Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar #1

An introduction to the Australian Unique Device Identification system

Tracey Duffy, First Assistant Secretary, Medical Devices Product Quality Division
Michelle van Wijk, UDI Project Lead, Medical Devices Surveillance Branch

Therapeutic Goods Administration

15 June 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: 165 283 9053

Purpose of today's presentation

To provide you with

- background to Unique Device Identification
- status of the Australian UDI implementation and progress to date
- opportunity to ask questions

Unique Device Identification webinar

- background to Unique Device Identification
- status of the Australian UDI implementation and progress to date
- opportunity to ask questions

What is Unique Device Identification?

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

HOME | ABOUT | NEWS | API | DOWNLOAD | HELP

DEVICE: Life Scope L (04931921101728)

DEVICE RECORD HISTORY | DOWNLOAD: XML | JSON | PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Life Scope L
Version or Model: BSM-2354A
Commercial Distribution Status: In Commercial Distribution
Catalog Number:
Company Name: NIHON KOHDEN CORPORATION
Device Description: Bedside Monitor

Primary DI Number: 04931921101728
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 690568050 *Terms of Use

CLOSE

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	No
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No

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

MMDR Recommendation 20
The regulation of medical devices by the Australian NRA is, wherever possible, aligned with the European Union framework…

2019 TGA Action Plan for Medical Devices – Parts 2 and 3:

- strengthen monitoring and follow up of devices already in use
- provide more information to patients about the devices they use

IMDRF

An **International Medical Device Regulators Forum Working Group** was established to create a framework for those regulatory authorities that intend to develop a globally harmonised approach to UDI. This work resulted in a set of guidelines and was completed in 2019.

FDA U.S. FOOD & DRUG ADMINISTRATION

The US FDA - UDI Final Rule implemented in 2013.
First compliance date September 2014

European Commission

MDR applies from May 2021

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

Model Information

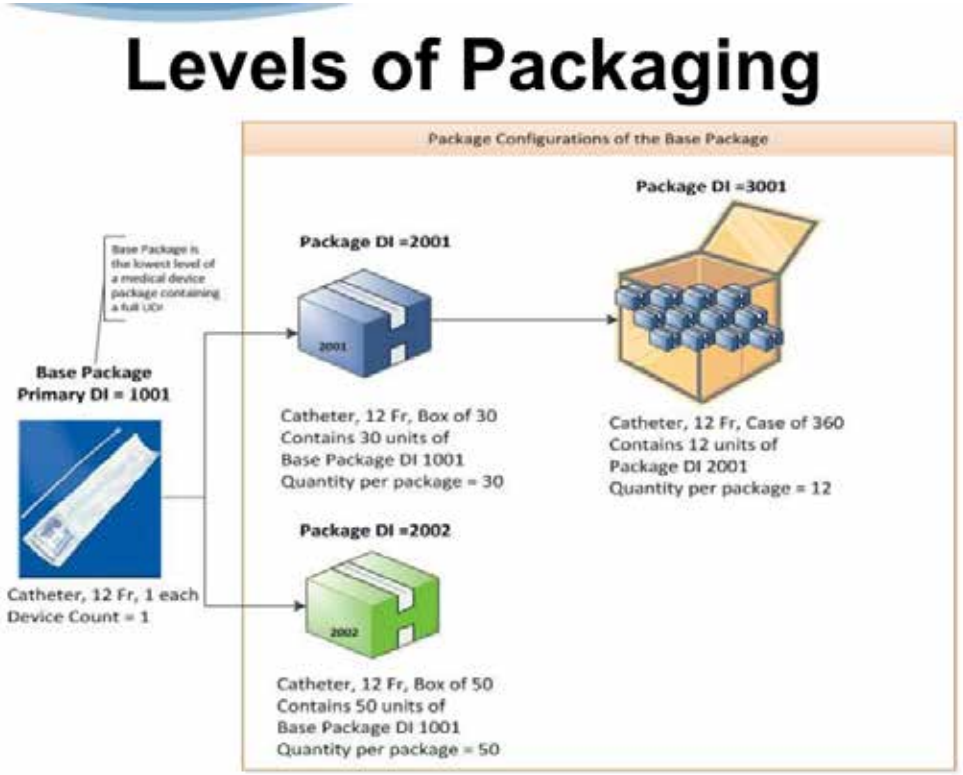
- Device Identifier (DI)
- A globally unique code specific to a model of medical device
- Used as the access key to data stored in the UDI repository

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

Example HIBCC UDI

Levels of packaging



Symbologies

Linear Barcodes

=/A9999004344T0480

2D Barcodes

+A999ABC123DE1/$$3221231LOT876S

Radio Frequency ID (RFID)

(01)09506000117843
(17)201231
(10)1234AB
(21)5678CD

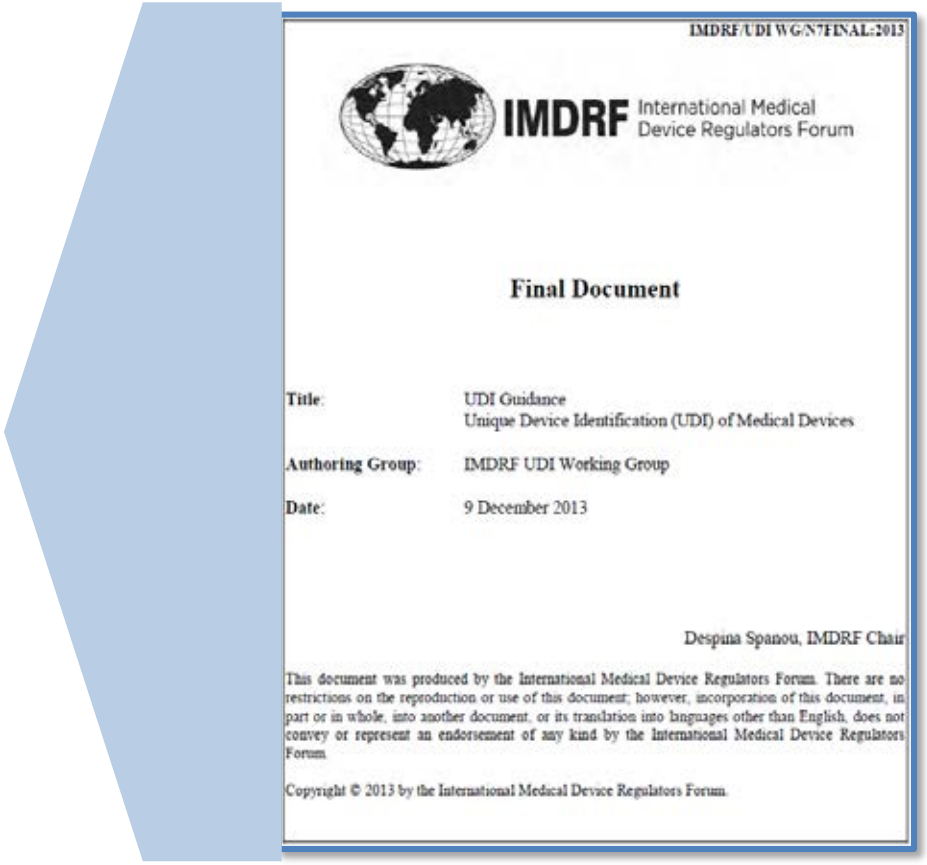
RFID

??? Future technologies

Source IMDRF

7 fundamental concepts of a globally harmonised UDI System

1. The UDI and UDI Carrier are based on standards
2. A UDI applied to a device anywhere in the world should be able to be used globally and to meet the UDI requirements of its regulatory authority
3. National or local identification numbers should not be a substitute for UDI
4. Regulatory authorities should not specify the procedure for modifying these UDI standards
5. The UDI core elements should not be modified
6. The UDID should use the Health Level 7 (HL7) Structured Product Label (SPL) and web-based interface for data submission
7. Every medical device needs to be identified by a UDI, unless it is exempted



IMDRF/UDI WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	UDI Guidance Unique Device Identification (UDI) of Medical Devices
Authoring Group:	IMDRF UDI Working Group
Date:	9 December 2013

Despina Spanou, IMDRF Chair

The UDI database

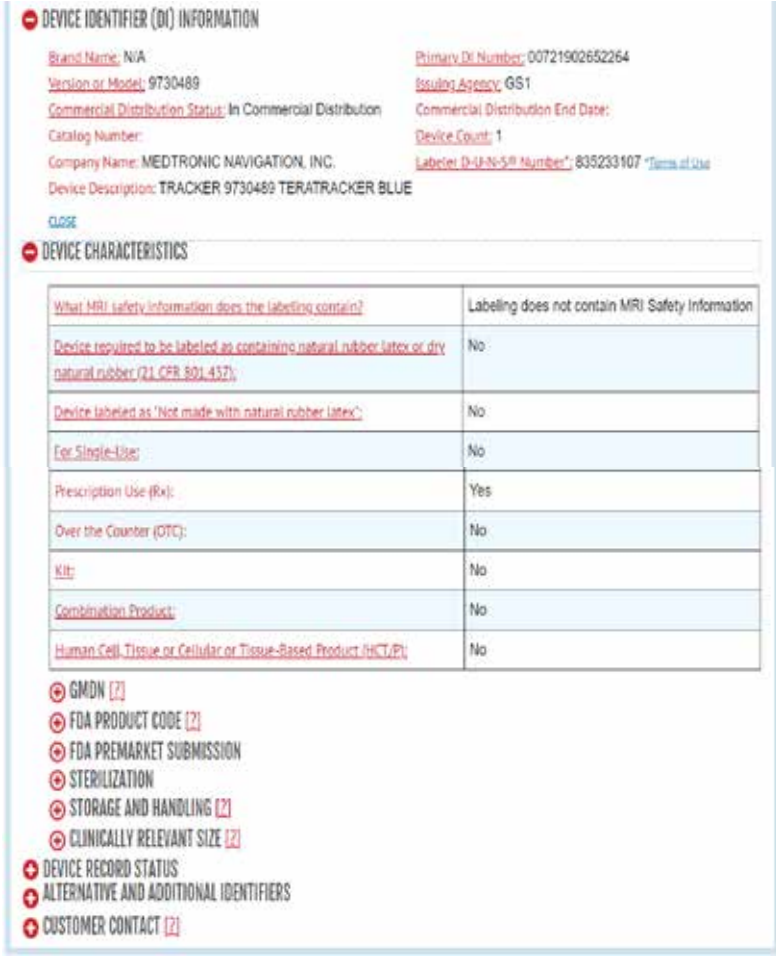
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

The Regulator's database

Only contains static information, and does not include the dynamic production information

Supply chain, hospitals, registries etc.

Will collect more information about the device, including the dynamic production data (batch number, expiry date, lot number, manufacture date)



DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: N/A
Version or Model: 9730489
Commercial Distribution Status: In Commercial Distribution
Catalog Number:
Company Name: MEDTRONIC NAVIGATION, INC.
Device Description: TRACKER 9730489 TERATRACKER BLUE

Primary DI Number: 00721902652264
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 835233107

CLOSE

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as 'Not made with natural rubber latex':	No
For Single-Use:	No
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN [?]
FDA PRODUCT CODE [?]
FDA PREMARKET SUBMISSION
STERILIZATION
STORAGE AND HANDLING [?]
CLINICALLY RELEVANT SIZE [?]
DEVICE RECORD STATUS
ALTERNATIVE AND ADDITIONAL IDENTIFIERS
CUSTOMER CONTACT [?]

What data are we proposing to store?

Device Information and Status

- UDI type (e.g. GS1)
- UDI-DI
- Quantity per package
- Additional device identifiers

to be provided in a related way for the entire packing hierarchy

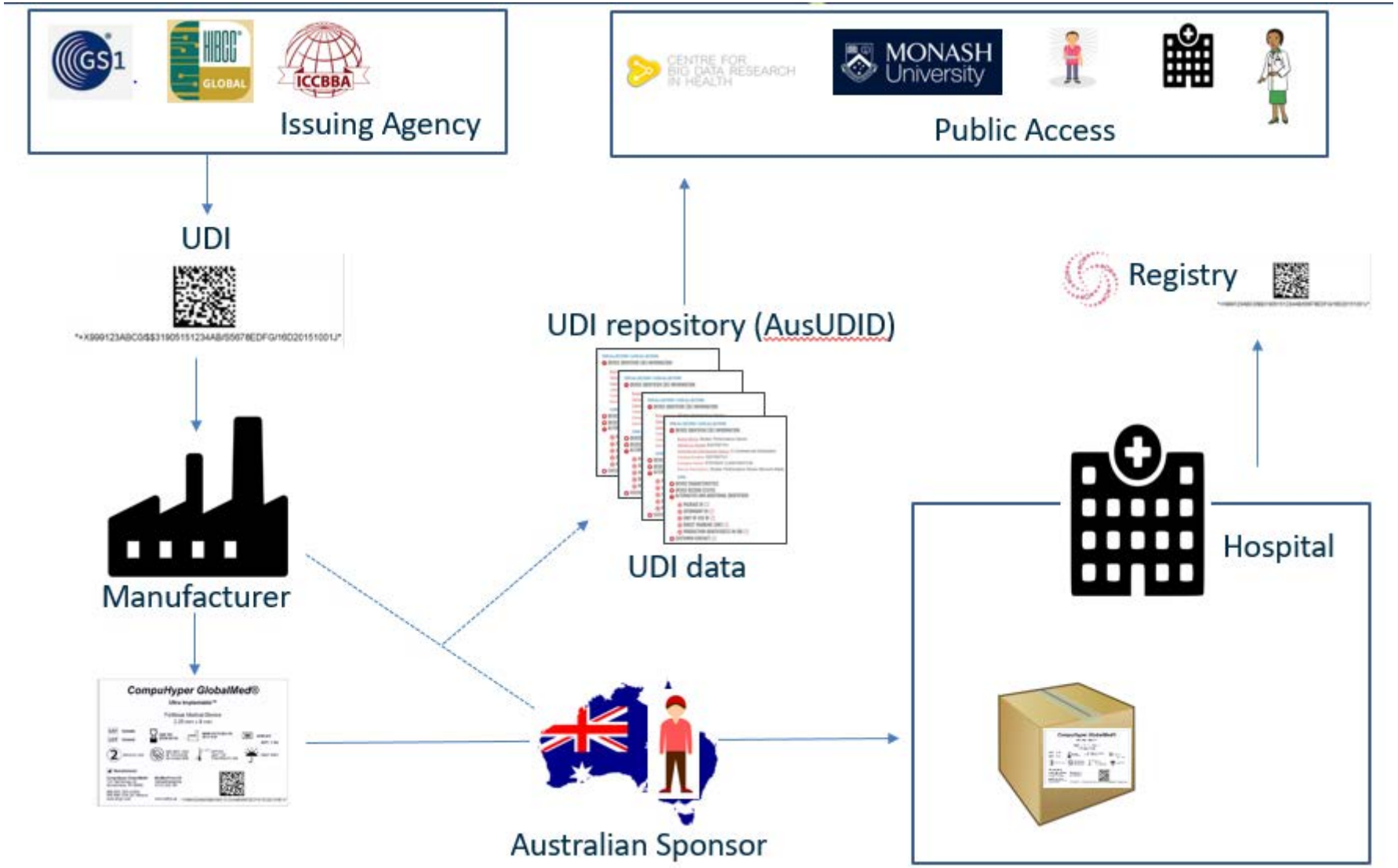
- Global Medical Device Nomenclature (GMDN) preferred code/term
- URL for additional information
- Configurable medical device systems

- Brand Name
- Device model or version
- Reference and/or catalogue number
- Additional product Description (additional clinically relevant information e.g. radio-opaque
- Date of discontinuance
- Authorized representative contact phone, email
- License and/or marketing authorization or registration number
- Package Type (e.g. each, shelf pack)
- Manufacturer's name and address
- Manufacturer's customer Service contact
- Authorized Representative name and contact (Regional representative responsible for the device

Device Characteristics

- How the device is controlled (serial, lot/batch number and/or expiration date (or manufacturing date) or software version or software release date)
- Restricted number of reuses
- Clinical Size (including volume, length, gauge, diameter)
- Storage & Handling Conditions (temperature range, needs to be refrigerated, relative humidity etc.). Handling conditions if difference to storage conditions
- Labelled as single use? (Yes/No)
- Packaged sterile? (Yes/No)
- Need for sterilization before use? (Yes/No)
- Method of sterilization
- Critical warnings or contraindications e.g. labelled as containing latex (Yes/no)
- Software Release Date (flag to indicate if software release data on the label)
- SAMD Version

Examples from IMDRF


Issuing Agency
Public Access
UDI
UDI repository (AusUDID)
Registry
Manufacturer
UDI data
Hospital
Australian Sponsor

What have we learned?

These will add value

- ü **Clarity of intent, benefits and clear guidance. In particular around definitions, labelling, data elements and roles and responsibilities**
- ü Create use cases for clarity and shared understanding
- ü Be clear in benefits for all stakeholders, especially for patients and healthcare such as hospitals and the hospital procurement areas
- ü Consider a pilot to promote clarity, especially around inventory and legacy products
- ü Ensure there is sufficient time for organisations to prepare
- ü Consider the data the manufacturers are already keeping and try to minimise the requirements around core data
- ü Understand the benefits of UDI-DI applied to levels of labelling

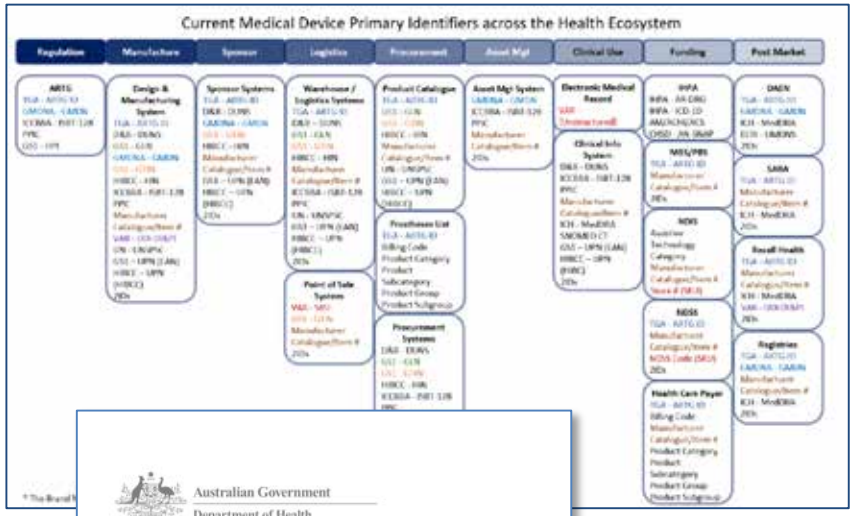
Some challenges to date

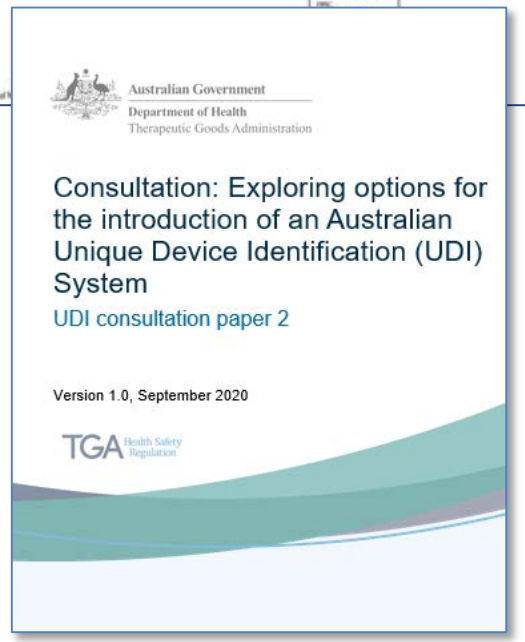
- ü What triggers the need for a new UDI (for example mergers)?
- ü Data quality and duplicates
- ü Existing inventory and legacy products (including reprocessing devices without direct marking)
- ü Responsibilities – manufacturers, labeller, brand owner etc.
- ü Ambiguity in requirements
- ü Clarity around lowest level of UDI-DI
- ü Class 1 high volume devices (if not exempted). For example contact lenses

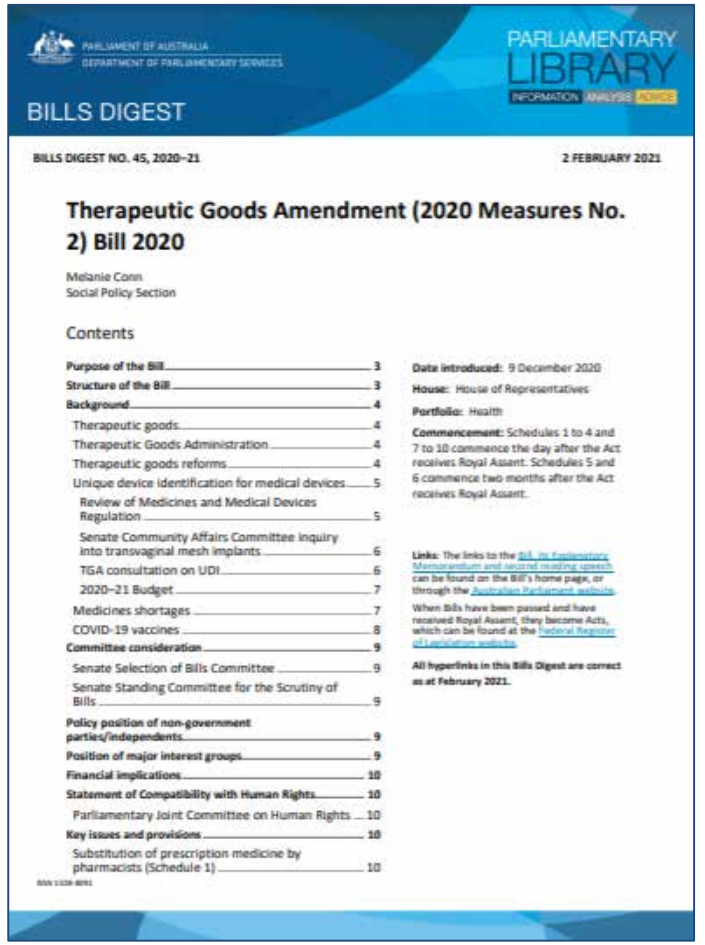
Unique Device Identification webinar

- background to Unique Device Identification
- status of the Australian UDI implementation and progress to date
- opportunity to ask questions

Progress and achievements







UDI Project established

Establishment of the Australian UDI database

8 streams:

1. Alignment with other regulators and organisations
2. Communications and change management
3. Technical – database and interoperability
4. Legal / legislative framework
5. Issuing Agency framework
6. Operational (labels etc.)
7. Plan for phasing (transition approach)
8. Governance

Sub-projects

GMDN

1. Automate GMDN updates in ARTG
2. Analyse and remediate 'linked' codes
3. UDI GMDN implementation
   i. Define requirements
   ii. Update legal framework

Publicly accessible data

1. Analysis and report on differences between EU (Eudamed) and TGA publicly available data

TGA Initial consultation complete and results published

Sought feedback on the proposal to introduce a UDI System in Australia, with the requirements aligned with the International Medical Device Regulators Forum (IMDRF) UDI Application Guide.

49 submissions

Industry
Industry associations
Research institutions/universities
Professional bodies
Consumer organisations
Government agencies

ü **A strong consensus for the need to introduce the UDI system in Australia**

ü **The majority considered that the TGA should be responsible for establishing and managing the repository, and that it should be linked to the ARTG as well as other databases**

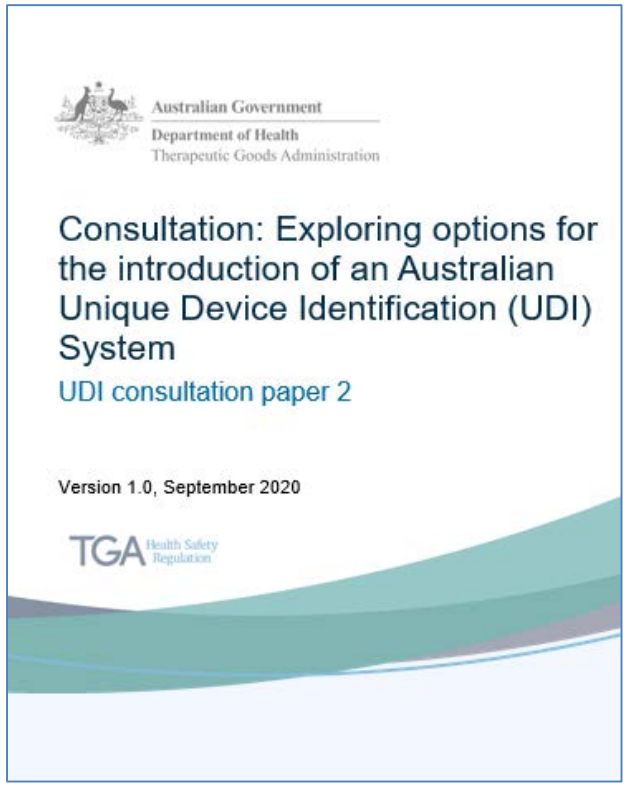
ü **Most submissions also supported the use of the IMDRF guidance as the basis for establishing the system**

Other feedback included:

- The Australian UDI requirements should be aligned with the IMDRF guidance, and be consistent with major jurisdictions
- Australia should accredit internationally recognised Issuing Agencies
- The need for clarity on who is responsible for submitting the UDI data into the UDI repository
- Strong support for a staged implementation of the UDI system and alignment with the European timeframes

Consultation 2 complete and results published

1. What are the benefits of an Australian UDI System across the broader health system?
2. Should the first phase of an Australian implementation be limited to a small number of high-risk devices?
3. If the Australian implementation fully aligns with the IMDRF guidance what will the impact be?
4. What mechanisms should be considered for submitting the UDI data to the TGA?
5. What might the benefits be for implementing the EU Basic UDI-DI in Australia?
6. What are the benefits of the Global Medical Device Nomenclature (GMDN) and how is it being used?



90 responses – mix of respondents

- Confirmed much of what we've heard through targeted discussions and lessons learnt from other jurisdictions
- Continued strong support for Australian UDI implementation
- Some concerns around cost for low-margin products
- Greatest benefits from a globally aligned system
- Introduced some new ideas – particularly around how we might leverage the U.S. implementation
- Still a number of key areas that require more work

Consultation 2 responses

Limited first phase	all respondents thought it will provide benefits, though some expressed concern at the overall implementation time. Differing views on scope, though majority see benefits in starting with high-risk devices. Most of the respondents are seeking a phased implementation, including a lead time of at least twelve months after the regulations have been finalised in order to prepare for the implementation
International alignment	strongly encouraged a system that mirrors the U.S. FDA or EU schemes. However almost an equal split of opinion on U.S. FDA or EU as the baseline / reference point. Strong concerns if Australia does vary from U.S. FDA or EU schemes. Many noted the benefits of the U.S. alignment as it is in use, while the EU is not yet implemented. Some feedback how to best leverage the U.S. implementation, including the GUDID data. The TGA could consider the benefits of leveraging data available from other sources (such as the GUDID and National Product Catalogue) and that may open up the opportunity for ‘simple experiments” across the broader healthcare environment

Consultation 2 responses

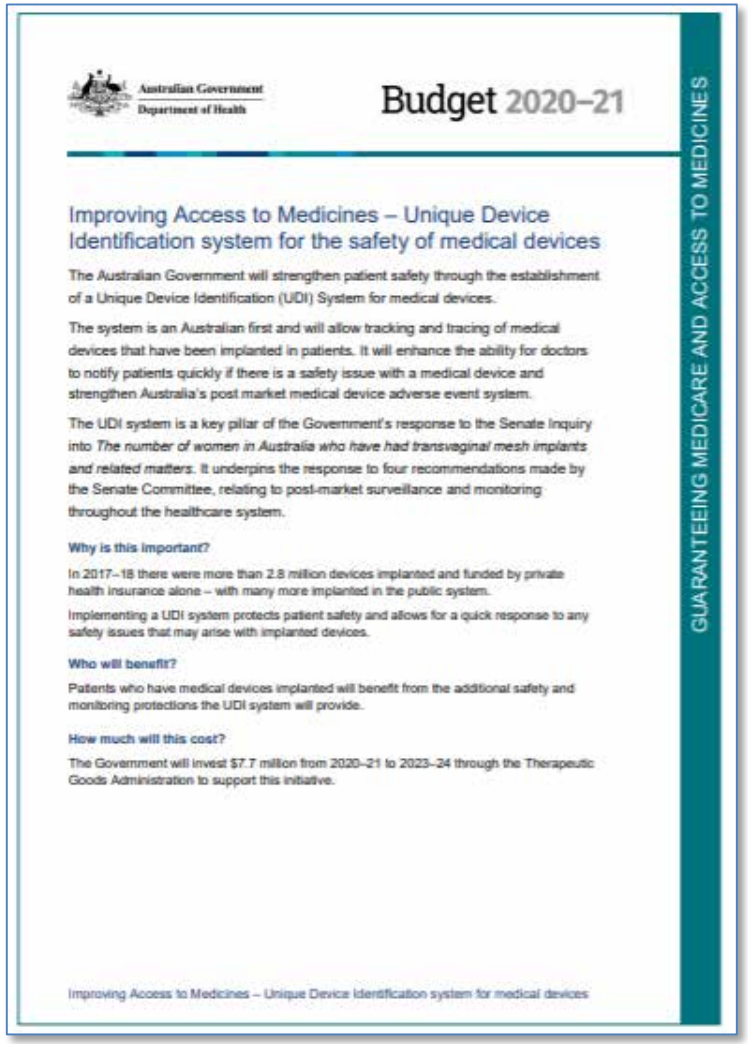
Provision of data	equal support for the manufacturer (creator of data) and sponsor (as Australian legal entity) to be responsible for the provision of information. Ability to bulk upload, download and upload of bulk changes. Formats included structured (such as HL7's SPL) and unstructured (such as Excel). Ability to edit data and correct errors without the requirement of a change in DI. Triggers were one area of concern, both in terms of the administrative overhead and the differences across jurisdictions. Requirement for an environment to correct data
Basic UDI-DI	equally strong views for and against. Benefits of including relate to ability to easily share data with the EU, and facilitates harmonisation and allows for reliance on CE certificates from EU notified bodies to support local device registrations. Many suggested the need for a grouping mechanism, and suggested the concept of a 'product family'. Others recognised the ARTG ID as already providing this grouping mechanism. Comments that EU implementation is still unclear, and the Basic UDI-DI complicates the DI model

Consultation 2 responses

Benefits	all respondents provided feedback on benefits across all parts of the health system, including suggestions on how those might be measured
TGA support	strong preference for extensive implementation support – help desk, data dictionary, ongoing communications and a test/sandpit AusUDID environment (per the U.S. FDA model)
GMDN	Most use GMDN terms, the largest driver was to meet regulatory requirements. 25% indicated that it is used to identify issues relating to devices or device use

Progress to date

- ü Approval for the TGA to invest $7.73m from its cash reserves to establish the AusUDID
- ü On 19th February 2021 the Therapeutic Goods Act changes necessary to establish the Australian UDI database received Royal Assent
- ü Regular meetings and ongoing discussions established/continue with other regulators, including US, the EU, UK, Singapore, Canada
- ü Regular meetings established with the Australian Digital Health Agency (ADHA)
- ü Ongoing involvement with the TGA Transformation, particularly with the Data and Analytics stream



Australian Government
Department of Health

Budget 2020–21

GUARANTEEING MEDICARE AND ACCESS TO MEDICINES

Improving Access to Medicines – Unique Device Identification system for the safety of medical devices

The Australian Government will strengthen patient safety through the establishment of a Unique Device Identification (UDI) System for medical devices.

The system is an Australian first and will allow tracking and tracing of medical devices that have been implanted in patients. It will enhance the ability for doctors to notify patients quickly if there is a safety issue with a medical device and strengthen Australia's post market medical device adverse event system.

The UDI system is a key pillar of the Government's response to the Senate Inquiry into *The number of women in Australia who have had transvaginal mesh implants and related matters*. It underpins the response to four recommendations made by the Senate Committee, relating to post-market surveillance and monitoring throughout the healthcare system.

Why is this important?

In 2017–18 there were more than 2.8 million devices implanted and funded by private health insurance alone – with many more implanted in the public system.

Implementing a UDI system protects patient safety and allows for a quick response to any safety issues that may arise with implanted devices.

Who will benefit?

Patients who have medical devices implanted will benefit from the additional safety and monitoring protections the UDI system will provide.

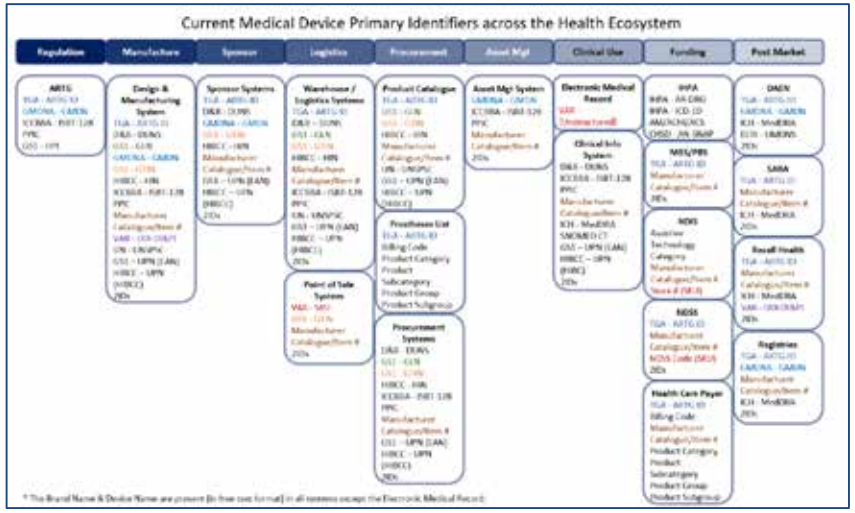
How much will this cost?

The Government will invest $7.7 million from 2020–21 to 2023–24 through the Therapeutic Goods Administration to support this initiative.

Improving Access to Medicines – Unique Device Identification system for medical devices

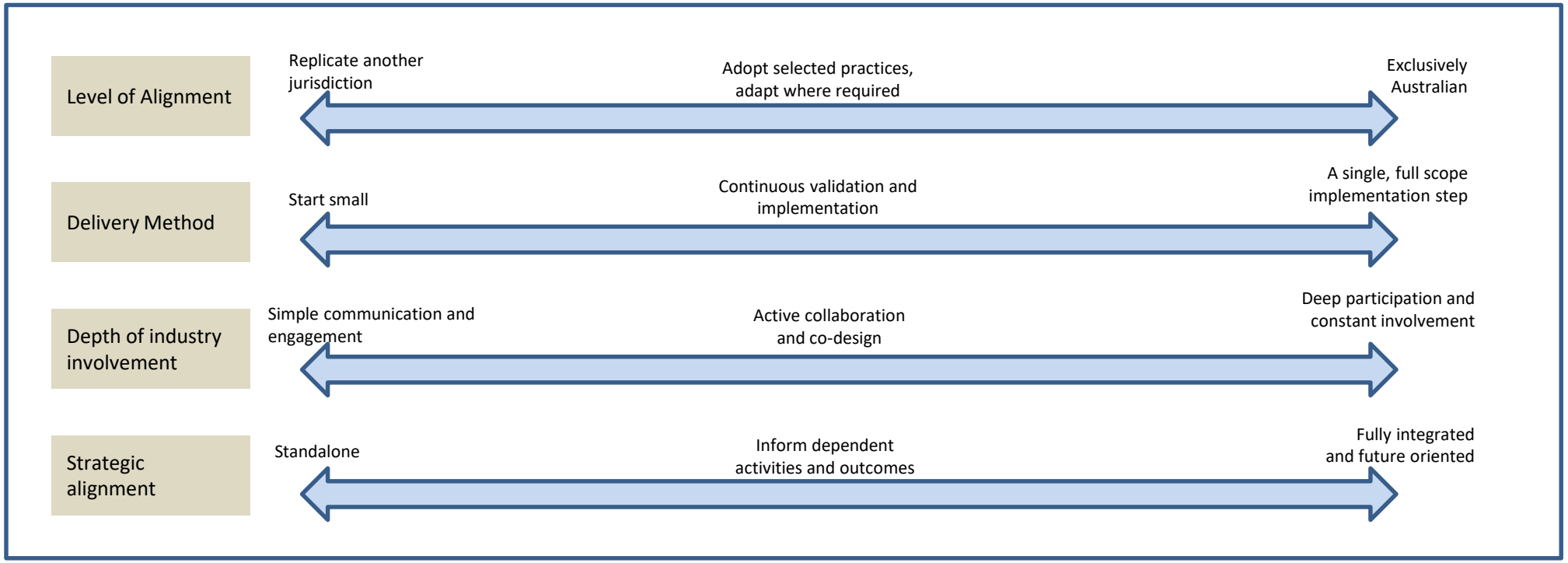
Progress to date (cont.)

- ü Engaged a delivery partner – to assist with the technical implementation
- ü Created a model of identifiers being used across the health system, which we are now in the process of validating
- ü Created list of issues to be resolved (such as Class I) – informed by discussions and consultation feedback
- ü Started work on identifying and prioritising use cases
- ü Started work to test the level of ‘match’ between devices on the U.S. GUDID public data and the ARTG
- ü Internal governance model agreed

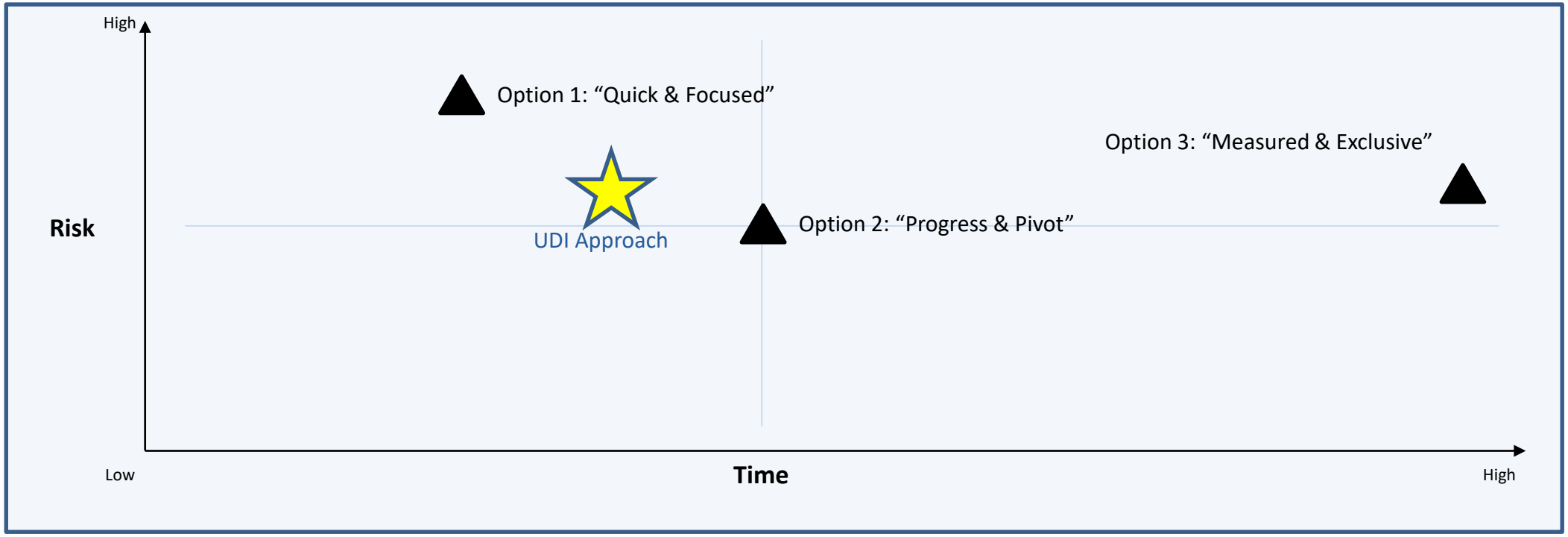


Delivery approaches are emerging

- As we progress, learnings from other jurisdictions (noting the delay to EU) and industry are emerging
- Potential considerations on how the project delivers, with an array of possible scenarios, built on a set of emerging “levers”

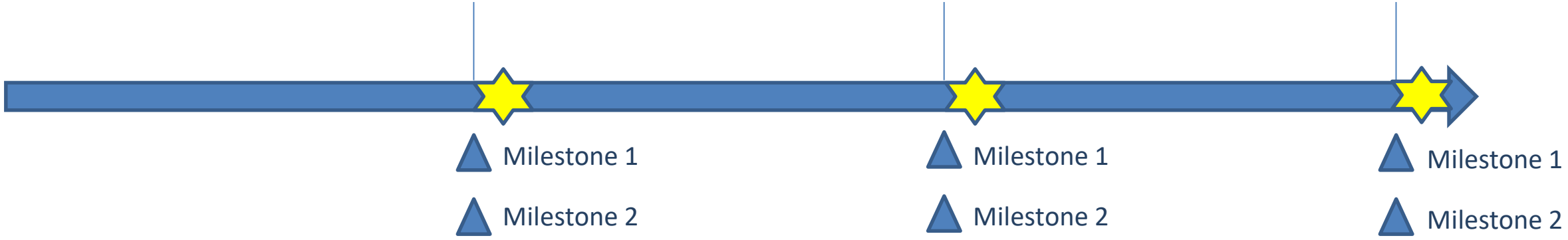


What is our approach?



What does this mean?

60-90 day time periods with defined milestones and “pivot” points



A milestone might be:

- Producing a tangible asset
- Testing a hypothesis
- Reaching a decision
- Starting some end to end exposure

- How many devices sold in Australia are on the GUDID?
- Defining the Issuing Agency Framework
- A decision on Class 1 devices
- Defining the linking between ARTG and AusUDID
- Creating a ‘sandpit’ technical environment
- Creating a UDI ‘Blueprint’

Examples of key questions/decisions

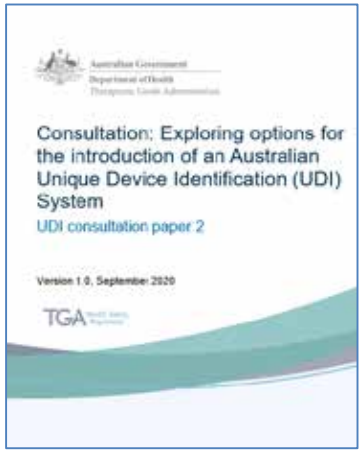
- Approach to linking ARTG ID to UDI-DI
- Approach to legacy devices
- Issues other regulators have yet to resolve
- Class I (high volume low risk devices)
- TGA position where U.S. FDA and EU regulations are not aligned
- Ability to leverage existing data sources (such as the U.S. FDA)
- Grouping mechanisms in addition to GMDN/ARTG ID (such as the EU BASIC-UDI-DI or Product Family ID)
- Aligning data that will potentially be stored in ARTG and GUDID

1. Prioritise
2. Decide approach to resolve
3. Resolve

UDI Working Group

dta

Australian Government



Who do we need to engage with?

- Manufacturers
- Sponsors
- Re-packagers (such as kit compilers)
- Healthcare providers (hospitals etc.)
- Industry bodies
- Issuing Agencies
- Patients and patient advocates
- Other regulators
- Researchers
- Software developers (of Hospital systems for example)
- Registries
- State and Territory governments
- Distributors (Supply Chain)
- Funders
- Other Government departments and authorities
- Internal Department of Health and agencies (including ADHA, Safety and Quality Commission)

How will we engage?

- ü Monthly webinars
- ü Workshops
- ü Working groups
- ü Consultation papers

Working group framework will be established

UDI Working Groups
(non governance)

UDI Working Group

UDI Working Group

UDI Working Group

1. Targeted focus on specific issues – known or emerging
2. Early exploration work, quickly learn/fail and then change direction if needed
3. Knowledge sharing
4. Scope is whole health ecosystem not just regulation
5. UDI champions

What are some of the specific challenges?

- Should Australia accept device labelling that is UDI compliant in U.S. or EU?
- Country-based labelling - are there scenarios where the same model of device may have multiple DIs?
- Personalised Medical Devices – what are the UDI requirements?
- Class 1 – should Class I devices be included? Are there logical ways to group them?
- Should there be an exemption process or alternative? Which devices should be exempt?
- Global Medical Device Nomenclature
- Triggers
- Should Australia store data from other jurisdictions that is outside that included in the IMDRF (for example additional U.S. UDI fields)?
- Legacy devices? Allow industry to deplete inventory before making the UDI mandatory?
- Multiple sponsors seeking authorisation for a single device and ensuring consistent numbering

Next steps

- Create a communications strategy and implement the communications plan
- Understand how we can leverage the data already available – continue to analyse the U.S. UDI data
- Analyse the alignment between the EU and U.S. data and rules, to inform implementation decisions
- Delivery partner first deliverables include a “sandpit” that will form the foundation of the AusUDID and enable ‘early adopter’ work to progress
- Define and establish help desk functionality and support for stakeholders and early adopter projects – strong feedback on the importance and value of this

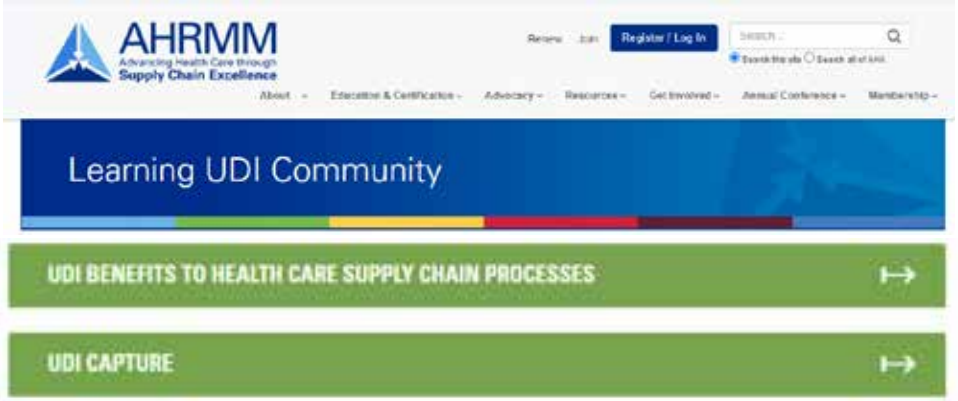
Source IMDRF

Early adopter projects

- To enable the early use of /experiments of using the UDI throughout the broader healthcare system
- Benefits for health care providers, and the TGA

Important as one of the issues identified from the US implementation – early focus on regulatory aspects rather than use - has meant a lag in the take-up of the identifiers

The US has established a Learning UDI Community, an industry collaborative effort designed to benefit the healthcare field by providing more consistent, consensus based processes to support UDI adoption



Source: ahrmm.org

We are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

LIVE POLL

Website and link references

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

Questions?

udi@health.gov.au

Contact us

UDI team

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