UDI Webinar 20

Launch of the Australian UDI regulatory framework and Australian UDI Database

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Therapeutic Goods Administration

Gary Pascoe
UDI Project Lead
Devices Reforms Taskforce
Therapeutic Goods Administration

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health, Disability and Ageing acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present, and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

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The Australian UDI System

The team and approach

The stakeholders and contributors

The international experience

The importance and value

The future

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Agenda

- Introduction
- Considerations for healthcare
- Considerations for industry
- Resources and tools
- Questions

TGA UDI Hub

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TGA UDI Hub

Therapeutic Goods Act
February 2021

Medical Device Regulations
24 March 2025

Implications

Device labels
UDI information on device labels and higher levels of packaging

Patient Implant Cards
Additional device information and more precise adverse event reports

Market actions
Streamlined recall processes in hospitals, improved recalls experience for consumers

Device incident reports
More precise reporting of device related incidents

Adverse event reporting by hospitals and healthcare
More precise reporting of device related incidents

Australian UDI Database (AusUDID)

Repository for UDI-DIs and related data for devices supplied in Australia

Sponsors and manufacturers submit and maintain device data

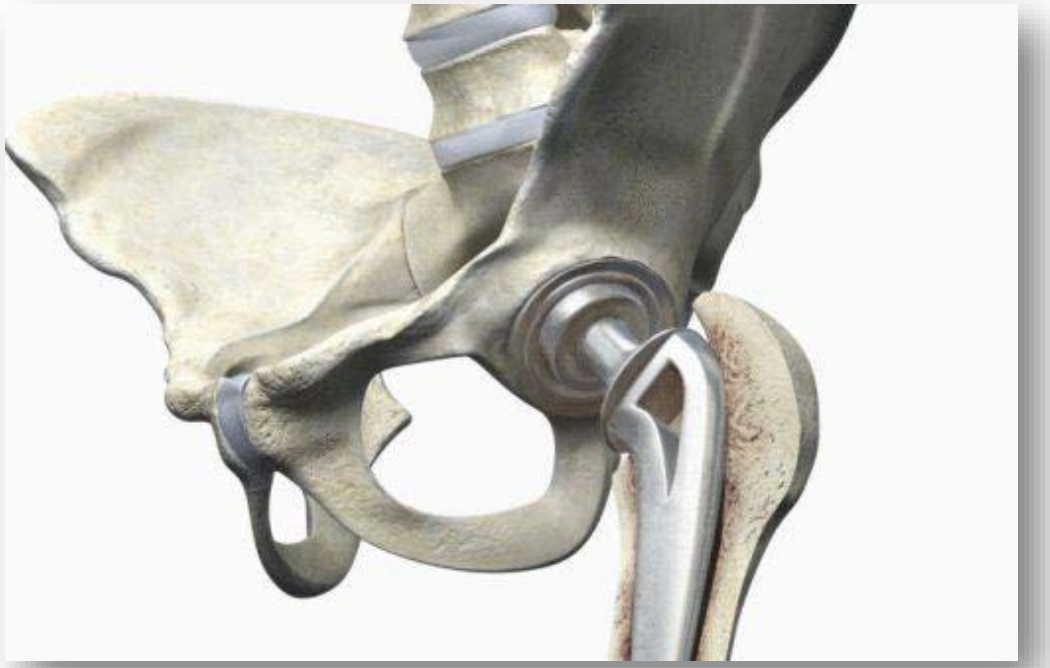
Health professionals and clinical quality registries can access medical device information

Patients can find more about the medical devices used on or implanted in them

Devices in scope

Medical devices

- Class I – supplied sterile
- Class IIa
- Class IIb
- Class III



In vitro diagnostic devices

- Class 1 (Software IVDs or Instrument/Analyser IVDs only)
- Class 2
- Class 3
- Class 4

Other classes of medical device or IVD can voluntarily comply.

UDI does not apply to other therapeutic goods.

Phased start dates

Voluntary

Device labelling

Data in the AusUDID

Phased introduction

Start with high-risk devices

Lower risk devices follow over later years

Full compliance

Devices labelled

Data in the AusUDID

Phased start dates

Medical devices

Requirement	Class III	Class IIb	Class IIa	Class Is
UDI on the label	1 July 2026		1 July 2027	1 July 2028
Data submission	1 July 2026		1 July 2027	1 July 2028
Direct Marking	1 Jan 2028	1 Jan 2029	1 Jan 2029	1 Jan 2029

In vitro diagnostic devices

Requirement	Class 4	Class 3	Class 2	Class 1
UDI on the label	1 July 2028		1 July 2029	
Data submission	1 July 2028		1 July 2029	
Direct Marking	1 July 2029		1 July 2030	

UDI Timing Guidance

International alignment

- Australia aligns closely with the International Medical Device Regulators Forum (IMDRF) guidance
- We accept UDI Carriers that meet the UDI requirements of the EU or US, if:
  - the UDI-DI has been issued by a TGA recognised Issuing Agency
  - the label complies with the existing regulatory and labelling requirements for Australia.
- Other considerations:

Data elements and UDI Triggers	• Core data elements and UDI triggers are consistent • Some variations for each jurisdiction, e.g. Basic UDI-DI, Master UDI-DI, GMDN and EMDN
Data submission	• Separate online portals for data submission • Manufacturer submits data in EU and US – multiple sponsor considerations in Australia • US and Australia use HL7 SPL for machine to machine
Device types	• USFDA and EU require UDI for Class I medical devices and Class 1 IVDs • Some variations for specific device types, e.g. reusable devices and direct marking, retail and OTC
Compliance timetable	• USFDA's UDI system fully implemented in 2018 • Australia's timetable considers EU's MDD to MDR transition

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TGA UDI Hub

Device information – brand name, description, model/version, catalogue number, sponsor, manufacturer

Clinical characteristics – size, storage and handling conditions, critical warnings, single use, sterilisation requirements

Packaging data – packaging type, quantity

Device details – whether the device is software or incorporates software, is a kit

Supporting documentation – patient information leaflet, instructions for use

Related Australian Register of Therapeutic Goods – approval details

AusUDID data available for healthcare / consumers

Use of AusUDID data in healthcare

Look up details of a medical device prior to patient use

Manage inventory and track products through the hospital system

Record of devices used through the Patient Implant Card and Discharge Summary.

Future considerations are My Health Record

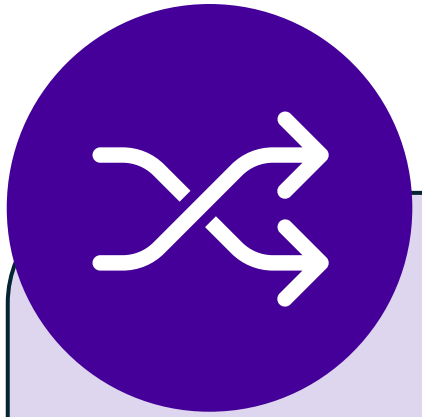
Streamlined response to market actions to isolate affected stock and identify impacted patients

Access the AusUDID

There is no cost to access the AusUDID

Search AusUDID

Search the AusUDID using criteria such as brand name or catalogue number



Integrate into systems

Incorporate full downloads of the AusUDID into your systems

Future: APIs to look up device data in real time

Accessing AusUDID data

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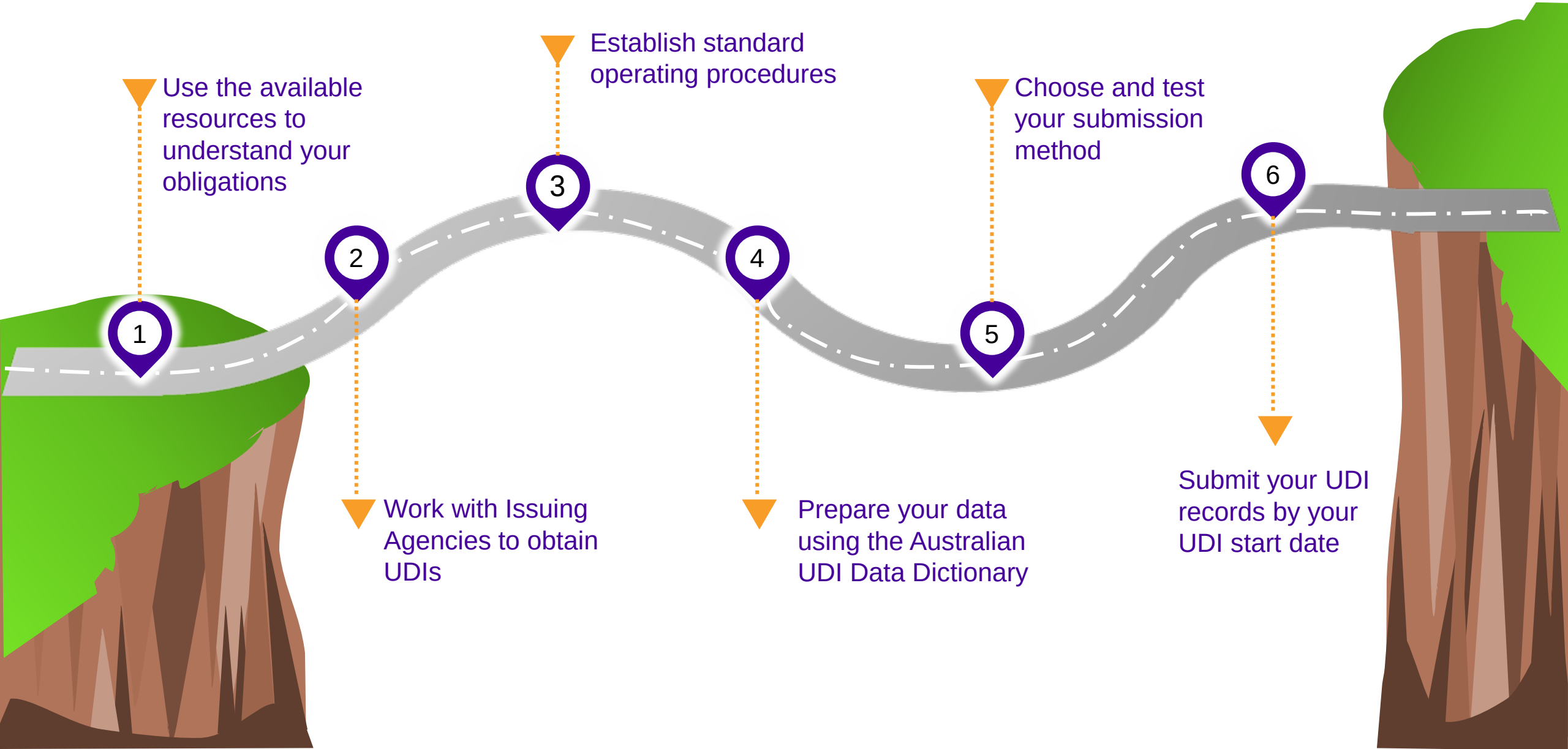
UDI Requirements Guidance

tga.gov.au

Start preparing for UDI



Start dates for mandatory compliance

Medical devices

Requirement	Class III	Class IIb	Class IIa	Class Is
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UDI Timing Guidance

Steps for regulatory compliance

Obtain a UDI from a TGA recognised Issuing Agency and allocate a UDI to each **model** of medical device or IVD

Apply the UDI to the device labelling and all applicable levels of packaging, including the device itself where applicable (direct marking)

Submit the UDI-DI and related data to the AusUDID, and maintain the UDI record while the device is in supply

Include the UDI on Patient Implant Cards

Include the UDI on notifications to the TGA, including adverse event reports and market actions (recalls, alerts and corrections)

Ensure additional device specific requirements are met

AusUDID data submission

Online portal
Manually submit one UDI record at a time

Bulk upload
Submit up to 200 UDI records at a time using the provided template

- Via **TGA Business Services (TBS)** homepage
- **Organisation** must have a TBS account
- **User** must have an account under the organisation
- User must have the TBS system role of '**Submitter**' to submit UDI records

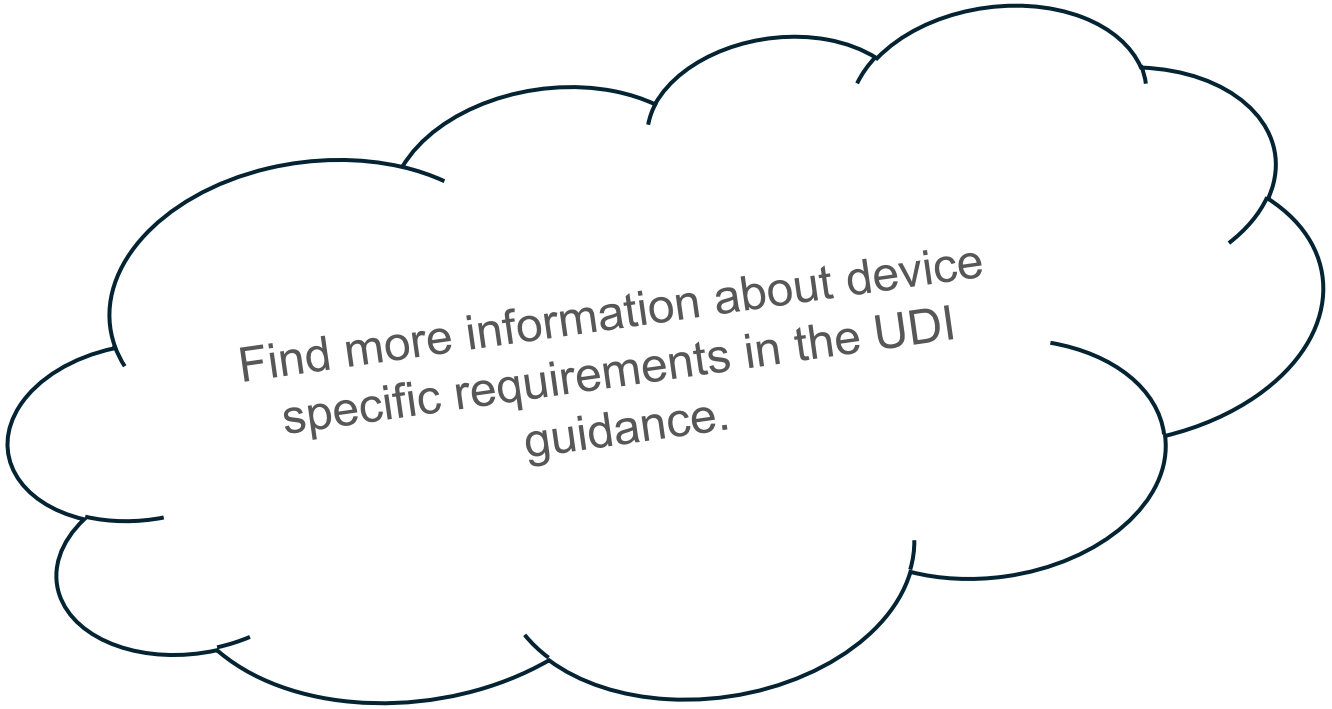
HL7 SPL
Submit many UDI records at a time through an electronic submission gateway

National Product Catalogue
Submit UDI records using GS1's NPC

See the **UDI Hub** for more information about how to access Machine to Machine data submission methods

Device specific requirements

- Implantables
- Single use devices
- Reusable devices
- Surgical Loan Kits
- System or Procedure Packs
- Software
- Devices principally sold in retail
- Custom made/patient matched medical devices



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AusUDID

Manufacturers

- Timing guidance
- Requirements guidance
- Technical resources
  - Bulk Upload template (Excel)
  - ARTG ID Mapping template (Excel)
  - Machine to Machine document suite

Consumers

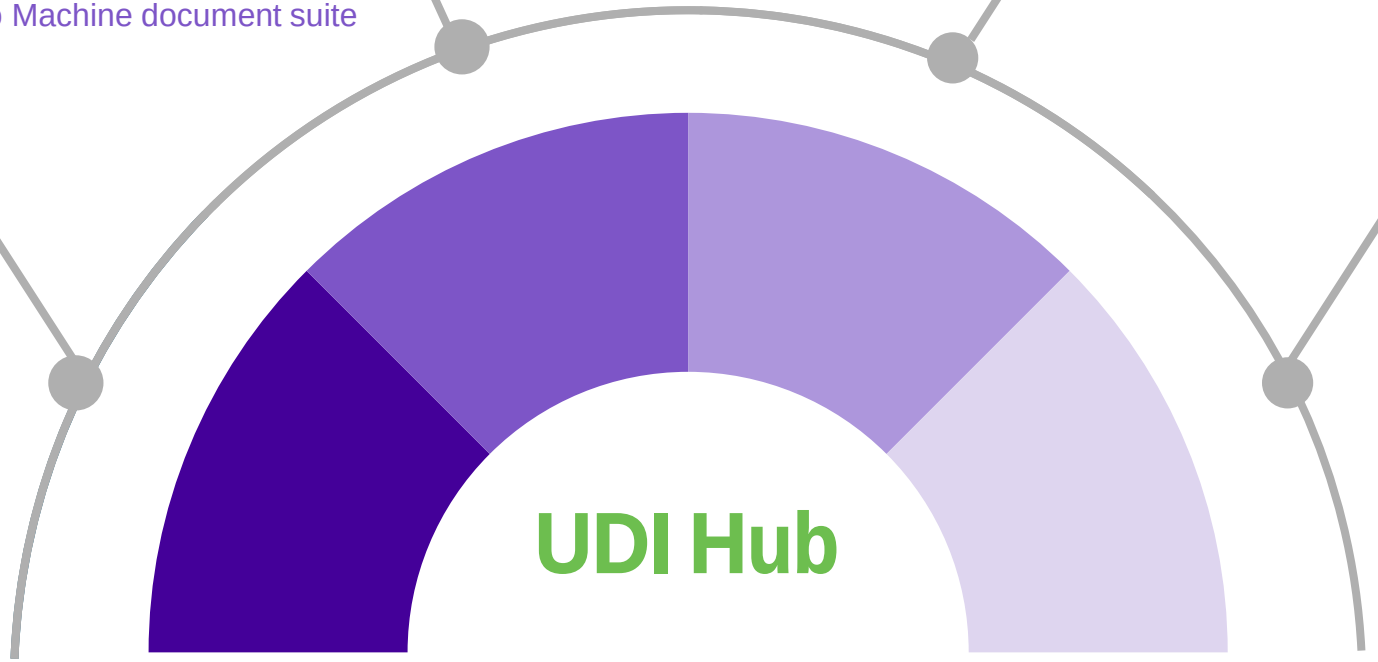
- UDI for consumers
- AusUDID Data Fields Summary

Sponsors

- Timing guidance
- Requirements guidance
- Technical resources
  - Bulk Upload template (Excel)
  - ARTG ID Mapping template (Excel)
  - Machine to Machine document suite

Healthcare

- Overview of UDI in healthcare
- AusUDID Data Fields Summary



Foundational resources

- AusUDID Regulations
- UDI Glossary
- Australian UDI Data Dictionary
- About UDI in Australia
- About AusUDID

Guidance Documents

- Detailed support for complying with the UDI regulations
  - Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA)
- Detailed explanation of UDI timeframes, in particular accommodating the EU MDD/MDR transition
  - Complying with the Unique Device Identification timeframes for medical devices | Therapeutic Goods Administration (TGA)

AusUDID Pre-Production

- **Test and training environment** for sponsors and manufacturers to:
  - familiarise themselves with the AusUDID
  - test their data submission methods prior to submitting live data.

- Pre-Production data is for testing and training. Therefore patients, consumers, healthcare and the public cannot access the data stored in this database.

Contact the UDI Support Team (udi@health.gov.au) to access Pre-Production

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TGA UDI Hub

Find out more / Contact us

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UDI Support Team: UDI@health.gov.au

ausudid.tga.gov.au

UDI Sponsor Launch

Expression of Interest - UDI Launch Workshops

Register your interest and help us tailor the UDI Launch for sponsors

Australian Government

Department of Health, Disability and Ageing