Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar No.6

Wrap-up, questions and answers

Michelle van Wijk
UDI Project Manager
Therapeutic Goods Administration

16 November 2021

TGA Health Safety Regulation

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- Questions – please use the **Q&A** tool when I open this function
  - Q&A will occur after todays presentation
  - Your questions are only visible to the panel
- If you need to contact the moderator – please use the **'Chat'** function
- Relevant links will be sent to you via the chat function box
- Let us know how we went – live poll

Difficulties hearing from computer?

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

OR

Dial: +61-2-9338-2221

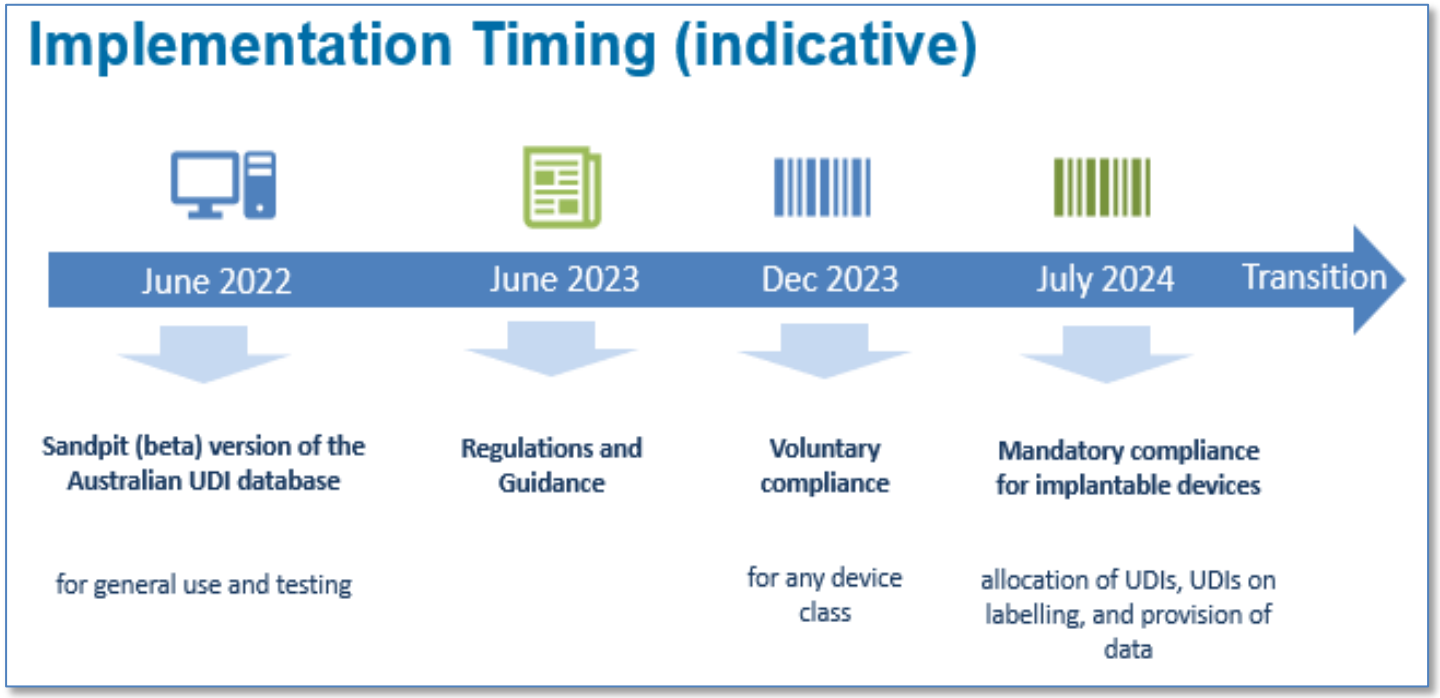
Access code: 2650 163 6007

Unique Device Identification webinar 6

- **The year in review**
- Questions and answers

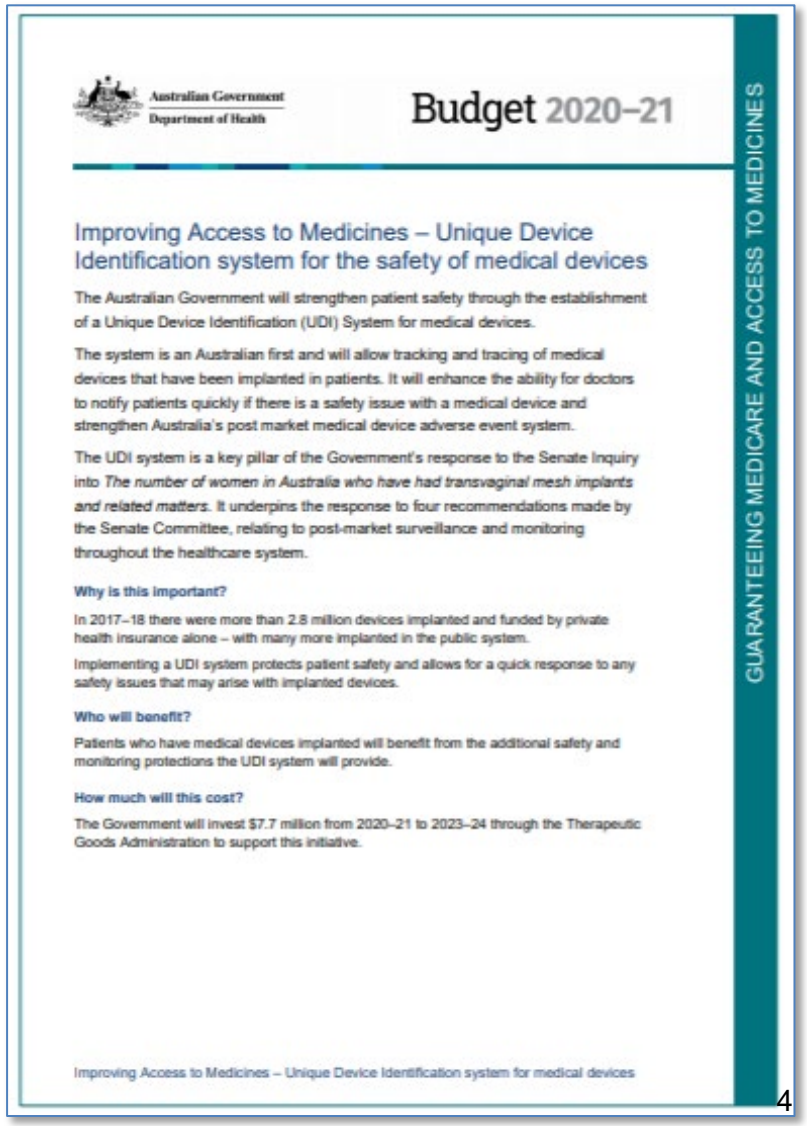
2021 Wrap-up

- Regulatory framework
- Database and technical solution
- Adoption
- Engagement



Regulatory Framework

- ✓ Approval for the TGA to invest $7.73m from its cash reserves to establish the AusUDID
- ✓ On 19 February 2021 the Government made amendments to the Therapeutic Goods Act to establish the Australian UDI database
- ✓ Undertook a second public consultation
- ✓ In progress - work to compare and identify gaps – International Medical Device Regulators Forum, U.S. and EU
- ✓ Attendance and presentations at various international fora and workshops



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.

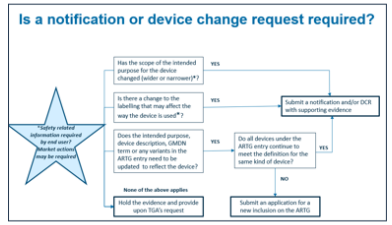
Improving Access to Medicines – Unique Device Identification system for medical devices

First working group established

- ✓ Weekly meetings
- ✓ “Discovery” discussions
- ✓ Knowledge sharing with Australian participants
- ✓ Summary of TGA considerations
- ✓ Emerging themes
  - ➢ Clinical versus non-clinical changes
  - ➢ Devices sold in multiple markets
  - ➢ Existing ARTG requirements and linkages

Australia already has rules relating to device/device data changes (ARTG)

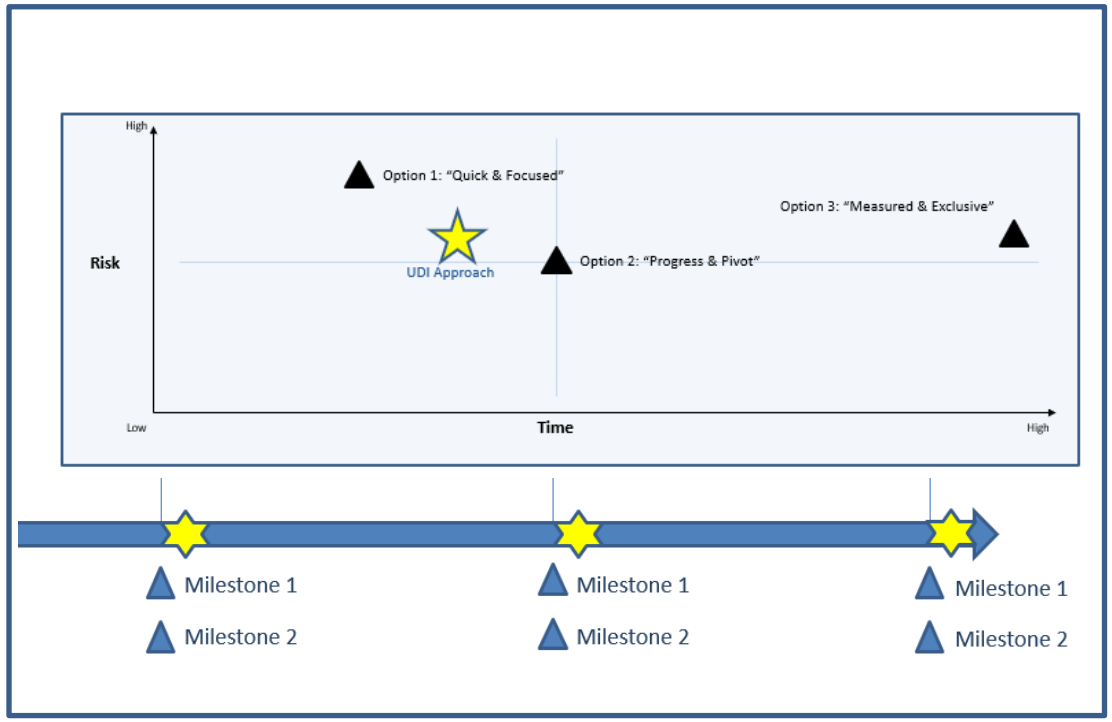
- ➢ Device Change Requests
- ➢ Conformity Assessments

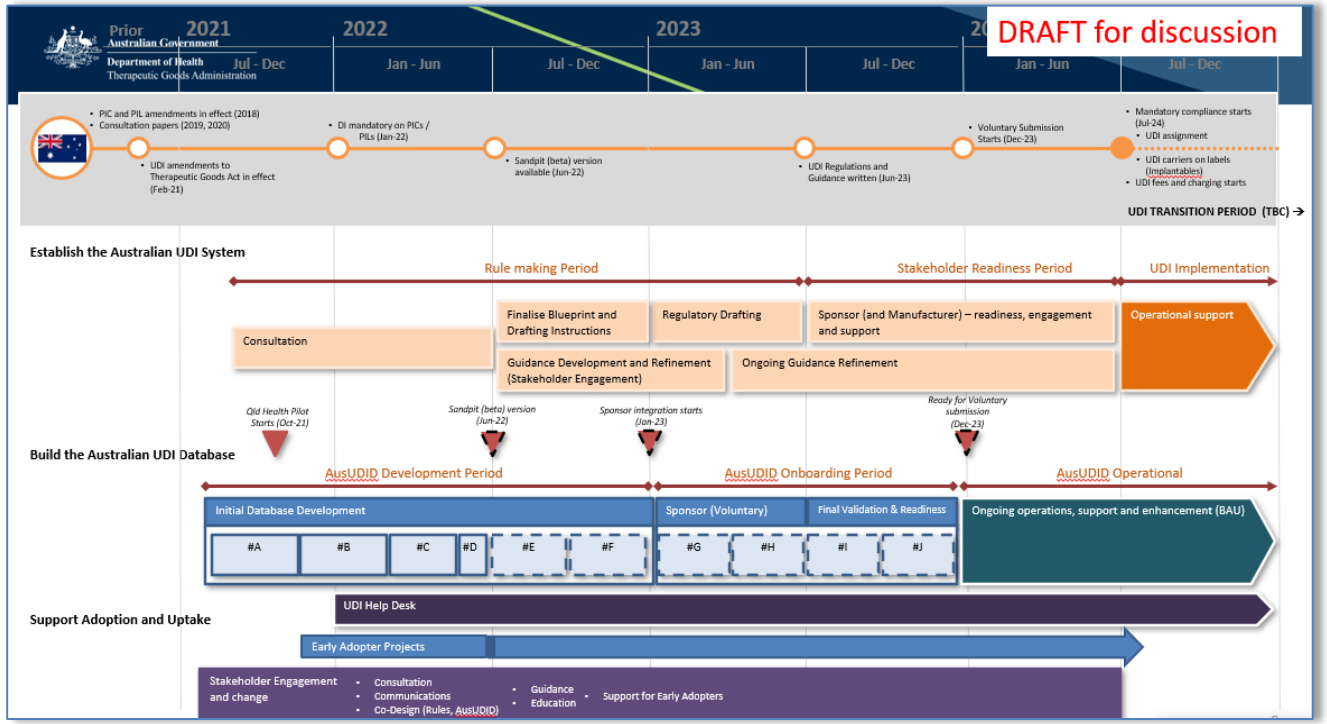


- **UDI rules will be additional**
- **Work is still required to define the processes and the linkages**
- **EU/MDR consideration**

28+ Manufacturers, issuing agencies, healthcare organisations, registries

Database and technical solution



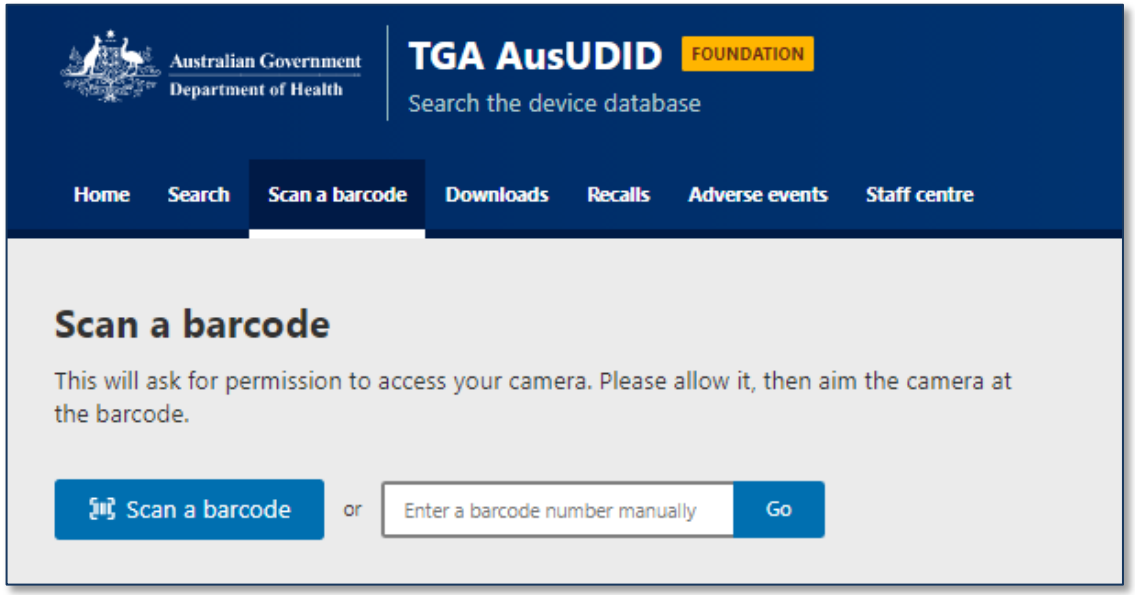


Database and technical solution

Working with our technology partner, Modis, we have created an initial version of the Australian UDI database

Early adopter version ready on 1 October 2021

Functionality will evolve over time, guided by our UDI Implementation Roadmap



- ✓ subset of U.S. UDI data uploaded
- ✓ ability to search for devices and view or download results
- ✓ access the data from desktop, phone, tablet
- ✓ scan a barcode and see device information
- ✓ add a new UDI record (portal)

Database and technical solution

- ✓ Commenced process to connect GS1 National Product Catalogue (Global Data Synchronisation Network) to sandpit AusUDID to explore potential future use of NPC for provision of data
- ✓ Completed development and User Acceptance Testing for the daily addition of new Global Medical Device Nomenclature (GMDN) codes to the Australian Register of Therapeutic Goods (ARTG)

Adoption

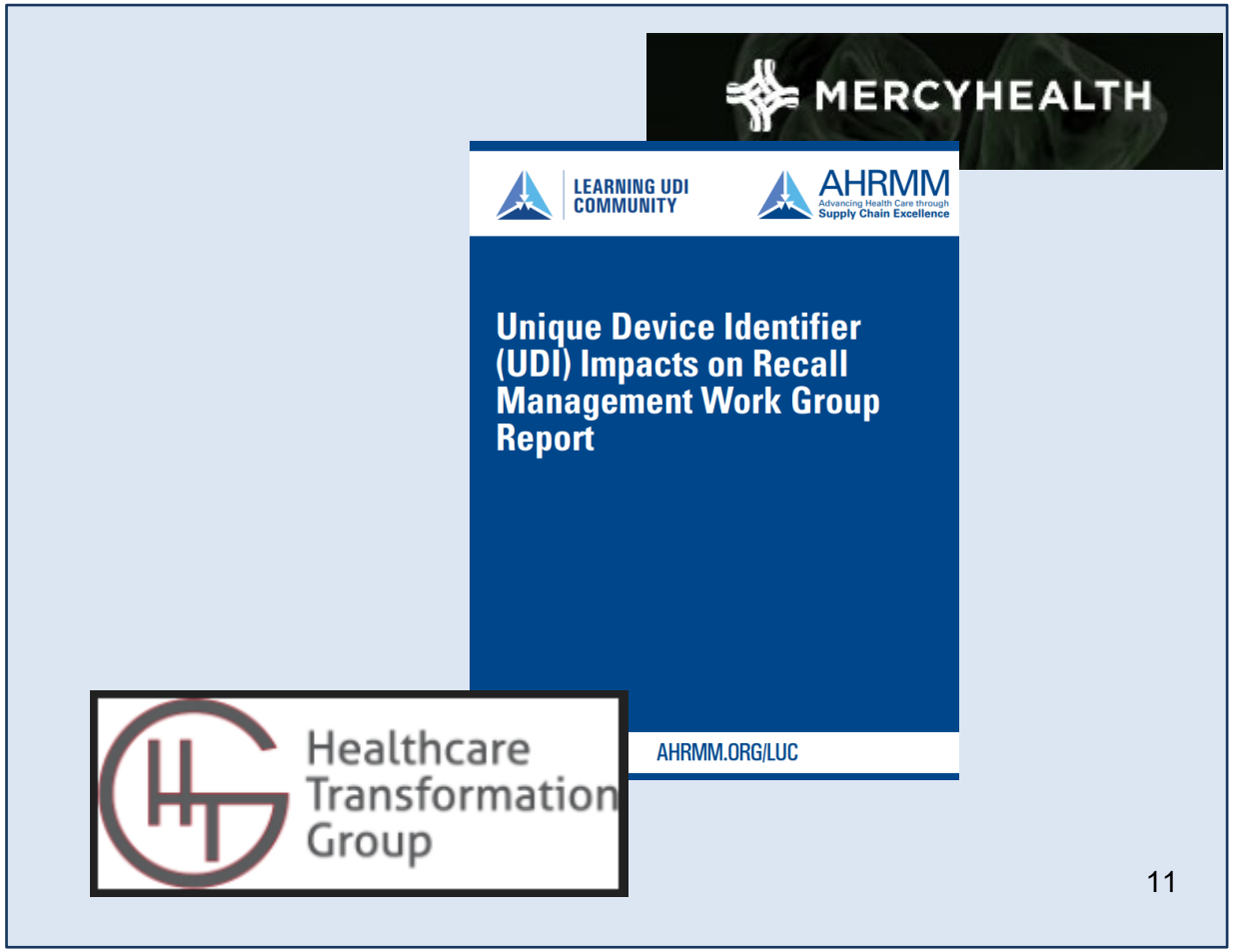
- ✓ Discussions and AusUDID demonstrations with registries and other health organisations
- ✓ Work started to develop the point of care scenarios and use cases
- ✓ Discussions with Mercy Health (USA) and Qld Health to leverage learnings and share experiences
- ✓ Presentation at the Australian Clinical Trials Association's Annual Science Meeting Registries Special Interest Group Day

Early adopter project 1 – Qld Health

- ✓ Ministerial and U.S. FDA approval to use U.S. GUDID data to support early adopter projects
- ✓ AusUDID ready on 1 October 2021
- ✓ TGA and Qld Health sponsorship agreed
- ✓ The Australian Commission on Safety and Quality in Health Care business case approved
- ✓ Work progressed on agreeing the in-scope hospitals and devices
- ✓ Work progressing to create Re-usable framework (UDI 4 Hospitals (UDI4H))

Engagement – ‘lessons learnt’

- ✓ Continue discussions with other regulators
- ✓ Targeted discussion with Mercy Health and Qld Health
- ✓ Learnings from the U.S. Learning UDI Community (recalls paper recently released)
- ✓ Discussions with U.S. surgeons / registries
- ✓ Presentations from Issuing Agencies
- ✓ Learnings from Triggers Working group

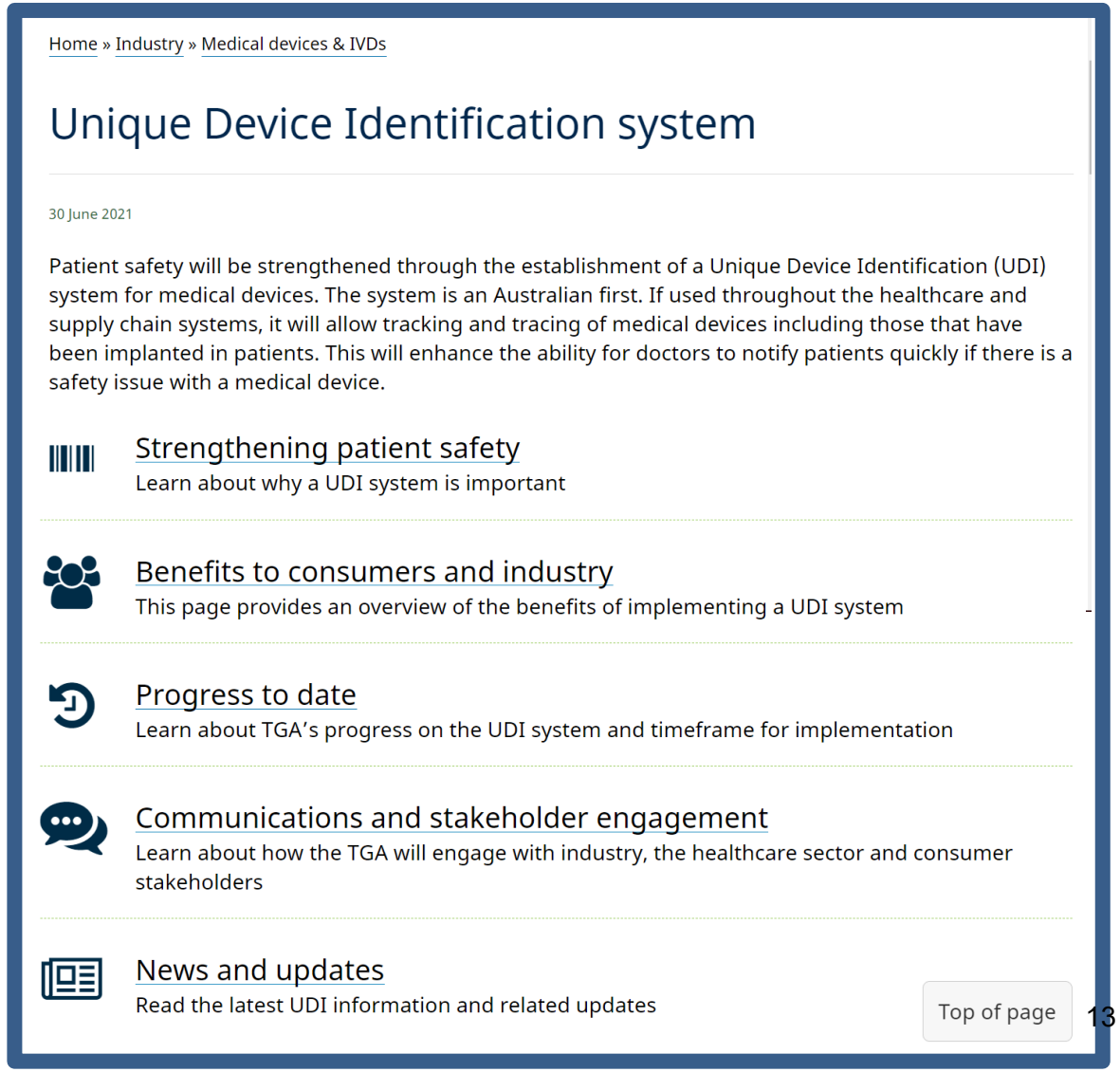


Webinars

- ✓ June — An introduction to the Australian UDI System
- ✓ July — Further considerations for the Australian UDI, including global alignment, GMDN and data elements (guest speaker Dennis Black, Becton Dickinson)
- ✓ August — Challenges and considerations on the journey to a global UDI system
- ✓ September — The role of a UDI Issuing Agency (guest speaker Géraldine Lissalde-Bonnet , GS1)
- ✓ October — The role of a UDI Issuing Agency (Part 2) (guest speaker Allison Mehr, HIBCC)
- ✓ November — Wrap-up for the year, Q&A

UDI hub

- New UDI hub on the TGA website https://www.tga.gov.au/unique-device-identification-system
- Webinars (presentations and recordings)
- Established UDI mailbox for correspondence
- In the process of responding directly to questions we have received from the first webinar, and to our udi@health.gov.au email address (this will be ongoing)
- We will update our hub with answers to frequently-asked questions



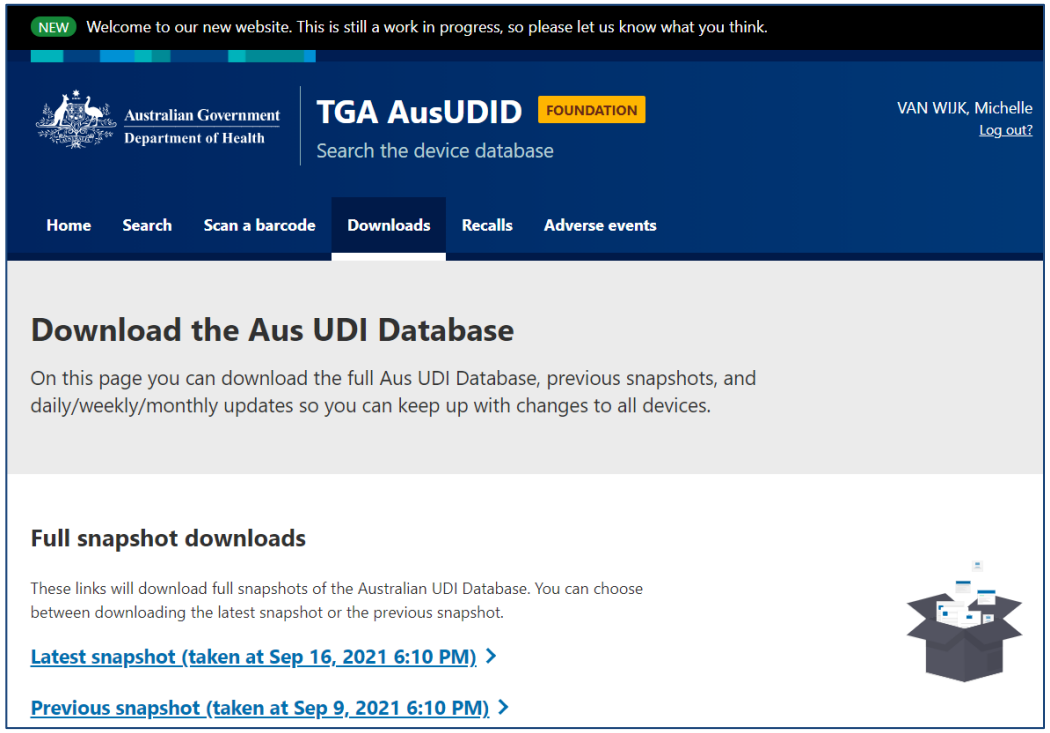
Unique Device Identification webinar 6

- The year in review
- **Questions and answers**

Questions to date

Over 150 questions received to date, key themes are emerging:

1. Implementation timing
2. International alignment
3. Scope of devices
4. Alignment with the ARTG and existing TGA processes
5. The Australian UDI database and data provision
6. Global Medical Device Nomenclature
7. Generation of UDIs and Issuing Agencies
8. Labelling
9. Use in clinical systems and patient records
10. Collaboration and engagement



Implementation Timing

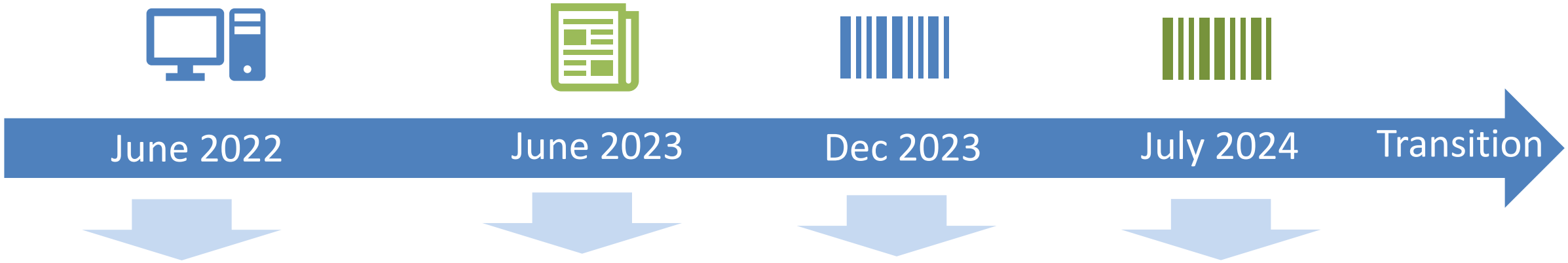
- The transition period and details of compliance dates are still to be confirmed but will begin with high-risk implantable devices
- We will continue to explore the possibility to accelerate Australia's transition period, particularly for those devices which are already compliant with U.S. or EU regulations

Our considerations informing these dates may include:

- Allowing 12 months from the finalisation of regulations to the first mandatory compliance date
- Consultation feedback that there may be opportunities to speed-up the Australian implementation, including voluntary submissions of UDI
- The development of the Australian UDI database will need to be finalised, including linkages with the Australian Register of Therapeutic Goods (ARTG)

Timelines will be published when agreed

Implementation Timing (indicative)



Sandpit (beta) version of the Australian UDI database

for general use and testing

Regulations and Guidance

Voluntary compliance

for any device class

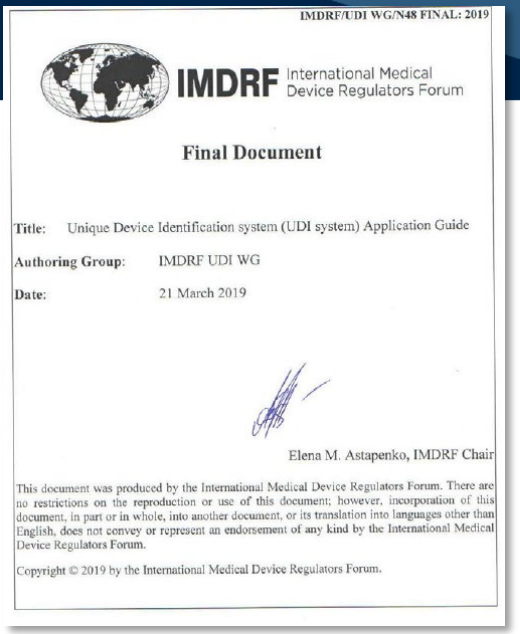
Mandatory compliance for implantable devices

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

International alignment

- U.S. FDA alignment continues to be the initial focus for alignment
  (*align with U.S. and then 'fold in' EU requirements*)

- We are considering what additional / different data is collected by the EU (such as EMDN) to assist in identification of devices, interoperability and harmonisation.



IMDRF/UDI WG/N48 FINAL: 2019

IMDRF International Medical Device Regulators Forum

Final Document

Title: Unique Device Identification system (UDI system) Application Guide

Authoring Group: IMDRF UDI WG

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

+

TGA Health Safety Regulation

Minimal additional requirements (e.g.)

- ARTG ID
- Patient Information Leaflet URL/PDF
- Prosthesis Billing Code

Scope of devices

What we know

- Where software that is a medical device is regulated by the TGA it must meet the UDI requirements unless it is exempt or excluded
- UDI will be required for every model of device

  UDI data is different to ARTG data, which contains information at the “kind of” device level

What we are still exploring

- Will non ARTG registered products be eligible to utilise a UDI?
- Will Class 1 devices be in scope?
- Will legacy devices be in scope?
- Kits, systems, procedure packs
- Exempt and excepted devices (patient-matched, custom-made devices)
- Will UDIs be required for spare parts used in repairs?

Australian Register of Therapeutic Goods (ARTG) and existing processes

What we know

- Each device record in the Australian UDI database will also include a list of all relevant ARTG IDs that relate to that model of device. There may be one or many
- Under current regulations, UDI is mandatory for the Patient Implant Card (PIC) if the device has a UDI, when the Australian UDI commences

What we are still exploring

- Will the Sponsor be required to submit a variation for each ARTG to provide a copy of the updated labels with the UDI on it?
- Linking of TGA data for ARTG, UDI, adverse events, recalls
- Changes to audit processes (including MDSAP)
- Changes to Quality Management System requirements

Australian UDI database and data provision

What we know

- The majority of the UDI data will be made publicly available through a web interface and through data downloads
- We will provide Machine to Machine capabilities for data transmission
- MRI compatibility is included in the IMDRF data set, and we are planning to capture it in the Australian UDI database
- We will be providing a web interface to allow the data entry for one device at a time, and functionality to allow data provided in bulk

What we are still exploring

- *Should the manufacturer be able to provide UDI data directly to the TGA?*
- *Use of the National Product Catalogue (Global Data Synchronisation Network) for the provision of data*
- *How is TGA considering the practical elements of this where a sponsor of a system/procedure pack (for e.g.) might supply multiple devices - thermometers, infusion sets etc. - as part of such a pack?*
- *The final dataset*
- *Does this mean that the manufacturer will have to create a new UDI and packaging for each device that may have multiple sponsors?*

Australian UDI database and data provision

What we know

- Device information consists of data such as manufacturer, sponsor, whether the device is supplied sterile, and so on. It generally remains reasonably static over time
- Production Information (such as a lot number, batch number, manufacture date, expiry date) changes every time the product is manufactured and therefore is not stored in the regulator's database
- The Production Information will need to be stored in other systems such as supply chain, hospital systems, patient electronic health records, registries, and so on
- A Sandpit (beta) version of the Australian UDI database will be available for general use and testing

What we are still exploring

- Options for data exchange and interoperability, with a focus on contemporary best practice and alignment with industry standards
- The final AusUDID data elements. We will be consulting on this as part of our stakeholder engagement and plan to publish a data dictionary of the data elements

Global Medical Device Nomenclature (GMDN)

What we know

- GMDN will be one of the data elements required to be provided with the device UDI data
- The UDI will not replace the GMDN
- Each model of device will require both a UDI, and a GMDN code
- Currently if there are no changes to the characteristics of a device, the GMDN is valid for the life of the device even if the GMDN agency amends that code or makes it obsolete
- As part of the ARTG clean-up there is no plan to force sponsors to lodge change requests
- There is no current plan to change the way the GMDN codes are implemented for Australian In Vitro Diagnostic devices

What we are still exploring

- *Benefits in potentially also collecting European Medical Device Nomenclature*
- *Potential processes for making changes to the GMDN over time*
- *Relationship between ARTG and UDI*

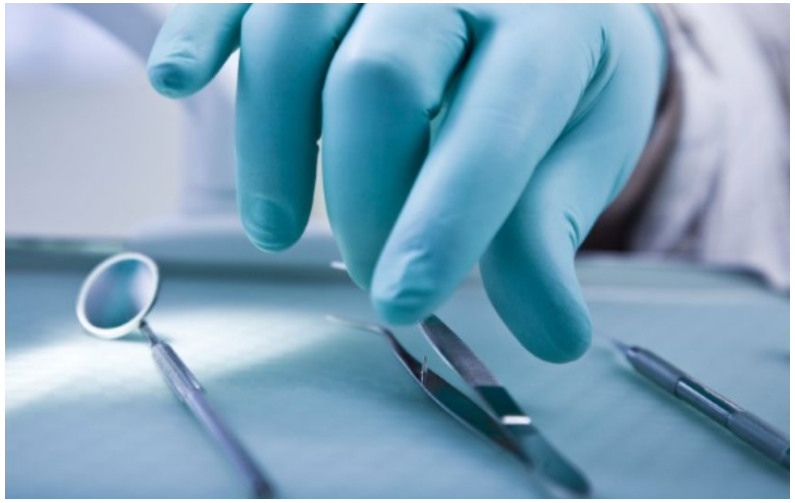
Generation of UDIs and Issuing Agencies

What we know

- Issuing Agencies are responsible for generating UDIs according to international standards
- Australia is planning to accept UDIs created by GS1, the Health Industry Business Communications Council (HIBCC) and International Council for Commonality in Blood Banking Automation (ICCBBA), including where those have already been applied to devices in the EU and U.S.
- The manufacturer is responsible for obtaining UDIs from an Issuing Agency and allocating them to devices

What we are still exploring

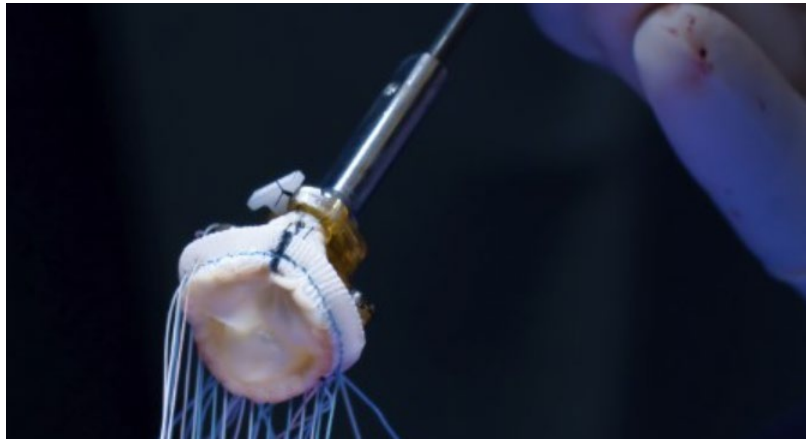
- *While Australia is still considering our position on the Issuing Agency framework, we recognise that there are three issuing agencies that are common across both the EU and U.S. (and other countries)*



Labelling

What we know

- Australia is planning to accept UDIs created by GS1, HIBCC and ICCBBA, including where those have already been applied to devices in the EU and U.S.
- UDI labelling will not be required for stock already supplied



What we are still exploring

- *Will the implementation of UDI barcodes into product labels be considered a substantial change, and is there a requirement for a conformity assessment review or can this be assessed at the next surveillance audit?*
- *What considerations are in place for small products that will be very difficult to put a UDI on e.g. endodontic files, endodontic paper points?*

Use in clinical systems and patient records

What we know

- The UDI can potentially be captured and linked to a specific patient in any system that stores that data.
- This is outside the scope of the TGA UDI project.

What we are still exploring

- *Early Adopter learnings*

Australian Government
Australian Digital Health Agency

My Health Record

Collaboration and Engagement

What we know

- Working groups are open to all, we welcome all participants and will seek interest for each new working group
- Register at any time for an Early Adopter project or working group via email – udi@health.gov.au
- Next year's consultation will seek feedback on the operationalisation of the UDI to inform the regulatory requirements and transition plan

What we are still exploring

- *Early Adopter learnings*

Next Steps

- ✓ Preparing for regulatory consultation (Q1/Q2 2022)
- ✓ Co-design and collaboration with stakeholders from 2022
- ✓ Additional early adopter projects

How did we go?

LIVE POLL

Michelle is currently reading over your submitted questions.

We'll be back shortly for Q&A

Contact us

UDI Project

udi@health.gov.au

Questions?

Website and link references

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

More information – Social media

TGA .gov.au

TGA	Website	https://www.tga.gov.au
f	Facebook	https://www.facebook.com/TGAgovau/
	Twitter	https://twitter.com/TGAgovau
You Tube	YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
	Topic blogs	https://www.tga.gov.au/blogs/tga-topics
LinkedIn	Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
	Instagram	https://www.instagram.com/tgagovau/?hl=en

Australian Government

Department of Health

Therapeutic Goods Administration