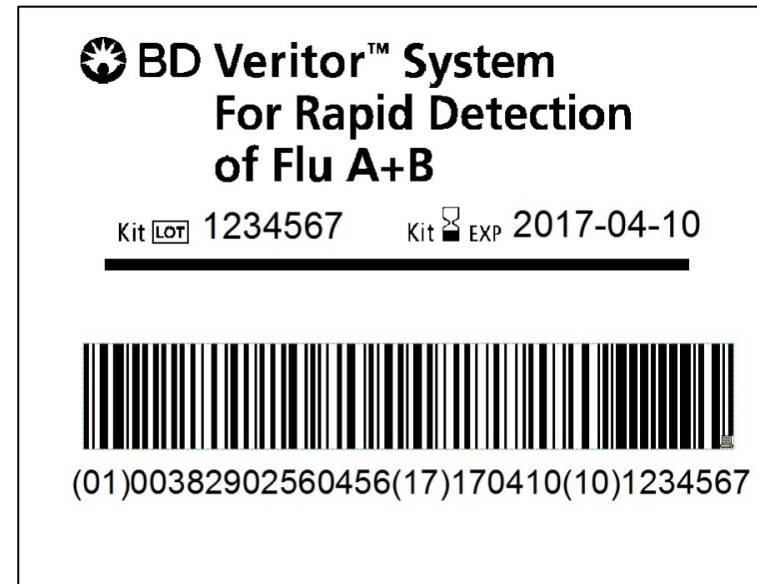
## **Post Implementation**

- Post Rule Community Engagement

# UDI: More than Device Identifiers and Bar Codes

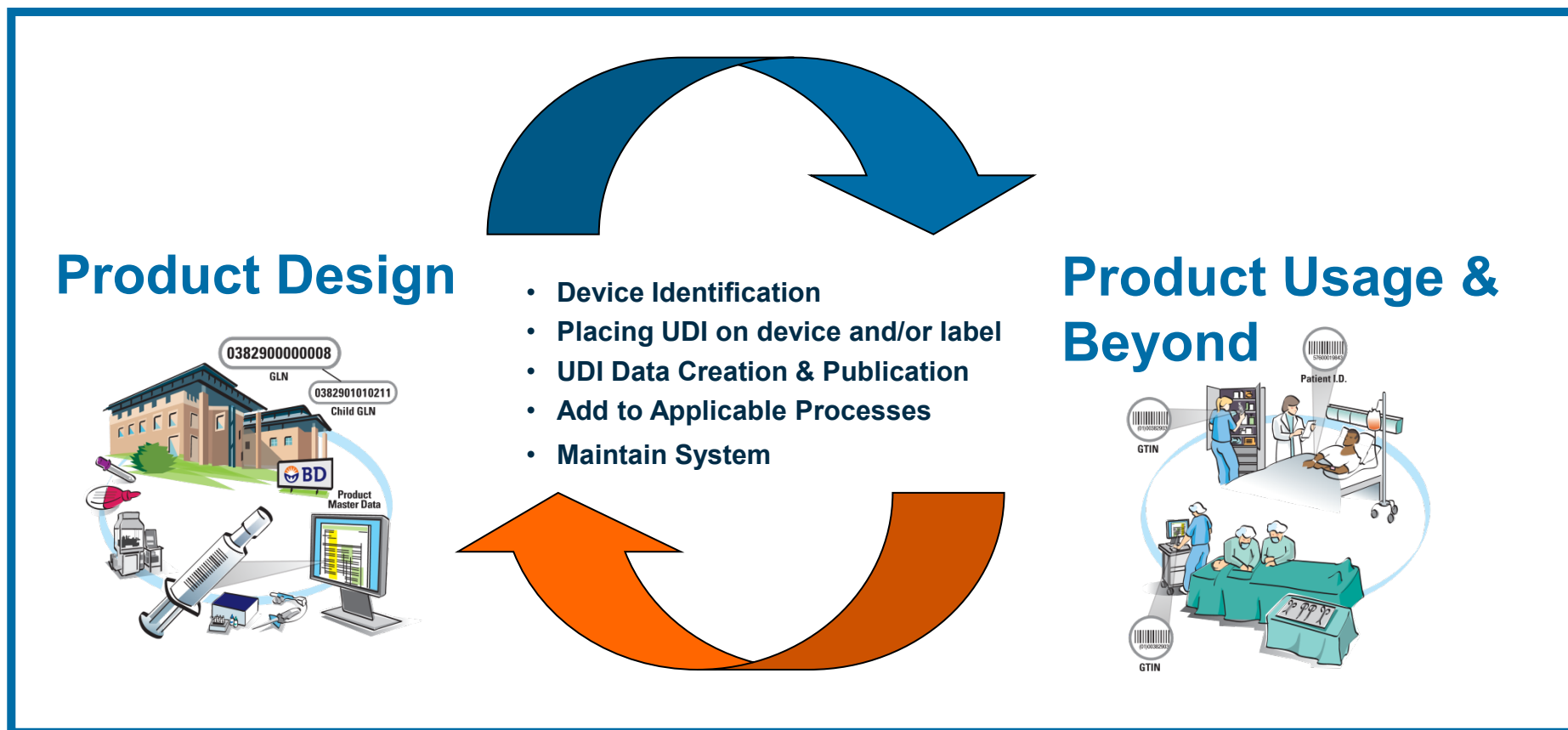
**UDI-DI = 00382902560456**

**UDI Device Identifier**



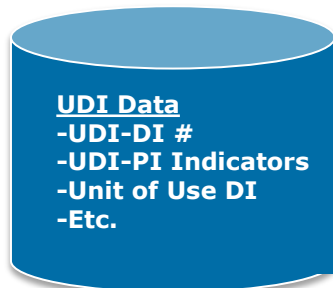
**UDI Bar Code**

# UDI: More than Bar Codes and Device Identifiers



# 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**

Lorem ipsum dolor sit  
 amet, consectetur  
 adipiscing elit. Maecenas  
 risus leo, vehicula  
 laoreet tellus sit amet,  
 placerat dignissim ante.  
 Phasellus elit neque,  
 mollis in nibh a, dictum  
 accumsan ante. Donec  
 scelerisque euismod  
 sapien non fringilla.  
 Donec quis aliquet justo,  
 a fermentum orci. Cras  
 et elit neque. Sed sed  
 semper orci, quis blandit  
 quam. Praesent vel  
 convallis lorem, ac  
 finibus metus. Nam eget  
 bibendum velit. Aliquam  
 sagittis arcu vel mi  
 egestas, Id consectetur  
 odio sollicitudin. Cras  
 viverra massa quis nisi  
 euismod, nec tristique  
 metus lobortis. Sed eget  
 malesuada est, eget  
 aliquam leo.  
 Pellentesque ut orci  
 pellentesque est  
 efficitur lobortis et vel  
 massa. Sed ultricies  
 fringilla vehicula.  
 Phasellus non commodo  
 arcu, dictum ultrices  
 turpis. In vehicula  
 finibus leo, quis aliquam  
 tortor dictum at.  
 Phasellus sollicitudin  
 quam ut lacinia gravida.  
 Etiam auctor dolor ac  
 est scelerisque,  
 venenatis convallis nunc  
 gravida. Phasellus elit  
 justo, accumsan a purus  
 at, scelerisque sagittis  
 ante. Aenean efficitur  
 mollis tortor eget  
 imperdiet. Praesent id  
 tortor non sed tincidunt  
 tempus. Integer faucibus  
 at tellus commodo  
 egestas. Donec ut

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

[illegible]

## Current Location

## Paper Files

## ERP

## Tech Files

## E-Catalog

WMS

## Product Labels

## TrackWise

## Other

## Other

## Other

**Data Storage System  
(PIM, ERP or other  
system)**

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

US FDA

**EUDAMED**

## China

## South Korea

## Saudi Arabia

## Australia

# 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 <u>health institutions</u> 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:	<ul style="list-style-type: none"> <li>Space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level</li> <li>AIDC (professional use)</li> <li>HRI (home use)</li> </ul>	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, <b>software identification</b> 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 <i>Draft</i> 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.”

## 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.)



Other Countries



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

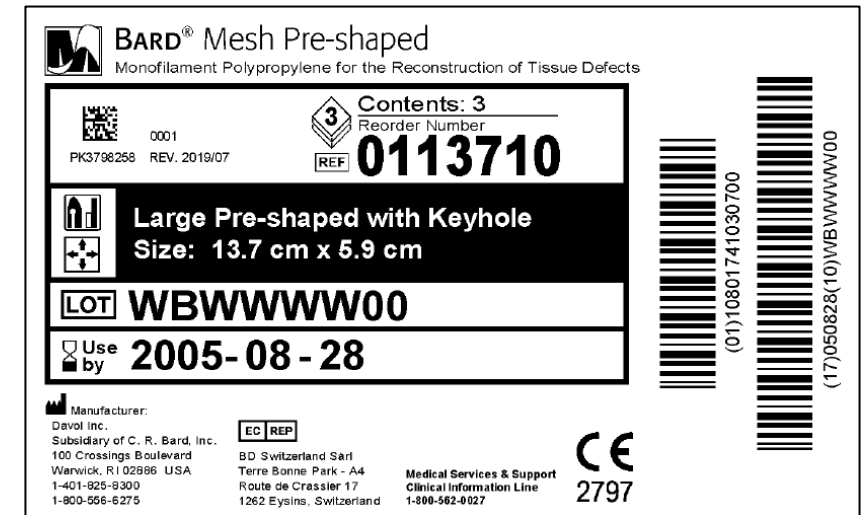
## Primary DI

- 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 countries



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.*

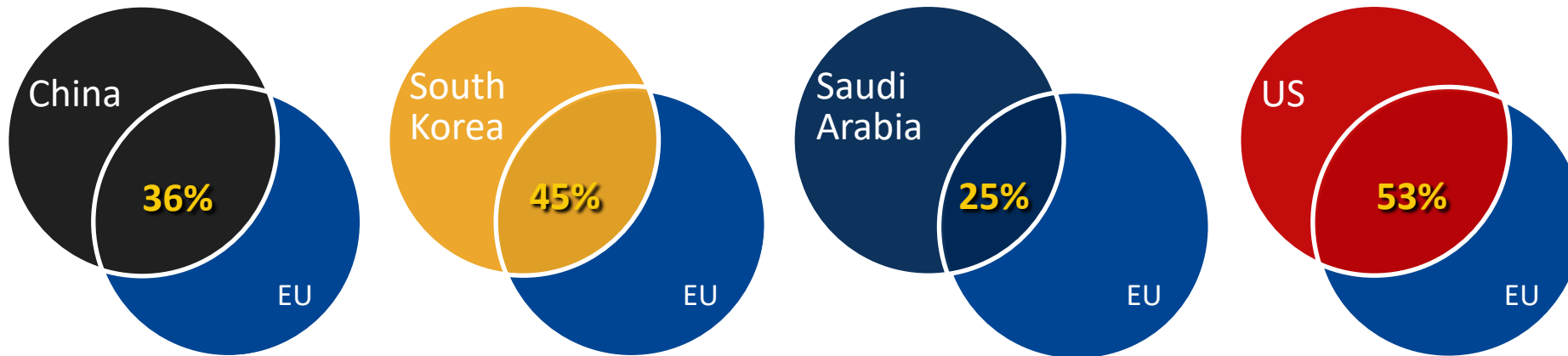
# Different List Values: Sterilization Method

China	S. Korea	USA
Cobalt-60 Gamma Radiation Sterilization	Chloride dioxide Sterilization	Chlorine Dioxide (ClO <sub>2</sub> ) 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 (H <sub>2</sub> O <sub>2</sub> ) 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 (O <sub>3</sub> ) 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

Preliminary Estimate of Country's Common Data Attributes with EU



Based on current understanding of analyzed Regulatory Data Requirements as of June 2021

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.*

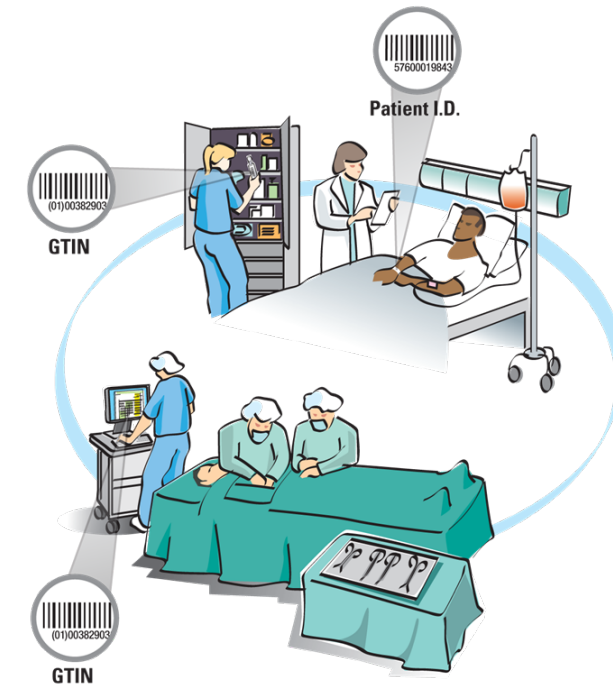
# Aligning UDI Regulations with Clinical & Supply Chain Needs

- 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.



# Clinical Usage of UDI

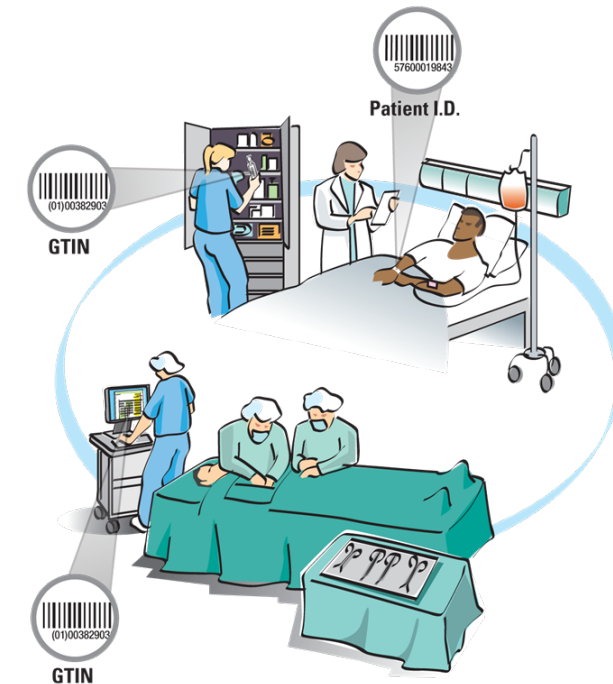
- UDI Needs Include:
  - Clarity on which Bar Code(s) to scan
  - Desire for 1:1 relationship between catalog numbers & UDI-DI
  - Stability and logic on UDI-DI assignments
  - Transparency and communication on UDI-DI updates
  - Accurate Master Data
  - Clarity on “Unit of Use”
  - Easy access to UDI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

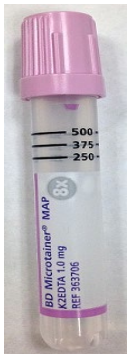
# Example of New Data Requirement: Pack Level Identification



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

# Example of Pack Level Identification

## UNIT/EACH/BASE



“Virtual” UDI-DI:  
00382903637065

Level 1

## SHELF PACK



## Pack Levels

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

UDI-DI:  
30382903637066

Level 2

## CASE




UDI-DI:  
50382903637060


Level 3

Material

363706



TUBE MICRO K2 EDTA LAV MAP



Units of measure/EANs/dimensions

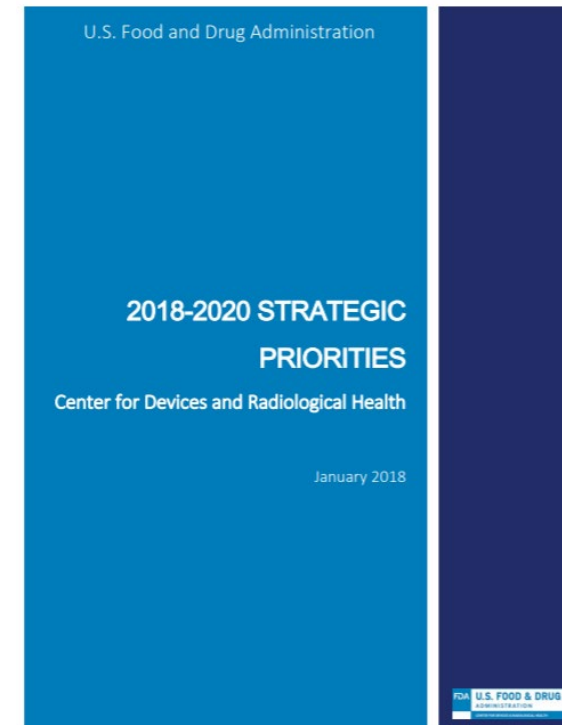
X	AUn	Measure...	<... Y	BUn	Measure...	EAN/UPC
1	EA	each	<=> 1	EA	each	00382903637065
1	SP	Shelfpack	<=> 50	EA	each	30382903637066
1	CAS	Case	<=> 200	EA	each	50382903637060
1	APL	US pallet	<=> 39 . 600	EA	each	

# 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 ecosystem 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

Aus UDI database Search Scan barcode

### Search results

stent [Advanced search](#)


Export all matching devices

	Brand	Model	Manufacturer	GMDN term	ARTG ID
<input type="checkbox"/>	VICI RDS™ Venous Stent System	H74916120790	Veniti Inc	Iliofemoral vein stent	235679
<input type="checkbox"/>	CoreValve™	CLS-3000-18FR	MEDTRONIC COREVALVE LLC	Aortic transcatheter heart valve bioprosthesis, stent-like framework	237259

Aus UDI database Search Scan barcode

### Scan a barcode

This app will ask for permission to access your camera. Allow it, then point your camera at a barcode on a flat surface

 Scan a barcode or Enter a barcode number manually [Go](#)

# 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](mailto:udi@health.gov.au)

# Demonstration - 'Sandpit' UDI database

**NEW** Welcome to our new website. This is still a work in progress, so please let us know what you think.

 Australian Government  
Department of Health


**TGA AusUDID** FOUNDATION  
Search the device database

VAN WIJK, Michelle  
[Log out?](#) 

**Aus UDI database** Search Scan barcode

## Australian UDI database


From here you can search the entire Australian UDI database by keyword and click on any individual device to see its details.

 or [Browse all devices by GMDN Term](#)

### All **707** devices right at your fingertips

Enter any ARTG identifier, device identifier, brand name, device name or GMDN term in the **quick search** above to instantly find all relevant devices. Search results will update as you type, making it easy to check multiple keywords in quick succession.

If you know specifically which fields you want to filter on, try [advanced search](#) to fine tune your results.



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](mailto: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](mailto:udi@health.gov.au)

# More information



TGA website <https://www.tga.gov.au>



TGA Facebook <https://www.facebook.com/TGAgovau/>



TGA Twitter <https://twitter.com/TGAgovau>



TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>





**Australian Government**

---

**Department of Health**  
Therapeutic Goods Administration