Australian Government
Department of Health
Therapeutic Goods Administration

Establishing the Australian Unique Device Identification (UDI) system

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Dr Jasjit Baveja
Senior Manager, Regulatory Affairs and Procurement, Ph.D.
Medical Technology Association of Australia
ARCS Annual Conference 2022

Michelle van Wijk
UDI Project Manager
Medical Devices Post Market Reviews and Reforms Section
Australian Government Department of Health, TGA
ARCS Annual Conference 2022

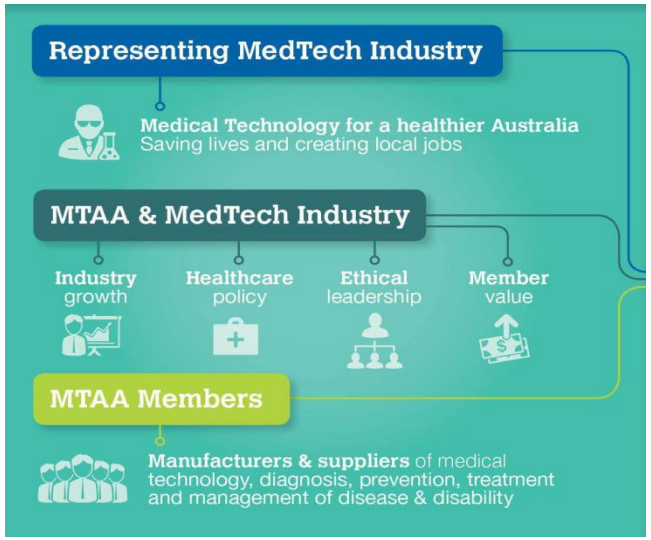
MTAA Medical Technology ASSOCIATION OF AUSTRALIA

TGA Health Safety Regulation

This is a joint presentation

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

TGA Health Safety Regulation



The Australian Government is in caretaker mode and in accordance with the caretaker conventions I will be limiting my statements today to factual issues and matters of administration.

Purpose of today's presentation

- What is Unique Device Identification?
- What does this mean for patients, hospitals, e-health records and supply chain?
- Establishing the Australian UDI system – progress to date
- What does this mean for manufacturers?

Background and key drivers

Worldwide recognition that, in the interests of patient safety and improved industry outcomes, the ability to unambiguously identify medical devices is essential

Demand for improved traceability of medical devices in the supply chain

Review of Medicines and Medical Devices Regulation

2019 TGA Action Plan for Medical Devices

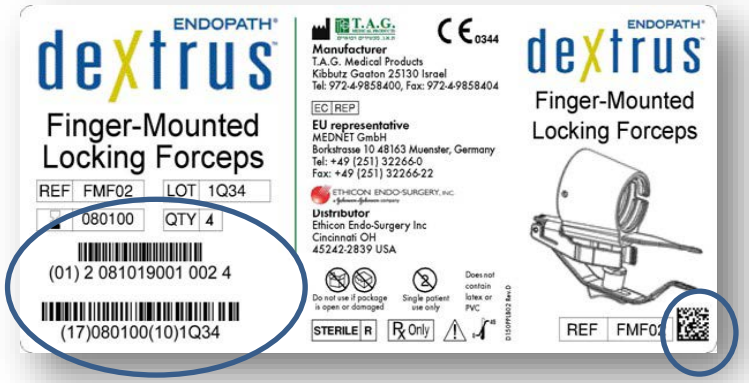
Senate Community Affairs References Committee Report

2013 UDI Guidance
2019 UDI Application Guide

What is Unique Device Identification?

- A globally unique series of characters that allows the unambiguous identification of a specific model of device on the market
- Created through a globally accepted standard and
- Applied to the device packaging (or device itself) and every level of packaging

GS1 Australia



Model Information

- Device Identifier (DI)
- A globally unique code specific to a model of medical device
- Used as the access key to data stored in the UDI repository

(01) 2 081019001 002 4

Production information

- Production Identifier (PI)
- A code that identifies the unit of device production
- There are different types, and the production identifier includes serial number, lot/batch number, Software as a Medical Device (SaMD) version, manufacturing and/or expiration date
- Not stored in the repository

(17)080100(10)1Q34

Example GS1 UDI

What are the benefits (why is it important)?

Patients:	**Faster and more accurate identification of patients who have devices that are included in a recall or safety action** **Help prevent recalled or expired products from being used in care process** **Enable accurate, real time details within digital health records**
Recalls:	Prevent use of recalled products, and enhance surveillance activities
Healthcare:	More reliable and efficient system of tracking and tracing medical device issues
Point-of-Care:	Ensuring correct product is utilised and recording of data in Electronic Health Record and Patient Implant Cards
Research:	Comparative studies on product, treatment outcomes or patient care Automation of accurate product data into registries to support research and monitoring activities
Supply Chain:	Tracking use of Product, Lot Numbers and Expiry Easier identification of recalled products within inventory Enablement of consistency in data capture capability across all products supporting greater automation
Commerce:	Improving accuracy in transactional, analytical and contractual processes
Reimbursement:	Accurately identify devices for reimbursement requirements
Anti-Counterfeiting:	May enable additional preventative measures

Vision – globally unique device identifiers

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衛 生 福 利 部
Ministry of Health and Welfare
促 進 全 民 健 康 與 福 祉

Government of Canada

FDA U.S. FOOD & DRUG ADMINISTRATION

European Commission

Australian Government
Department of Health
Therapeutic Goods Administration

NATIONAL MEDICAL PRODUCTS ADMINISTRATION
国家药品监督管理局

GOV.UK
Medicines & Healthcare products Regulatory Agency

pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Issuing Agency

Public Access

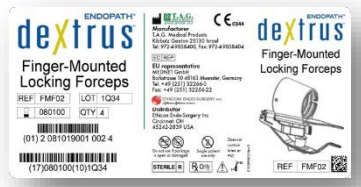
UDI

UDI repository (AusUDID)

Registry

Manufacturer

UDI data



Australian Sponsor

Hospital

The UDI database

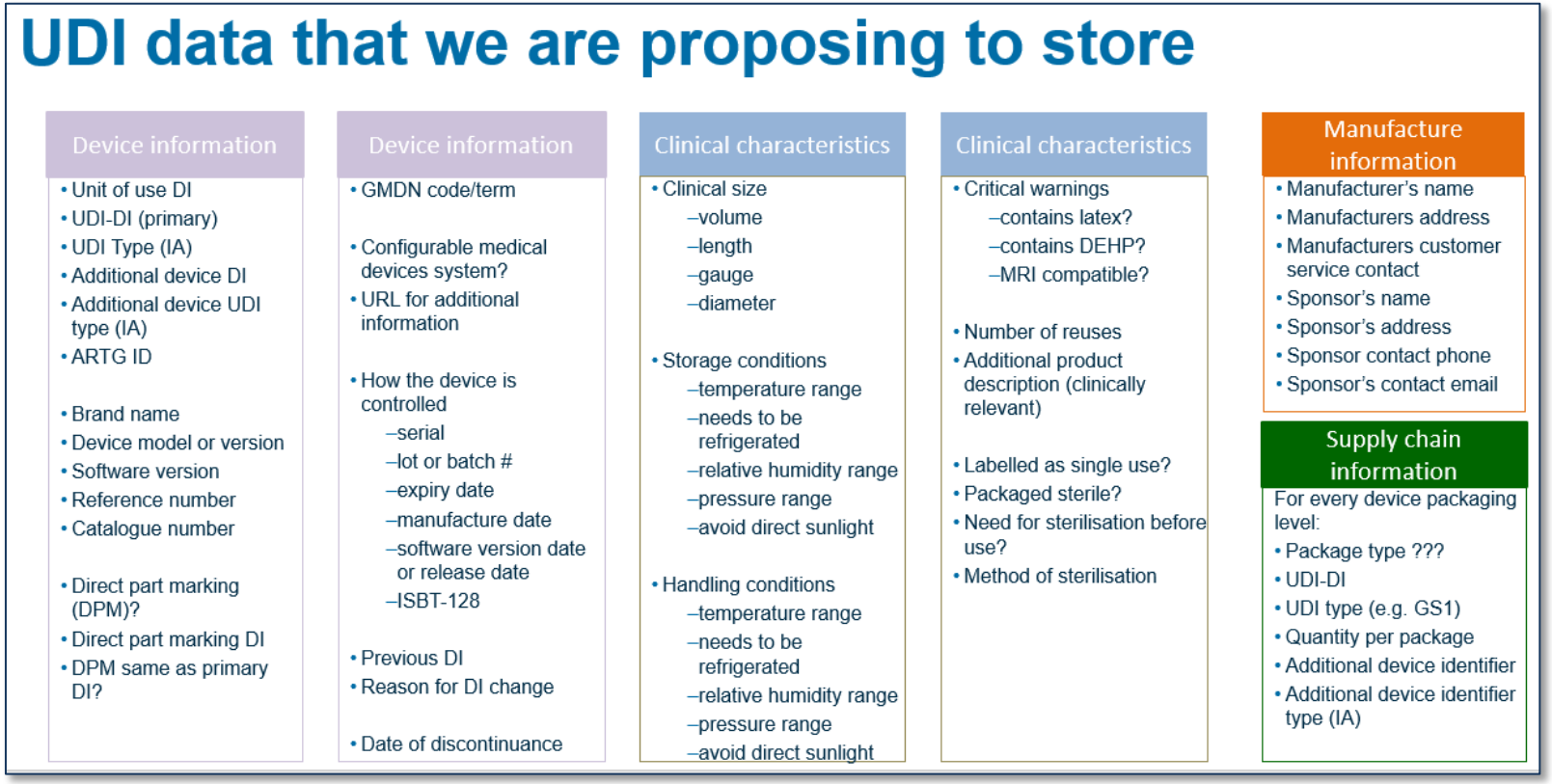
The Regulator's database

Contains static information
Does not include production information
Does not contain patient or personal data

Supply chain, hospitals, registries etc.

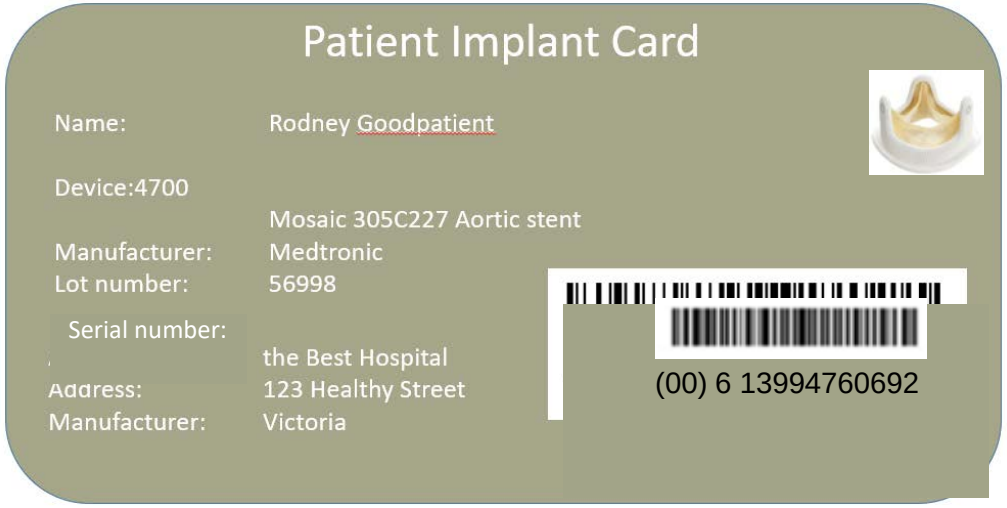
Will collect device data and production data (batch number, expiry date, lot number, manufacture date)

Will link to patient data (in hospital, registry and billing systems for example)



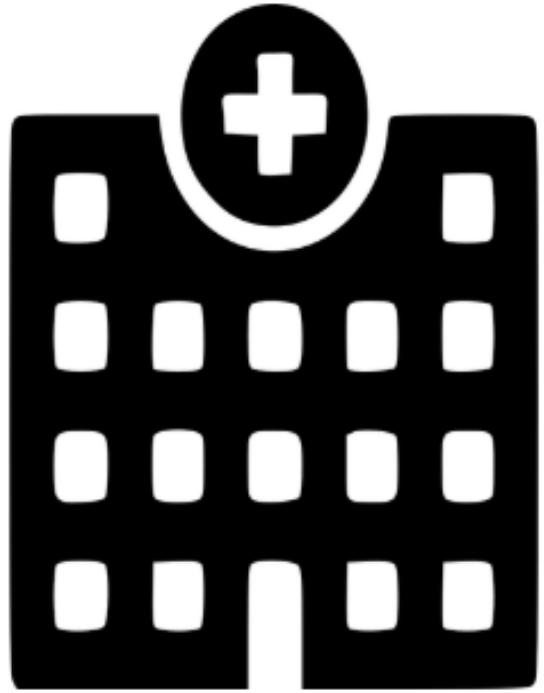
For patients

- Improved ability to find information about device options prior to surgery
- Help prevent recalled or expired devices from being used in care process
- Improved access to data about implanted devices through inclusion on Patient Implant Card, can potentially be included in discharge papers and digital health records (such as My Health Record)
- Ability to search other data sources using the UDI – for example recalls, adverse events, Australian UDI database
- Ability to scan device UDI to link directly to device data held in Australian UDI database. Includes ability to see production information (lot number etc.) noting this is not stored in the Australian UDI database



For hospitals and e-health records

- Enables tracing of devices implanted in patients
- Help prevent recalled or expired devices from being used in care process
- Scan at point of care reduces errors with manual entry
- Publicly available access to the Australian UDI Database (search, scan, download)
- Automate the download of device data into local data sets
- Enables longitudinal analysis
- Limit free text
- Note mapping of data changes over time (where a new UDI might be created)
- Accelerate adoption using the UDI for Healthcare (UDI4H) and UDI for Registries (UDI4R) frameworks (UDI “in a box”)



For supply chain

- Supports a future of improved visibility and traceability of products throughout the supply chain
- Supports improved consignment management
- Enables greater automation and data capture, reducing errors and manual intervention in supply chain processes
- Greater inventory accuracy in real time
- Less reliance on manual processes to manage products
- Improved accuracy and timeliness where devices are used, enabling automation of ordering, reconciliation and reimbursement
- More accurate data capture to support improved analytics, especially in areas related to patient level costing, value based health and procurement
- Common business language

TGA will build and manage the UDI system

Greater benefits for patients if

UDI is adopted in hospital and other systems

Cerner

HealthShare Victoria

Ramsay Health Care

My Health Record

AOANJRR Australian Orthopaedic Association National Joint Replacement Registry

AUSTRALIAN Breast Device REGISTRY

NSW GOVERNMENT HealthShare

Epic

SAP S/4HANA

National Capital PRIVATE HOSPITAL by Healthscope

Queensland Government Queensland Health

Australian Government Department of Health

Celebrating 100 YEARS OF HEALTH

Prostheses List

AUSTRALASIAN PELVIC FLOOR PROCEDURE REGISTRY

Purpose of today's presentation

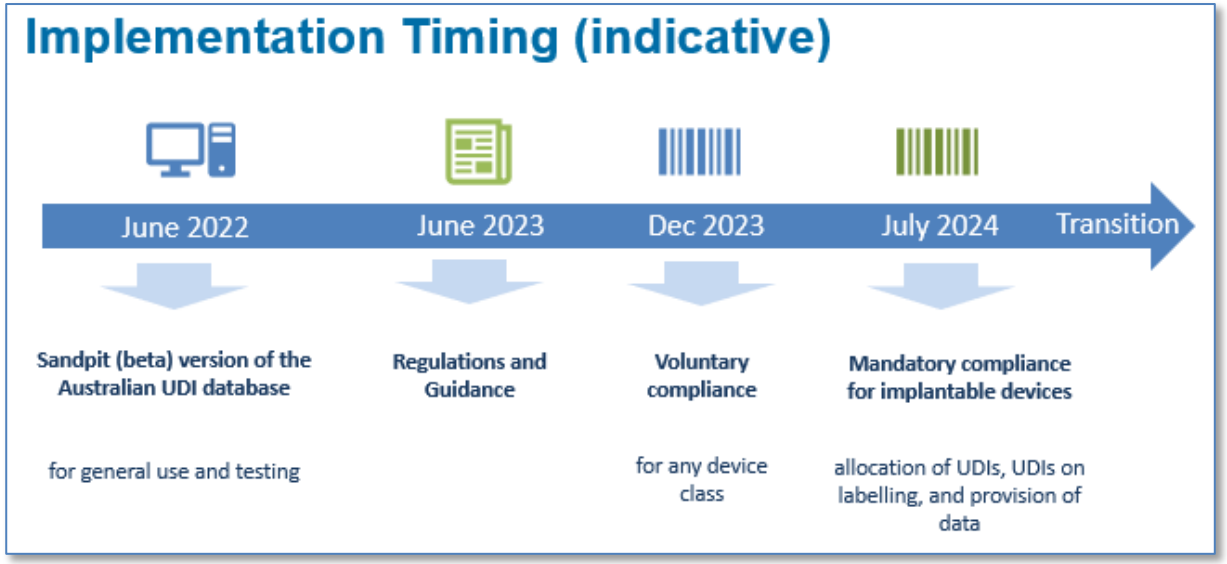
- What is Unique Device Identification?
- What does this mean for patients, hospitals, e-health records and supply chain?
- Establishing the Australian UDI system – progress to date
- What does this mean for manufacturers?

UDI development – four streams in parallel

- Engagement
- Regulations
- Database and technical solution
- Adoption

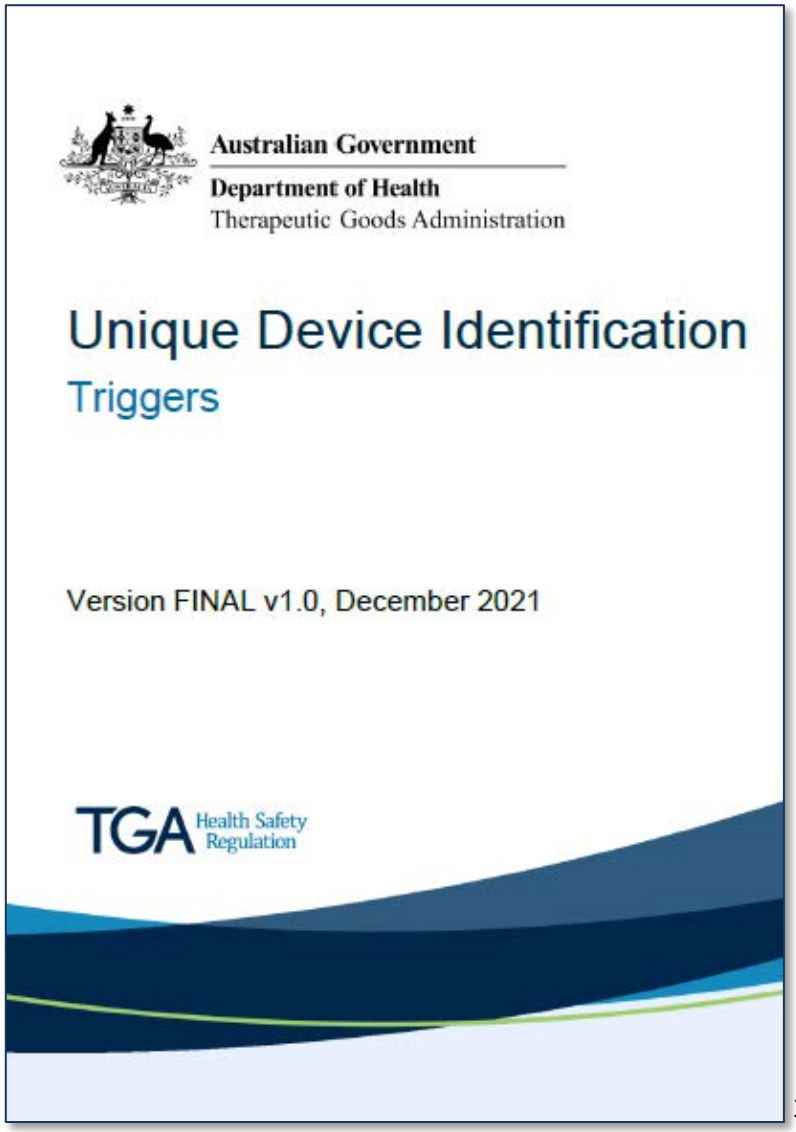
Timing

- Sandpit version available June 2022
- Regulatory consultation 1H 2022
- Voluntary compliance 1 January 2023



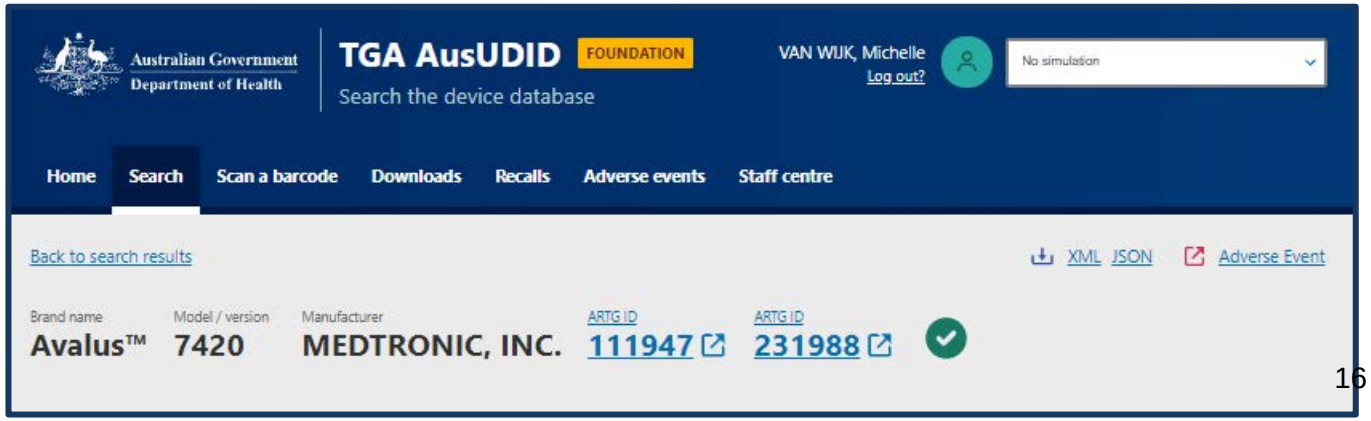
Progress to date

- Approval and funding to build the Australian UDI database within a four year timeframe
- Legislation changed to allow for the TGA to collect UDI data
- Extensive consultation – including ‘lessons learnt’
- UDI Triggers Working Group complete and final report produced
- Technical Working Group established
- Early Adopter Projects (UDI4H, UDI4R)
  - Qld Health Early Adopter Project - scoping continues
    Likely to be expanded to include mesh devices (such as hernia mesh)
  - Discussions continue with a second jurisdiction
- Successful connection of National Product Catalogue (beta) to the sandpit AusUDID
- ARTG/UDI alignment work being planned
- Planning started for adopting UDI in other TGA processes such as recalls and adverse events



Australian UDI database

- Contemporary design – including the use of APIs to enable interoperability
- Ability to download publicly available data using a variety of standards (exploring Health Level 7 standards SPL and FHIR, JSON, CSV for example)
- Full database or regular changes
- Minimal free text
- Links to existing reference numbers (catalogue #, ARTG ID, Prostheses List billing code)
- Snapshot of UDI records over time, ability to see data changes and UDI Device Identifier changes
- Publicly available through a portal (no login)
- Historical and current data
- ‘Sandpit’ version as well as production
- Joined-up data sets (future state)
- Static data only

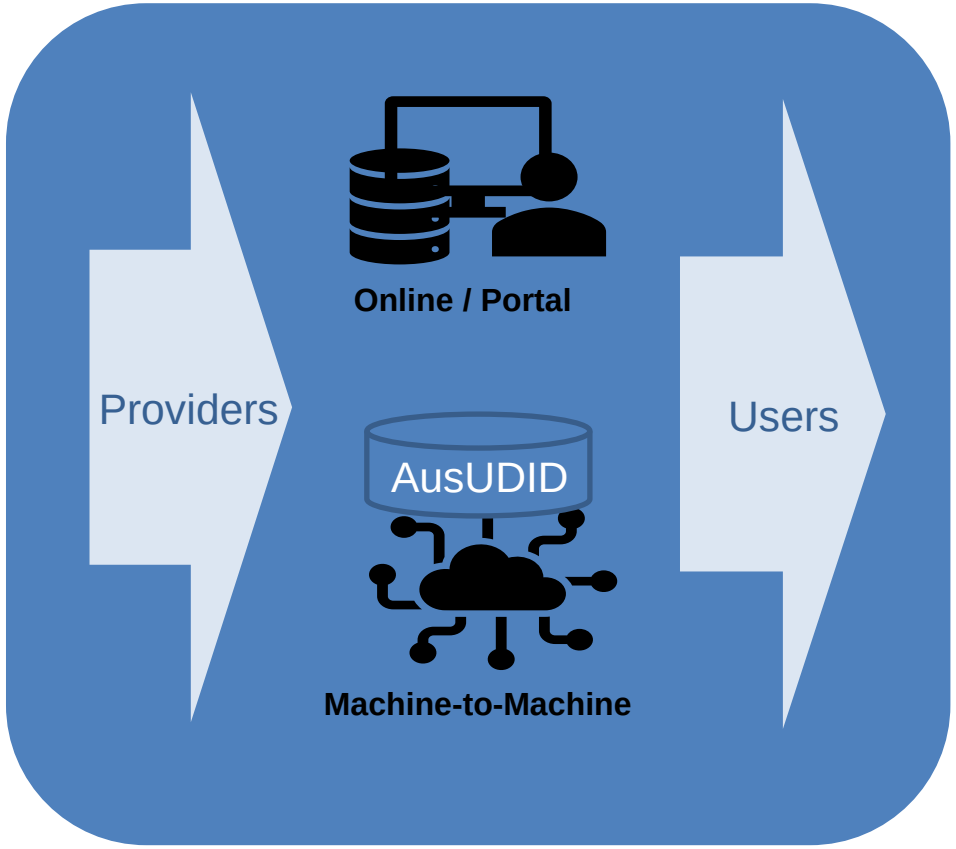


Technical Working Group

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



Early adopter projects

- To enable the early use of / experiments in using the UDI throughout the broader healthcare system
- Project 1 – government public hospitals (Queensland)
- Ongoing discussions with registries, and software providers

Benefits

- Use of identifiers in hospitals and health system
- Improve speed of uptake in health
- Information gathering (issues, costs etc.) to inform planning
- Re-usable framework (UDI 4 Hospitals (UDI4H))

Qld early adopter project - considerations

Queensland Government
Queensland Health

Hospitals
Inventory control


Surgery


Patient Implant Card
Discharge papers


Public patient
Private patient

PRO

Patient
Outcome Analysis

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Registries

Procurement and supply chain

My Health Record
Electronic Medical Record
Non-Electronic Medical Record

$ Invoices

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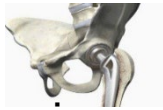
Department of Health
Therapeutic Goods Administration

Manufacturers

Recalls


Devices

National Product Catalogue

Issues affecting adoption

- Lack of translation between different issuing entities
- Preparation time and costs
- Purchasing uses “REF” or catalogue numbers
- UDI carrier being easily identifiable

UDI

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

Collaboration and engagement

- Manufacturers
- Sponsors
- Healthcare providers (hospitals etc.)
- Industry and peak bodies
- Issuing Agencies
- Patients and patient advocates
- Researchers
- Other regulators
- Device registries
- State and Territory governments
- Distributors (Supply Chain)
- Funders
- Software developers
- Other Government departments and authorities

udi@health.gov.au

UDI hub - https://www.tga.gov.au/unique-device-identification-system

- Sandpit will enable focus on experience in using what has been built, opportunity for feedback and to make changes
- Webinars will continue, focus on guest speakers to benefit manufacturers and sponsors
- 9 webinars to date
- Other work will benefit from engagement:
  - Operational support
  - ARTG/UDI alignment project

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UDI Value – Manufacturer perspective

Pre-market

- A more robust pre-market assessment of medical devices due to the availability of better quality, evidence-based data that is presented consistently and which includes post market data and analysis
- Enhanced analysis and research through the uniform documentation of devices in electronic health records, clinical information systems, registries and other data sources

Post-market

- Enhanced effectiveness of post-market safety-related activities:
  - Improved complaint reporting
  - Monitoring of trends
  - Adverse event reporting

Supply and Clinical

- Improved traceability to end users
- Reduction in medical and surgical procedural errors by allowing HCPs and others to quickly trace a device and obtain vital information about it's characteristics
- Manage any potential shortages by knowing product location
- Enhance patient safety and treatment outcomes

Implementing UDI

Implementing UDI

Timing in different jurisdictions

2014	2019	2021	2022	2023	2024
		  	 		

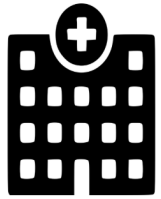
Unique jurisdiction requirements

Jurisdiction	Unique Requirement
USA	Text to describe the outer packaging of the product that allows users to understand higher level packaging configurations Requires entry of labeler DUNS number
EU	Requires Basic-DI
China	Requires the 20 digit medical insurance code
Saudi Arabia	Arabic version of the brand/trade name and the device description for home use devices If the barcode is linear, it must be a single barcode
Taiwan	Labels needs to state "containing DEHP (di-(2-ethylhexyl)phthalate) if applicable
Singapore	Need to use HAS issuing agency if the device is not marketed in US or EU

Data

- Data gathering
- Data submission
- Maintenance
- Changes to device

Supply chain and Clinical use



Supply chain

- Ability to use UDI in ERP and other systems
- Must work on conveyers
- UDI on multiple layers of packaging
- Different UDI standards
- Triggers – need for a new UDI-DI
- Changes to device data over time – from a supply chain perspective
- Supply-chain use of AIDC symbology vs other users

UDI

Clinical use

- Ability to scan and interpret different UDI carrier formats and standards
- Changes to device data over time – from a clinical perspective
- Incorporating device data into clinical device catalogues

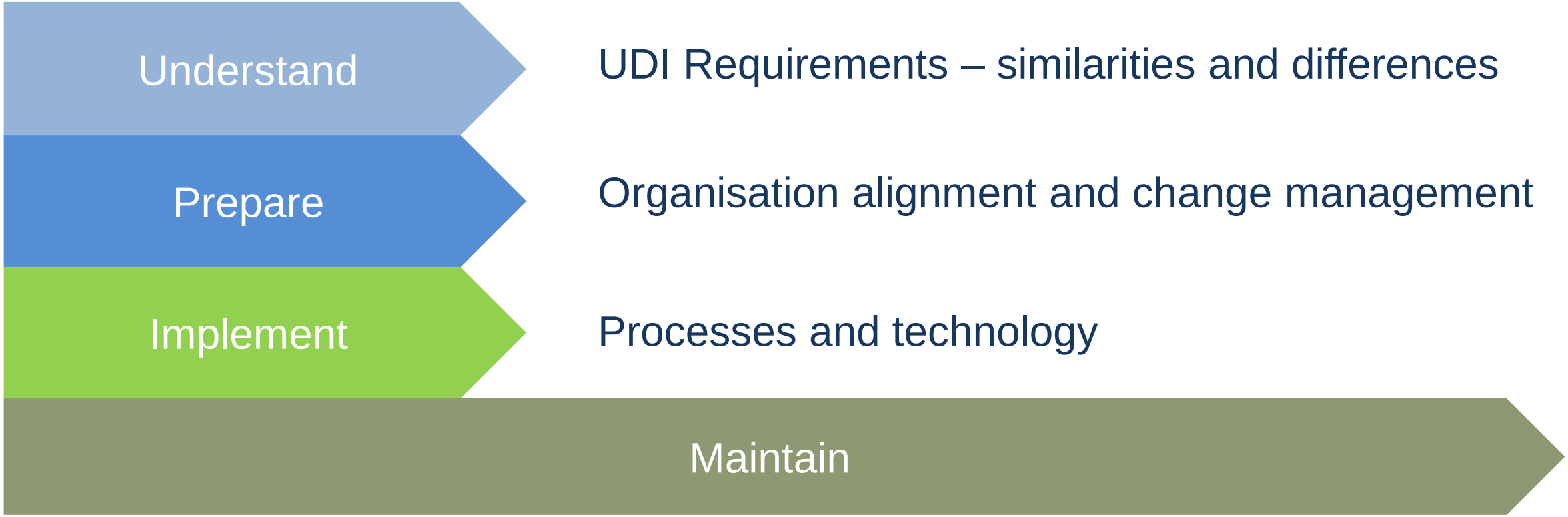
With thanks to Dennis Black, Becton Dickinson for the seesaw idea

Integration into the QMS

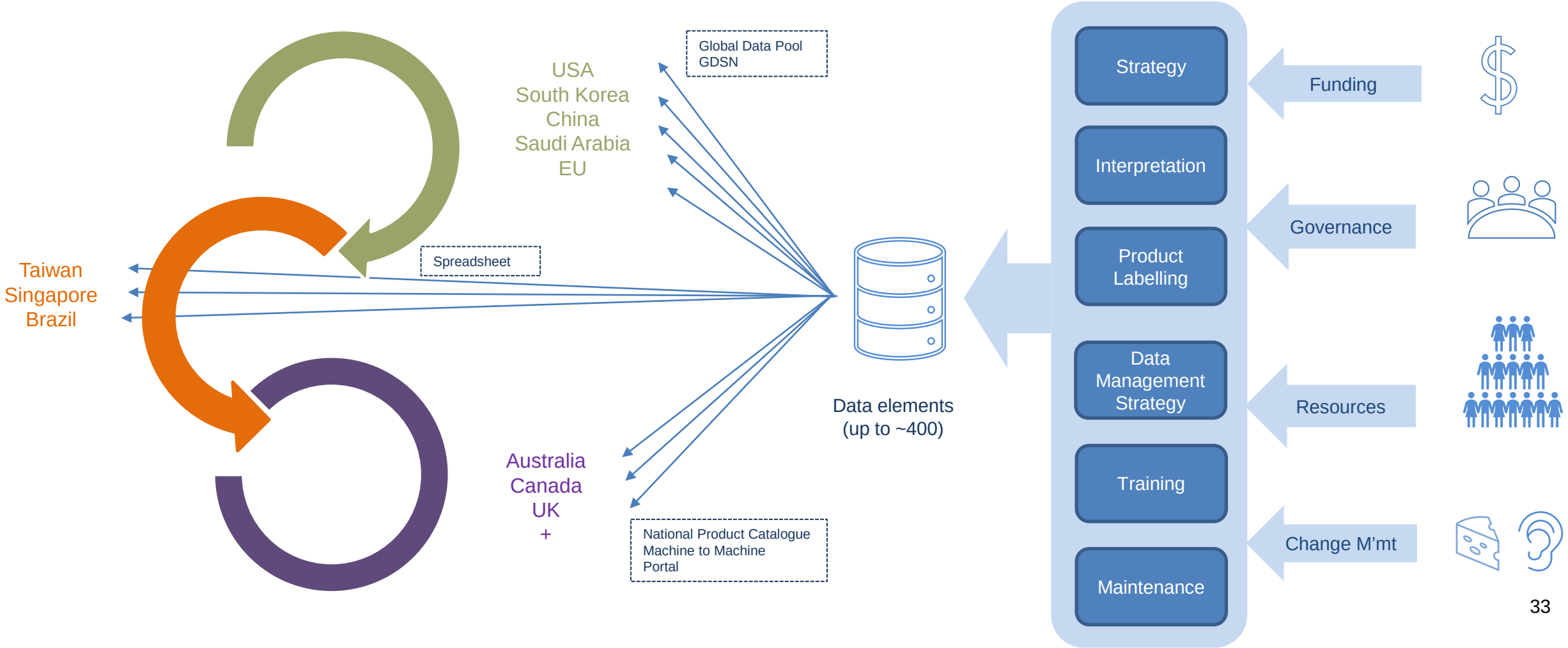
- Impacts the whole lifecycle of the device

- https://ec.europa.eu/health/system/files/2021-07/md_2021-19_en_0.pdf

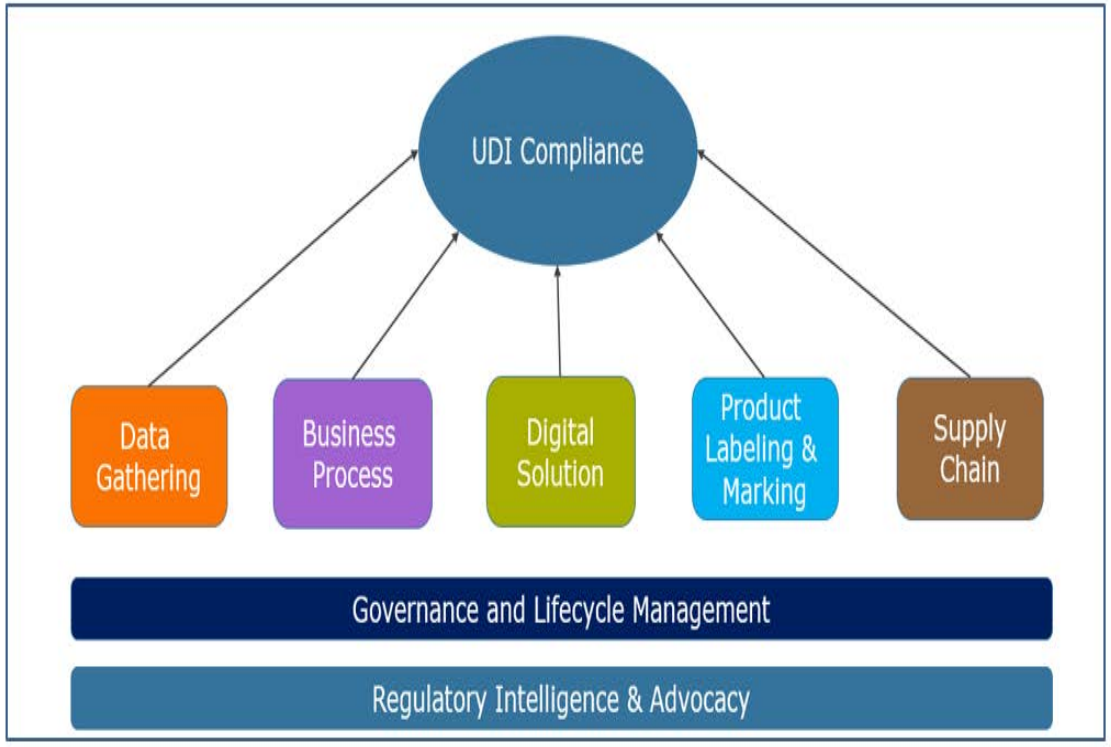
At a high level



Extent of impact for manufacturers



Industry examples



- **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.

Source: TGA UDI Webinar 7 – presentation by Debbie Connors, Smith + Nephew and TGA UDI Webinar 8, presentation by Roger Peterson, Arthrex

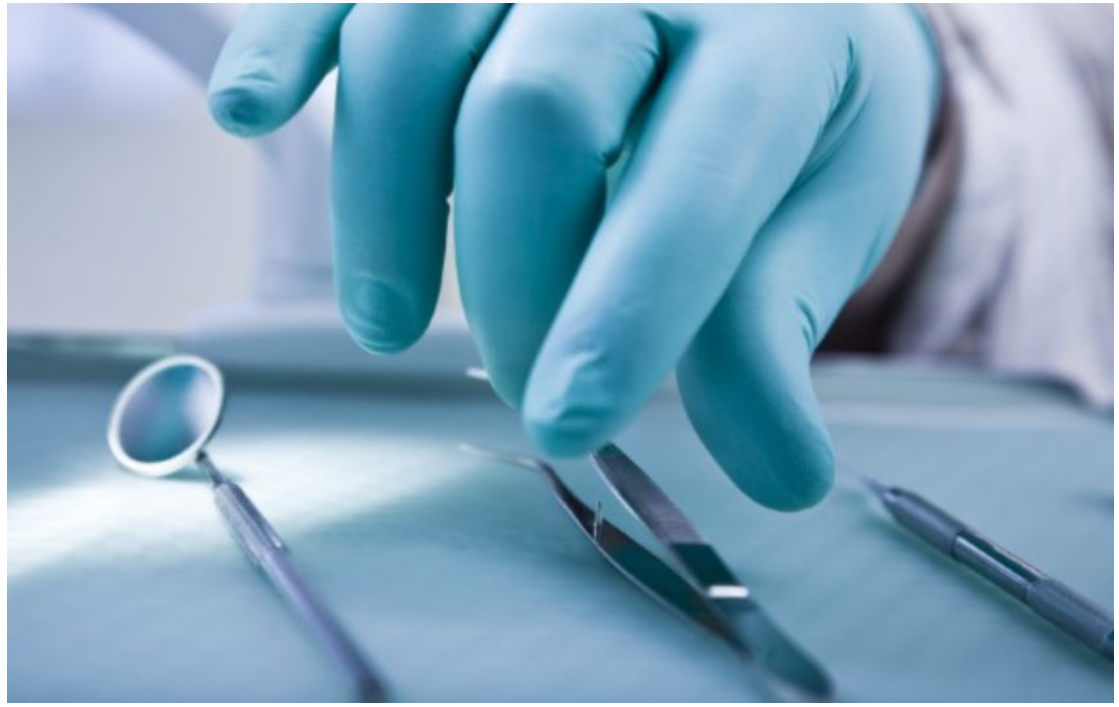
UDI Journey (experience with regulators)

- What some companies have done so far, most have implemented in US, Korea, Saudi Arabia
- Working with other regulators to influence direction of regulations
- Master database is built, and UDI tools have been identified
- Lessons learnt from other regulators
  - Global UDI strategy should be flexible to accommodate new and changing requirements
  - Establish one source of truth and data governance early
  - Maintain a global UDI Data Dictionary with clear definitions
  - Understand internal/external impacts of UDID Triggers
  - Scheduling/staging initial submissions based on volume
  - Review data before submission
  - Develop internal audit process
  - Different requirements in jurisdictions e.g. Fahrenheit vs Celsius, countries requiring entries in local language, difference in data field definitions
  - M2M has unique challenges

Challenge and request

Lack of harmonisation across countries is one of the biggest challenges and leads to additional administrative burden

- UDI triggers
- Data elements and their definition
- Scope of devices included
- Bar code requirements
- Direct marking
- Existing inventory and legacy products
- Lack of clarity around lowest level of UDI-DI



UDI success in Australia

- Globally harmonised regulatory frameworks and data elements
- Standardisation of issuing agencies
- Clear definition of requirements
- Appropriate support and guidance from TGA
- Sufficient planning time
- Adoption and use by healthcare providers
- No Australian specific attributes or requirements (other than ARTG in AusUDID)
- Ability to make corrections to the AusUDID without penalty
- Ability to submit in multiple formats - Manual/M2M etc.
- Open and transparent process during development of AusUDID, learning from experience (good and bad) from other jurisdictions, IT system proves reliable and stable, technical support during data upload
- Meeting the intention of UDI as a global system for clearly and accurately identifying a device through distribution and use via alignment to global data elements/triggers e.g. US FDA GUDID.

What should local sponsors be thinking about?

- Globally harmonised regulatory frameworks and data elements
- Communication with manufacturers
- Time/resource/system requirements to provide data to TGA
- Changes to systems and processes if required
- How to provide data and maintain it over time
- Model of device level, not “inclusion” level (Australian Register of Therapeutic Goods)
- One UDI record if the same model of device has multiple sponsors

Call to Action

- Participate in TGA activities – Working Groups, Early Adopter Projects, Consultation (June 2022)
- Reach out internally to learn from UDI experience already in your organisation, share this with TGA and MTAA
- Give the TGA your feedback on the look and feel and usability of the AusUDID before the start of voluntary compliance
  - register to use the Sandpit between July and December 2022
  - this will help to ensure there are a diverse range of sandpit users to maximise the feedback on usability before the launch for voluntary compliance
- Join the MTAA UDI WG
- Attend one of the monthly TGA webinars (11.30-12.30 on the third Tuesday of every month) – they are recorded
- Check in regularly at the TGA UDI web hub
- Email the TGA udi@health.gov.au or the MTAA jbaveja@mtaa.org.au

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

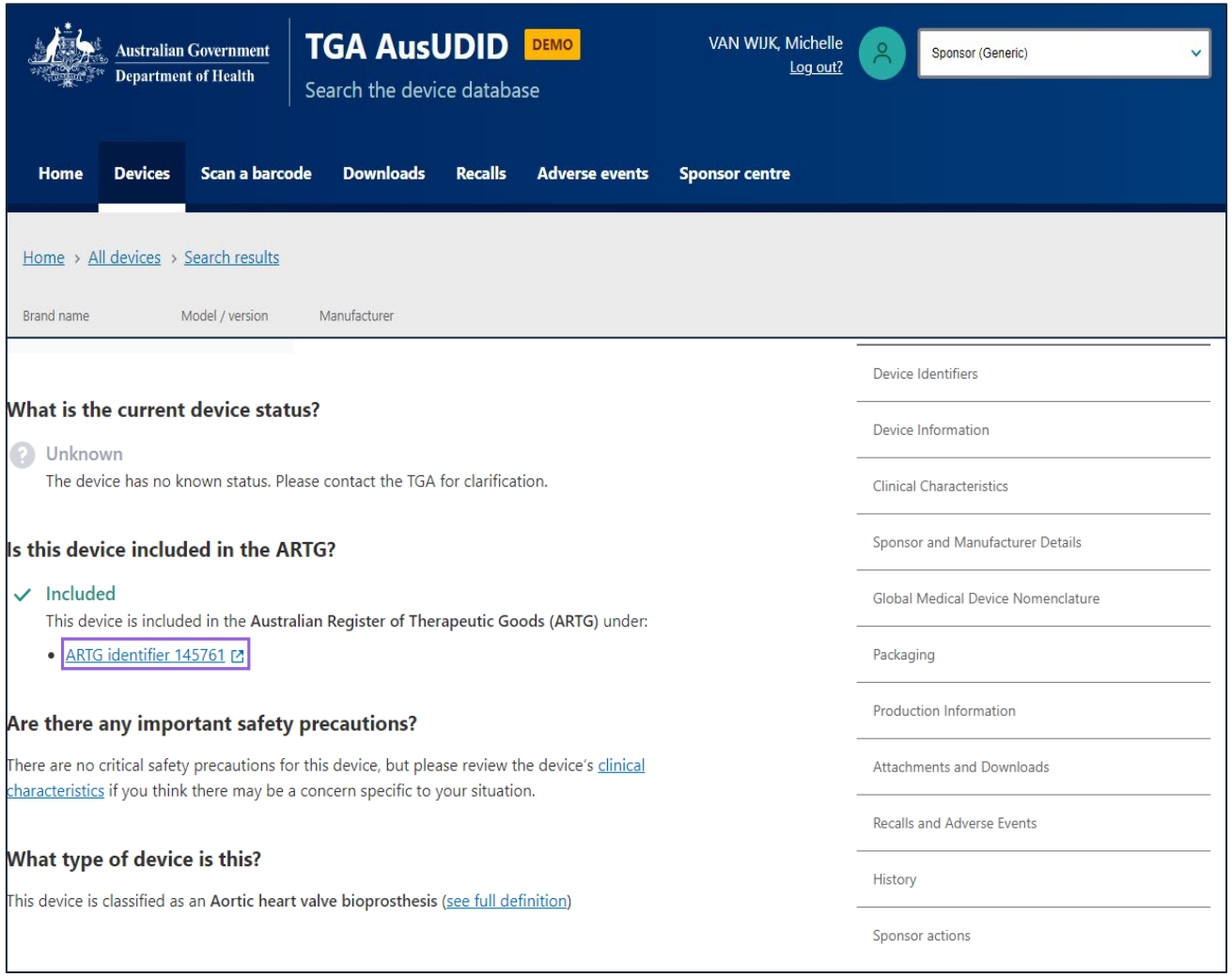
TGA

- 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 support
- Guidance
- June webinar

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



Questions?

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