Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar 8

Global Manufacturer UDI Learnings and Project Update

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Therapeutic Goods Administration

TGA Health Safety Regulation

19 April 2022

Welcome

- This webinar is being recorded
- Presentation will be made available on the TGA website
- Questions – **Q&A** tool will open midway through the session (slido)
  - Q&A session will occur at the end of today's presentation.
- Contact the moderator – please use the **'Chat'** function ONLY
- Relevant links will be sent to you via the chat function box
- A live poll will be conducted at the end of the presentation.

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Agenda

- **Invited guest speaker – Roger Peterson, Arthrex**
- TGA UDI Project update
- Questions and answers

Guest Presenter – Roger Peterson

Arthrex Senior Manager, Global Labeling – Regulatory

- Over 20 years of experience in the medical device industry within several roles including Product Development, Quality Assurance, Operations, and Regulatory Operations.
- Roger joined Arthrex in 2016 with previous experience at Integer, Abbott, and Steris Corporation.
- Roger is an active member of Association for the Advancement of Medical Instrumentation (AAMI), ISO Technical Committee 210 WG 03 - Graphical Symbols & Nomenclature, MedTech Europe labeling, MedTech Europe implant card, and EUDAMED working groups.
- Roger's current focus is on leading the Arthrex EUDAMED and global unique device identification initiatives.

Introduction to Arthrex

Locations

Auckland | New Zealand
Bern | Switzerland
Boston | United States
Copenhagen | Denmark
Dubai | United Arab Emirates
Eindhoven | Netherlands
Helsinki | Finland
Kontich | Belgium
Lille | France
Lisbon | Portugal
Madrid | Spain
Moscow | Russia
Nápoles | Mexico
Ontario | Canada
Oslo | Norway
Pendleton | United States
Prague | Czech Republic
Rome | Italy
São Paulo | Brazil
Santa Barbara | United States
Seoul | Korea
Shanghai | China
Sheffield | United Kingdom
Stockholm | Sweden
Sydney | Australia
Tokyo | Japan
Torrance | United States
Vienna | Austria
Walnut | United States
Warsaw | Poland
Zagreb | Croatia

Over 19,000 Product Innovations

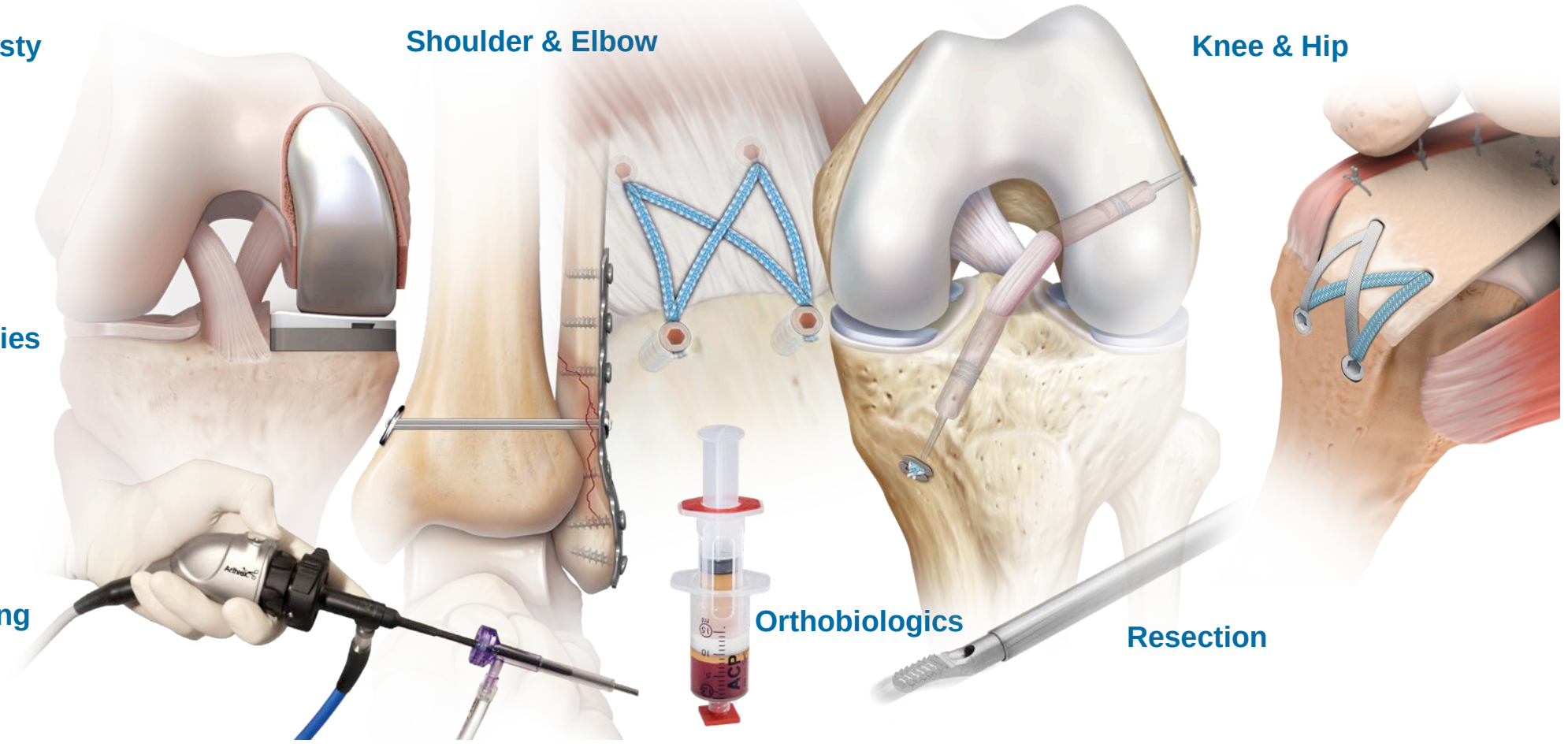
Helping Surgeons Treat Their Patients Better™

Arthroplasty

Shoulder & Elbow

Knee & Hip

Distal Extremities



Synergy Imaging

Orthobiologics

Resection

Arthrex Global QMS Certifications

Medical Device Single Audit Program (MDSAP), recognized by:

Country	Agency
USA	FDA
Australia	TGA
Canada	Health Canada
Brazil	ANVISA
Japan	MLHW

ISO 13485

BSI Certification FM **84661**

MDSAP Certification **619148**

What is UDI and why do we use it?

The Unique Device Identification (UDI) is a system used to mark, identify, and track medical devices through the healthcare supply chain to the patient at point of care.
The three pillars of UDI:

Device Identifier + Production Identifier > Unique Device Identifier Database < Automatic Identification and Data Capture (Bar codes)

Arthrex UDI issuing agency – GS1

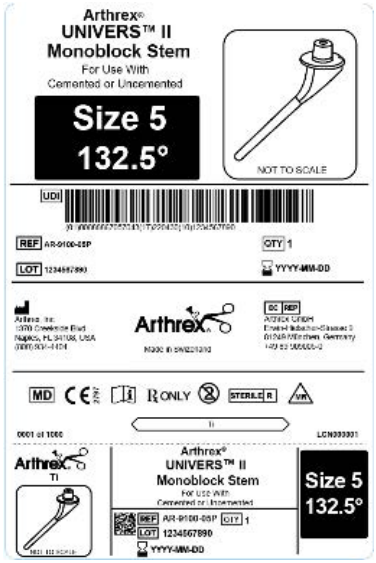
- **UDI-DI (GS1 Global Trade Item Number)**
- **UDI-PI (Production Identifiers, expiry date, MFG date, lot and or serial number)**

IMDRF UDI Requirements

The Unique Device Identification (UDI) system as described in IMDRF guidance shall provide identification to facilitate the traceability of devices throughout distribution to the point of care and shall consist of the following core components:

Assign

Device identifier ‘DI’



Label

Device identifier ‘DI’ +

Production identifier ‘PI’

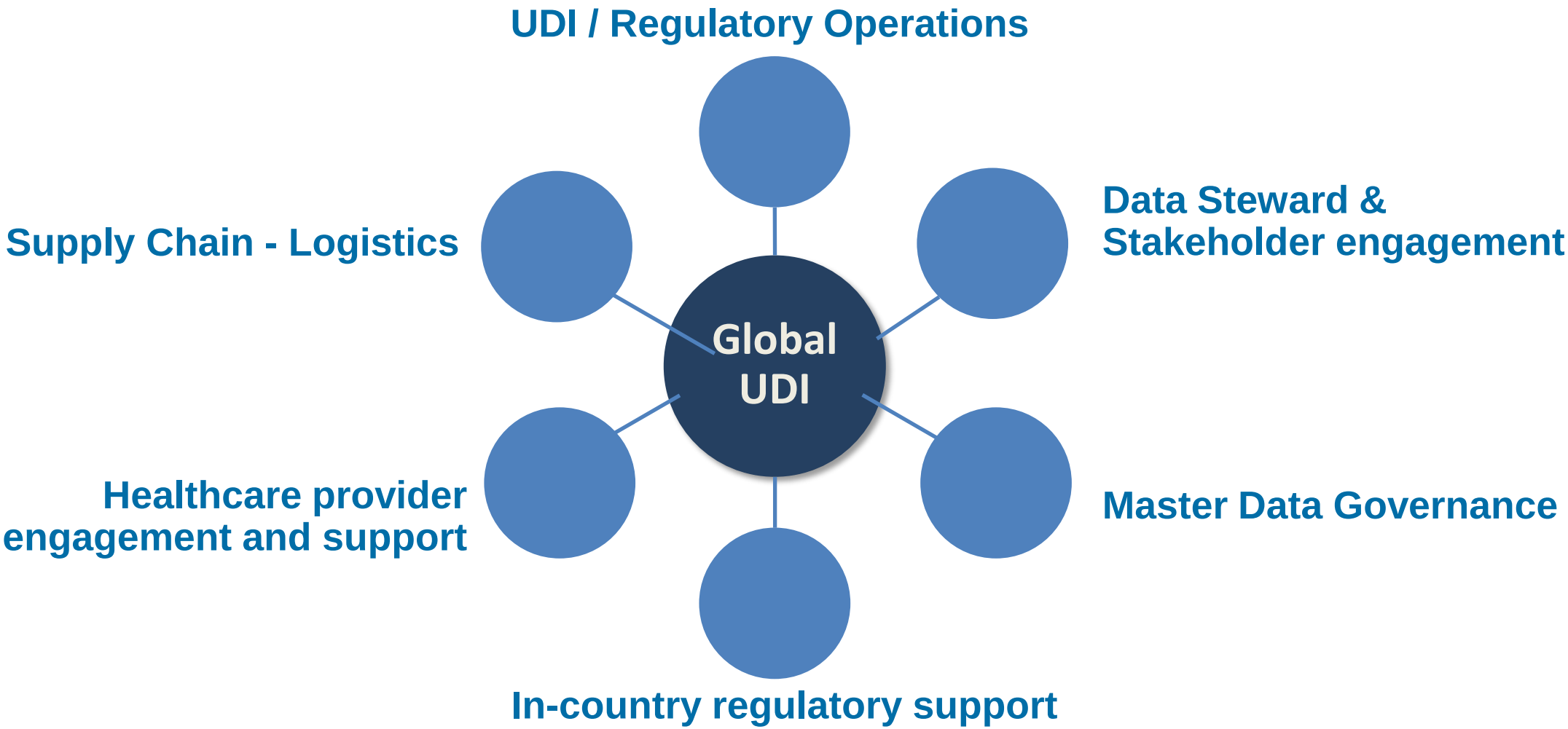
Register

AusUDID

Store

Scan, transact and retain UDI information by healthcare institutions

Arthrex Global UDI Strategy



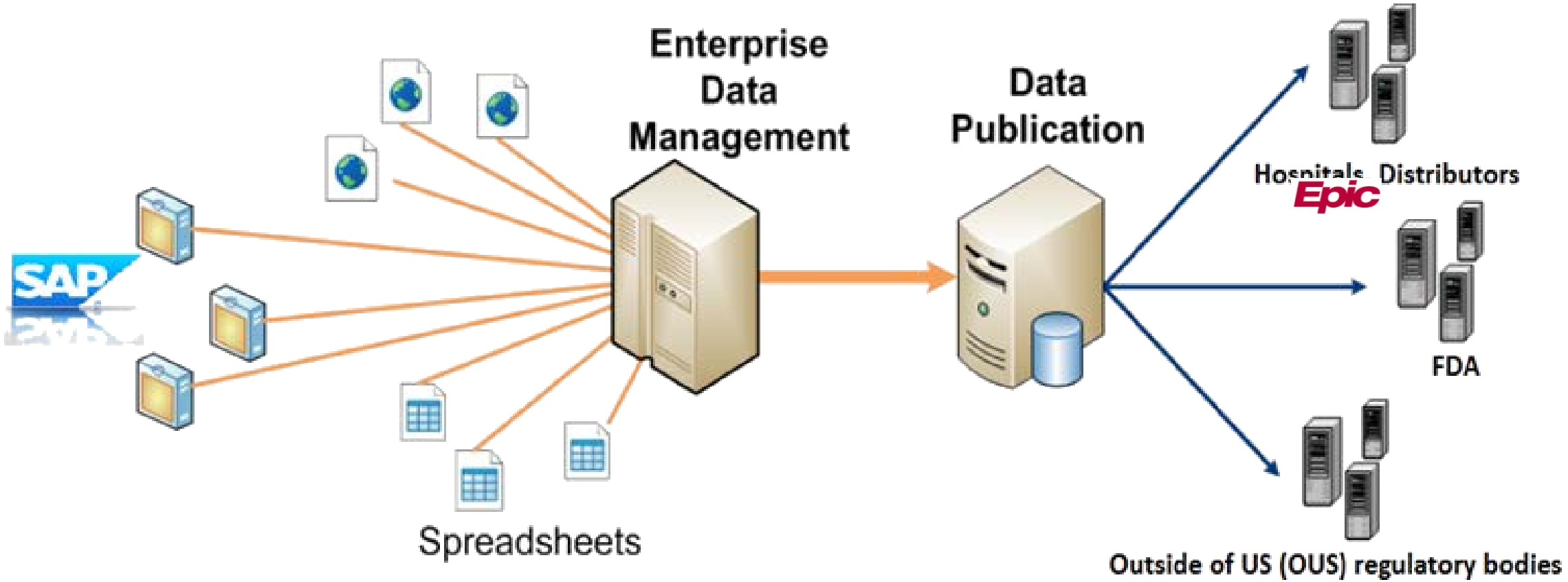
Arthrex UDI Global Program

- USA (GUDID)
- European Union (EUDAMED)
- Saudi Arabia (SAUDI-D)
- South Korea (IMDIS)
- Australia (AusUDID)
- China (CGUDID)
- Singapore (UDID)
- Brazil (UDI regulation RDC 591 published Dec 2021)
- Taiwan
- Canada
- India
- Turkey
- United Arab Emirates
- Egypt
- Columbia
- Ecuador
- MHRA, UK

Arthrex UDI Program

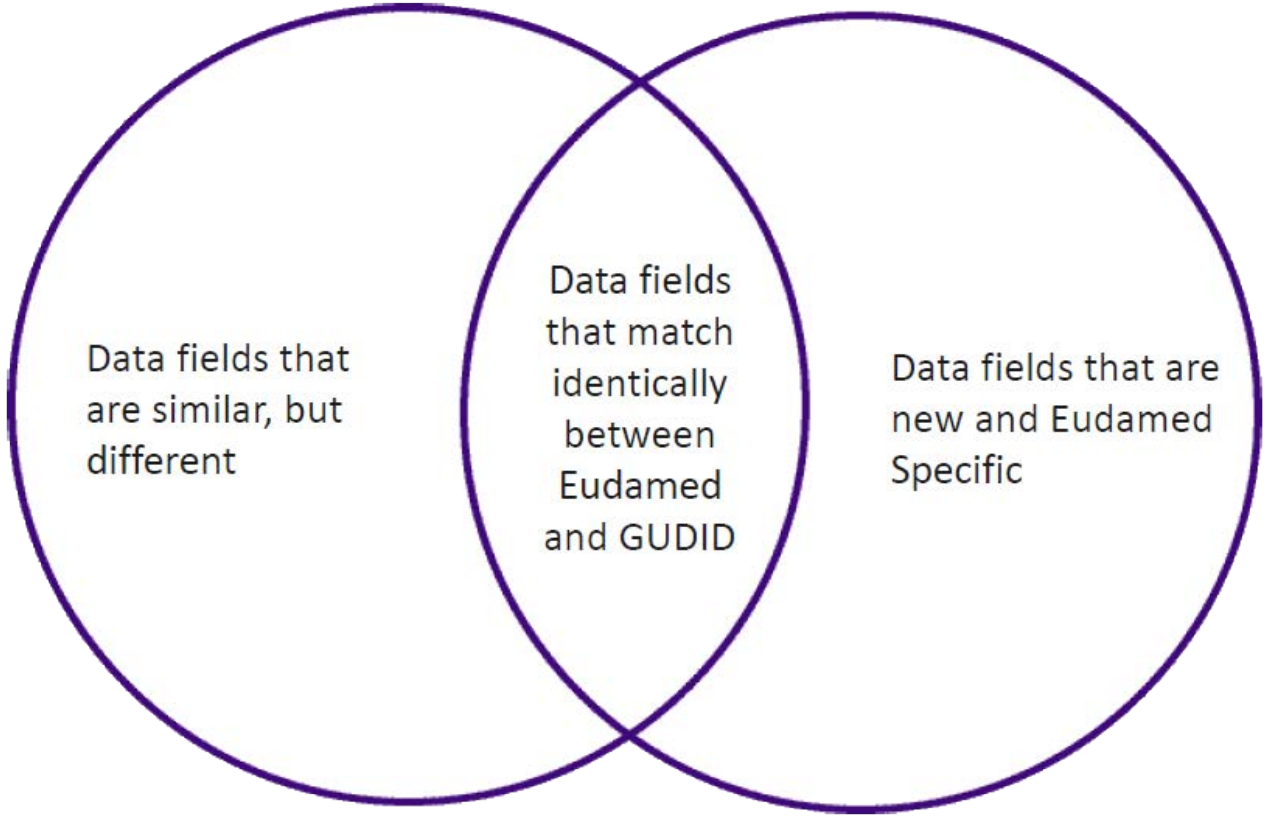
- **Product Development & Engineering**
  Creating new materials, bill of materials, and all associated product attributes (part description, GTIN, serial, sterility, clinically relevant size, etc.).
- **Label Development and UDI**
  Designing labels with the required information (e.g. date of manufacture, shelf-life expiry, magnetic resonance safety info, etc.), publishing the data to the FDA GUDID database and jurisdictional registries.
- **Supply Chain**
  Managing product effectivity, material status, country of origin, and distribution channels.
- **Label Operations**
  Managing enterprise labeling master data within enterprise software, printing correct and legible labels, and ensuring barcode scanability.
- **Manufacturing & Operations**
  Direct part marking, proper packaging, labeling application, and product traceability.
- **Warehouse & Logistics**
  Material transactions and customer order fulfillment.
- **Quality Assurance & Control**
  Maintaining GTIN functional name, verifying labels.
- **Regulatory Affairs**
  Maintaining correct FDA product codes, submission files, inclusion listings, and other regulatory data.

How Arthrex Provides UDI Data



UDI Challenges - Data Attribute Comparison

- FDA GUDID vs. EUDAMED



EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

***EUDAMED Only Attributes Include:**

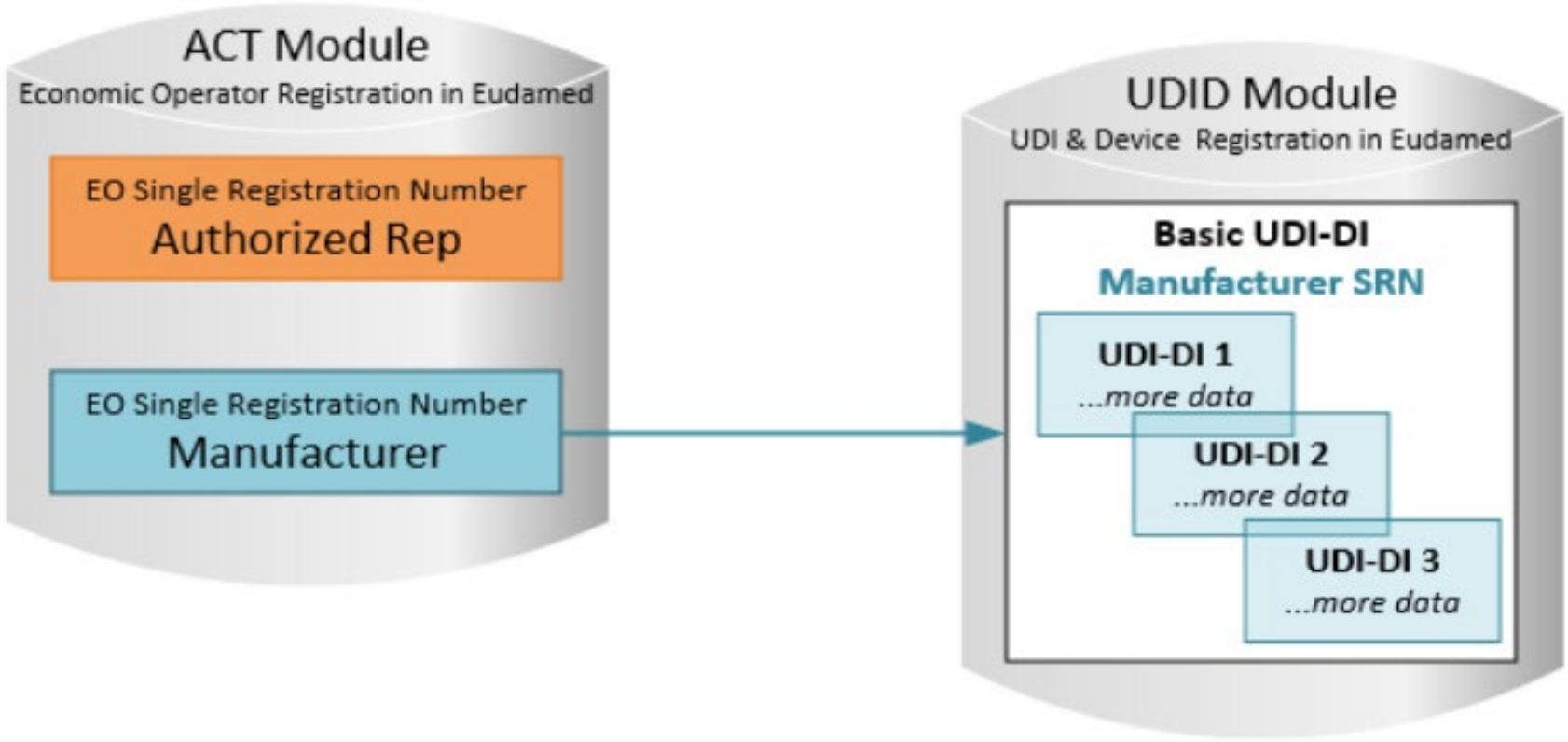
- ✓ Single Registration Number (SRN) Manufacturer
- ✓ Authorized Representative
- ✓ Authorized Representative Contact Info
- ✓ Risk Class
- ✓ Additional Trade Item Names
- ✓ Restricted Number of Reuses
- ✓ URL for Additional information
- ✓ Critical Warnings

Data attributes in scope for Arthrex

- GUDID 59 data attributes
- EUDAMED legacy device, 81 data attributes
- EUDAMED EU MDR, 135 data attributes

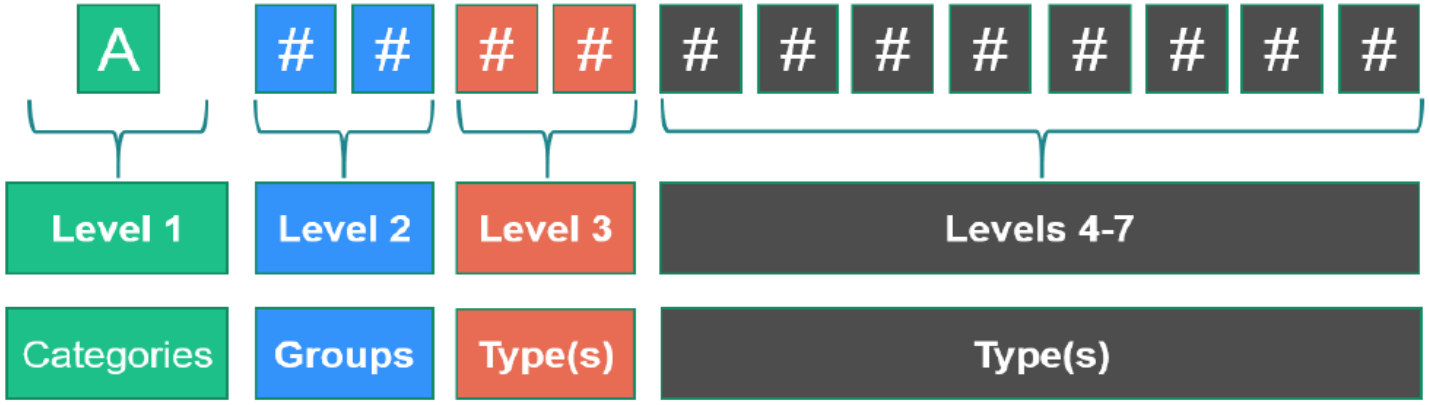
UDI Challenges - Data Attribute Comparison

- Medical Device Directive (MDD) devices - EUDAMED DI one to one relationship with UDI-DI
- EU MDR devices - structuring multiple UDI-DI(s) with Basic UDI-DI, (Global Model Number)



European Nomenclature Codes - EMDN

- Based on CND Italian Ministry's 'Classificazione Nazionale Dispositivi medici
  - Nomenclatures (EMDN) - EUDAMED (europa.eu)
- Manufacturers are responsible for allocating the most granular codes available.
  Examples:
  - AR-1319FT, Suture Anchor, Mini Corkscrew® = **P09120102** [Anchors, Tendon and Ligament Synthesis]
  - AR-1530DS, Bio-Tenodesis™ Disposables Kit for 3 mm Screw = **K010102** [Minimally Invasive Surgery Kits, Single Use]
  - AR-7500, Suture Tape, White/Blue, 1.3mm with Needle = **H0102010299** [Synthetic Non-absorbable Multifilament Sutures – Other]



Healthcare Consumption of UDI

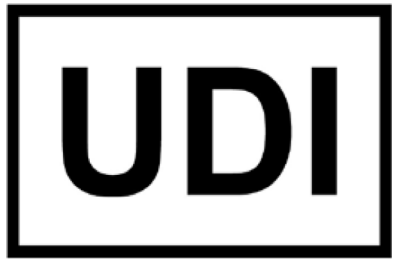
UDI data carrier being readily identifiable

- European MDR 2017/745, Annex VI, Part C 4.5

  When AIDC carriers other than the UDI carrier are part of the product labeling, the UDI carrier shall be readily identifiable

- US FDA 21 CFR 801.40(c)

  …If the AIDC technology form (e.g., bar code) used to convey the UDI is not evident upon visual examination of the device label or device package, the device label or device package must disclose the presence of AIDC technology



ISO 15223-1 UDI Graphical Symbol 5.7.10

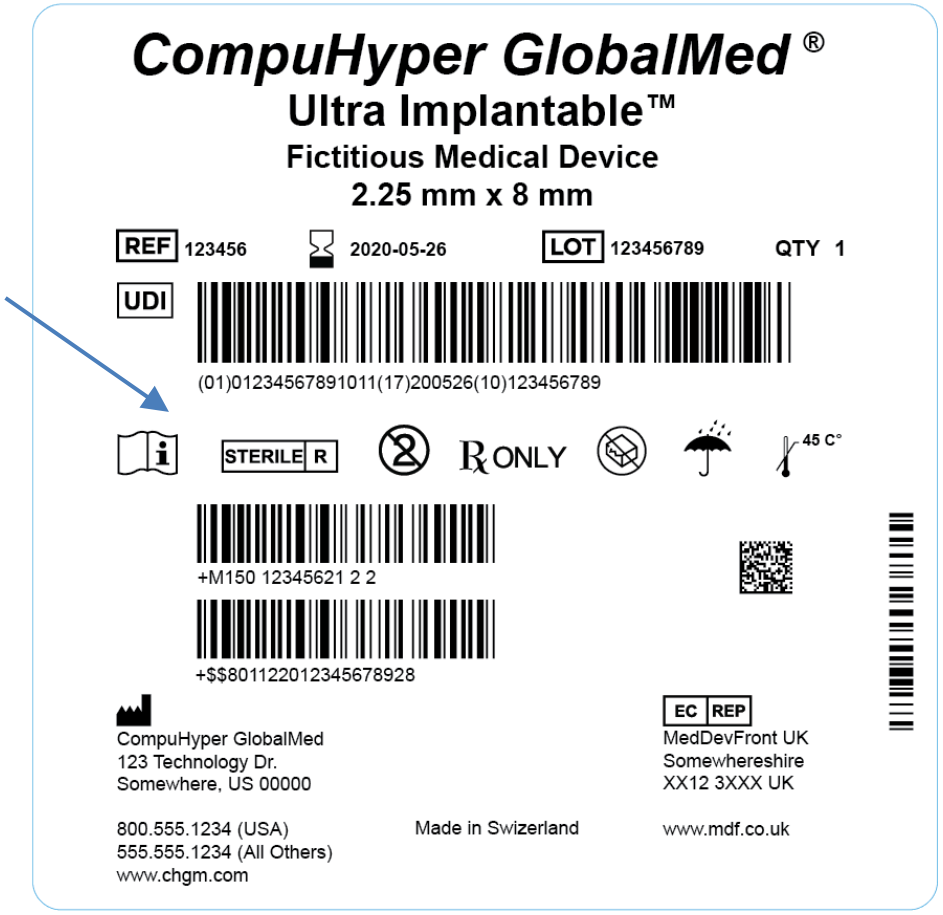
(Published, July 2021)

Genesis: Association of Health Care Resource & Materials Management (AHRMM) Learning UDI Community

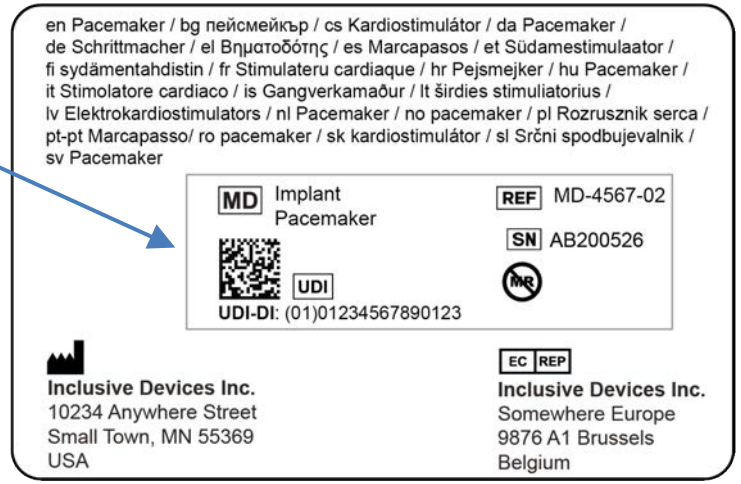
Healthcare Consumption of UDI

- Finished good barcoding, UDI symbol – use case examples

Multiple Barcodes



Implant Card



Healthcare consumption of UDI

The United States Centers for Medicare & Medicaid Services, (CMS)

Open payments

- 42 C.F.R. § 403.904 Reports of payments or other transfers of value to covered recipients.
  - (c) Required information to report.
    - (8) Related covered drug, device, biological or medical supply.
      - (ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

Future of UDI

NEST

National Evaluation System for health Technology coordination center, FDA Centre for Devices and Radiological Health (CDRH)

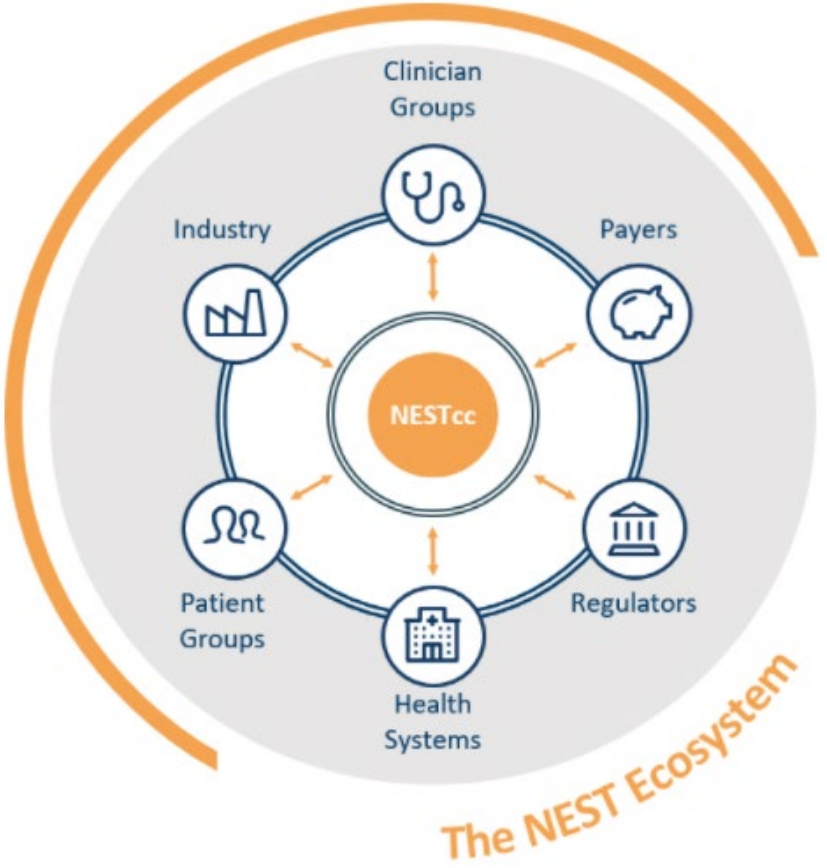
- Based on foundations of UDI

What is it?

- Voluntary data ecosystem consolidating Real World Evidence, (RWE) from clinical registries, Electronic Patient Health Records (ePHRs), medical billir claims, patient-mediated data and material logistics.

Why?

- When collected and used effectively, RWE can benefit all stakeholders in th NEST ecosystem by informing and empowering patients, accelerating medical device innovation, and improving health care outcomes.

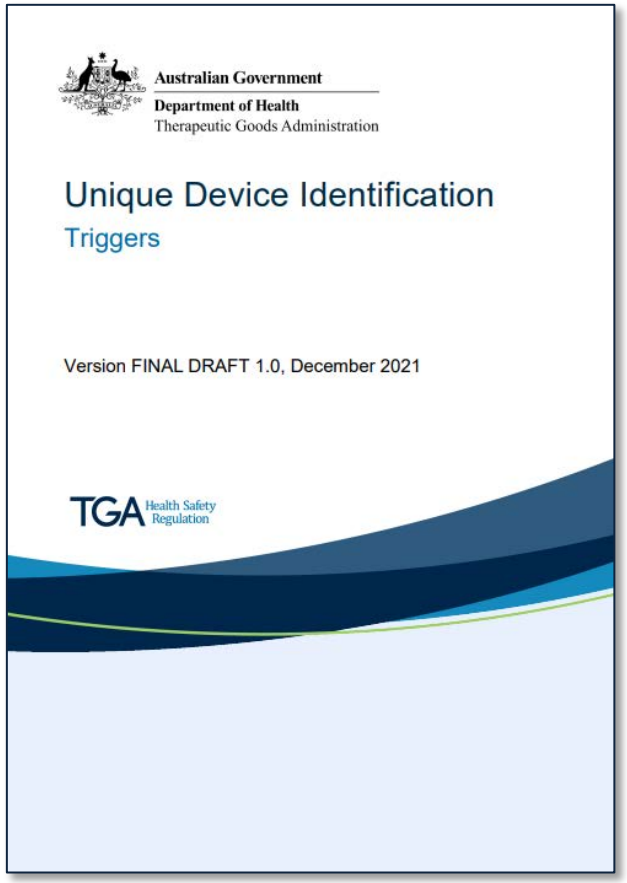


Agenda

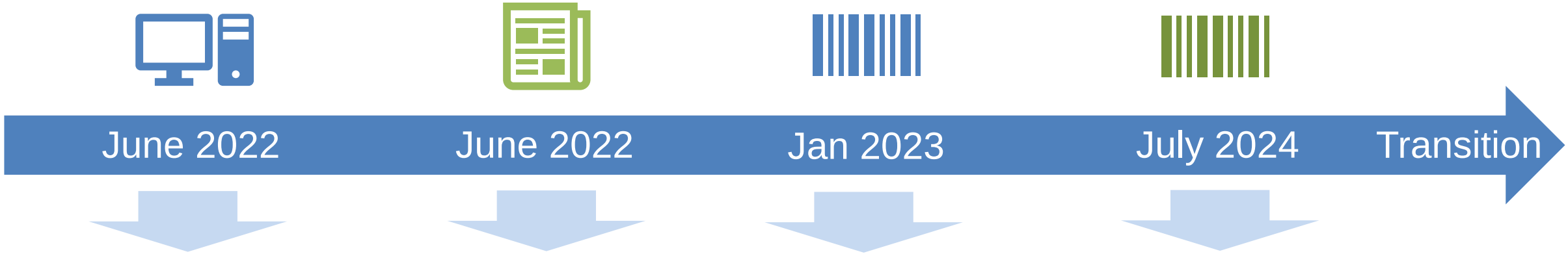
- Invited guest speaker – Roger Peterson, Arthrex
- **TGA UDI Project update**
- Questions and answers

Progress Update

- ✓ Successful connection of National Product Catalogue (beta) to the sandpit
- ✓ Project Plan for the ARTG / UDI alignment work
- ✓ Technical Working Group established and meeting regularly



Implementation Timing (Indicative)



Sandpit (beta) version of the Australian UDI database

For general use and testing

Third consultation paper

Voluntary compliance (Regulations in effect)

For high risk devices (Class II, III, AIMD)

Mandatory compliance for implantable devices

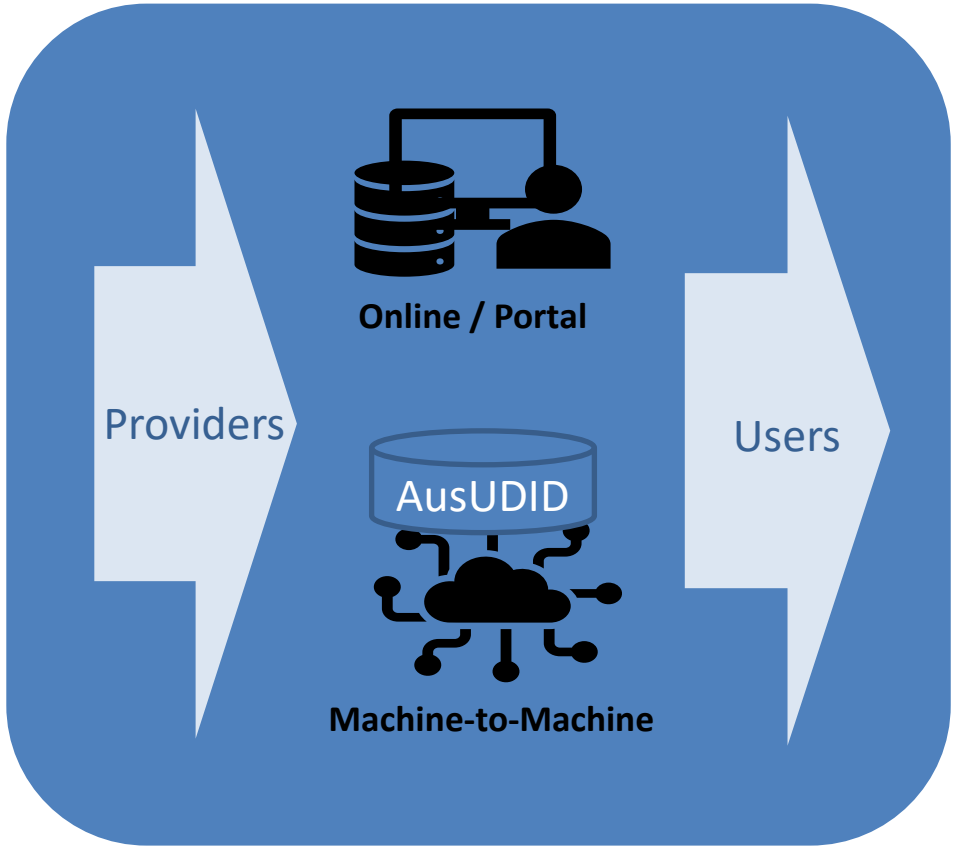
Allocation of UDIs, UDIs on labelling, and provision of data

Technical Working Group

ICT design, interoperability and data exchange between AusUDID and external ICT systems

Emerging themes/discussion

- Minimise any additional data elements
- Make the definitions for the elements clear to avoid confusion
- Allow changes to data
- Data upload preferences - M2M, HL7 Structured Product Labelling (SPL)
- Base initial considerations on U.S. FDA UDI
- Support for automated versioning of records
- The importance of a help desk for support
- Relationship between Catalogue number and UDI



AusUDID Sandpit (beta)

DRAFT

Early Adopters

- View and download UDI data, full device versions, history and relationships (CSV and M2M (HL7))
- Scan labels and barcodes
- Device data (based on GUDID) to support agreed Projects

Public

- View and download UDI data, full device versions, history and relationships (CSV)
- Scan labels and barcodes

Sponsors and Manufacturers

- Create, update and delete UDI records via the Portal
- Create, update, delete UDI records via M2M (beta NPC and other systems using HL7)
- Bulk upload of new UDI records
- Link UDI to ARTG
- Sponsor access and authentication
- Manufacturer access and authentication
- Attach documents to UDI records
- Support clean-up of ARTG data and alignment / integrity with UDI

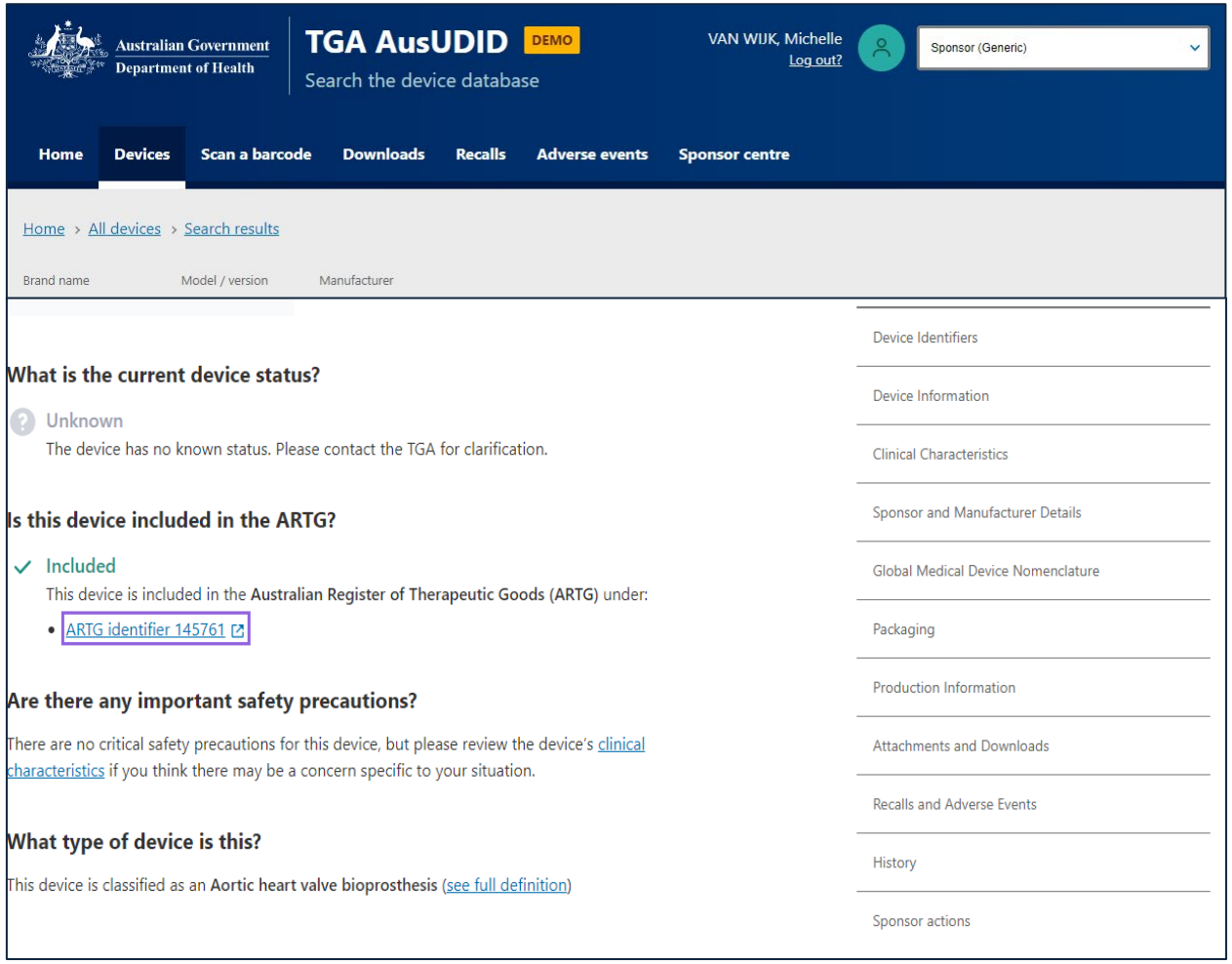
TGA

- Manage UDI record and device status
- Verify integrity of UDI data
- TGA Staff Centre (access operational statistics, manage and release reference data)
- Manage reference data sets

Sandpit – Some more specifics

- Onboarding process
- Separate logins for this environment
- Dedicated help desk support
- Guidance
- June webinar

Expressions of interest now open
Email **udi@health.gov.au**



Next Webinar – 17 May, 11.30-12.30pm AEST

Two invited guest speakers

- Software organisation that incorporates UDI in clinical and other systems
- Speaker from a UK hospital using unique device identification for products as an embedded part of the hospital processes

21 June, 11.30-12.30pm AEST - Sandpit

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To Inform the Regulatory Framework

UDI Consultation 3

Focus areas include

- Impacts of accepting both U.S. and EU labels and data
- Transition approach

- Likely to be from June 2022 using the TGA Consultation Hub
- Notification to existing sponsors and UDI stakeholder list
- udi@health.gov.au

How did we go?

LIVE POLL

Michelle is currently reading over your submitted questions.

We will be back shortly for Q&A

More Information

TGA website	https://www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
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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

Questions?

Website and Links

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
Previous webinars	https://www.tga.gov.au/unique-device-identification-system-communications-and-stakeholder-engagement

Contact Us

UDI Project

udi@health.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration