UDI Information Session

Clinical Quality Registries

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

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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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Agenda

- Introduction
- UDI requirements
- AusUDID live demonstration
- TGA support
- Questions

UDI Hub – TGA website

Introduction

Why Australia introduced UDI

The Therapeutic Goods Administration (TGA) introduced UDI in response to medical device crises such as:

- transvaginal mesh
- breast implants
- hip implants.

UDI is one of the key actions undertaken by the TGA to improve patient safety outcomes and improve how medical devices can be identified and tracked.

2018
Senate Community Affairs References Committee Report

Introduction

UDI impacts many stakeholders in the healthcare system

TGA

Device review and approval, adverse events, recall management, market availability

Manufacturer

Commercial distribution, conformance/global compliance

Clinical Quality Registries

Device performance
Recalls and remediation
Research and analysis
Longitudinal studies

Australian UDI

Australian Sponsor

Supply, Australian compliance

Payers

Claims
Health rebates
Data analytics

Healthcare Provider

Supply chain, EHR, Recalls, Adverse Events, Mandatory Reporting, PIC/PIL, Data analytics

Individuals Health Records

My Health Record
International Patient Summary

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Benefits of UDI for registries

- **More accurate device performance assessment:** Supports clearer identification of device models and versions
- **Enhanced comparative studies:** Product specific outcomes comparison
- **Recall response:** Enables faster patient identification and intervention during recalls
- **Automation of data capture:** Can reduce errors through barcode data capture
- **Longitudinal outcome analysis:** Linking UDI data with broader health records enables long-term monitoring of device safety and performance over time.

How registries can leverage UDI

CQR collects data to calculate indicators

Assess patterns or processes of care involving medical devices (process indicators)

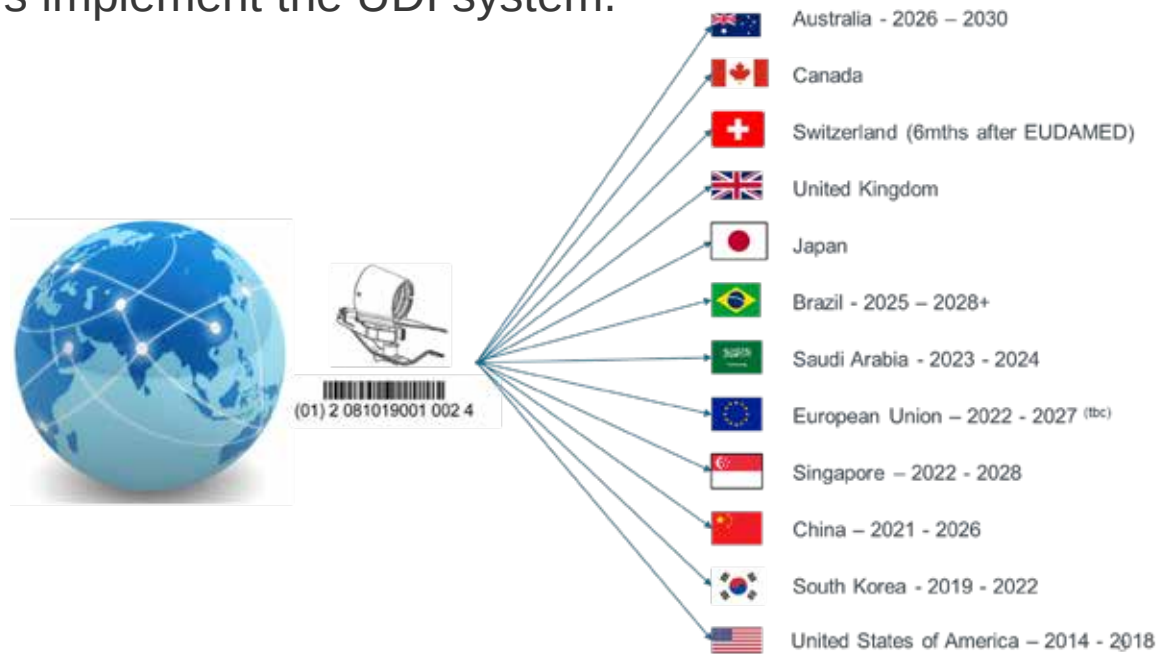
Assess patient outcomes associated with device use (outcome indicators)

Why is UDI important

Global consistency

There is global recognition that clearly identifying medical devices is essential to **protect patient safety** and **improve outcomes** across the medical device industry.

Demand for improved traceability of medical devices has seen other regulators implement the UDI system.



IMDRF International Medical Device Regulators Forum

Final Document

le: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

thoring Group: IMDRF UDI Working Group

te: 9 December 2013

Despina Spanou, IMDRF Ch

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2013 UDI Guidance
2019 UDI Application Guide

Helping Registries benefit from UDI

UDI supports high quality standardised device data that can support clinical quality registries in fulfilling their role

Today's data challenges

- Data quality
- Lack of standardisation
- Limited data linkage
- Delayed data capture
- Missing device data
- High clinician burden
- Limited traceability

How UDI can help

- Data accuracy
- Enables standardisation
- Facilitates data linkage
- Enables real-time capture
- Enhances completeness
- Reduces manual workload
- Strengthens traceability & safety

CQR Benefits

- Improved patient care and clinical practice assessment
- Better data linkage for adverse event reporting and recall actions
- Enhanced device performance assessment and longitudinal studies
- Enriched data insights

UDI requirements

Key requirements of a UDI system

Labelling

- A UDI-Device Identifier (UDI-DI) is assigned to each device model. A UDI-Production Identifier (UDI-PI) is assigned to each production run, containing data such as batch, lot, serial number or expiry date.
- The UDI-DI and UDI-PI form the UDI, which appears on the device label and all applicable higher levels of packaging.
- Global uniqueness is maintained by an Issuing Agency assigning the UDI-DI.

UDI Database

- The UDI-DI and related device data is stored in a central UDI database. In Australia, this is the Australian UDI Database (AusUDID).

In Australia

- The UDI record is linked to the relevant Australian Register of Therapeutic Goods (ARTG) inclusion(s) within 30 days after the device is first supplied into Australia.

UDI requirements

Which devices UDI applies to

Medical devices	In vitro diagnostic (IVD) devices
• Class III • Class IIb • Class IIa • Class Is	• Class 4 • Class 3 • Class 2 • Class 1 (Software IVDs or Instrument/Analyser IVDs only)

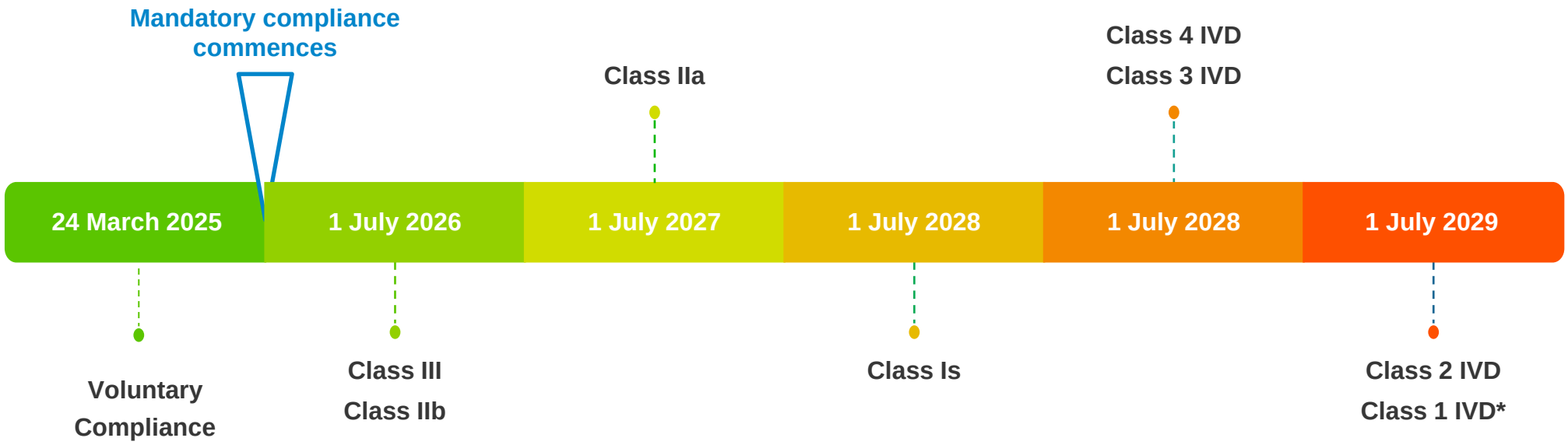
UDI does **not** apply to:

- Class I (nonsterile non-measuring) or Class Im (measuring) medical devices
- Class 1 IVDs (remainder)
- In house IVDs
- Devices **not** included on the ARTG
- Devices exempt under the Special Access Scheme (SAS) or Authorised Prescriber (AP) Scheme.

UDI requirements

When UDI becomes mandatory

UDI requirements become mandatory for high-risk medical devices from **1 July 2026**, followed by lower classes over later years.



UDI requirements

UDI Triggers

When a device changes in certain ways, this is considered a ‘UDI Trigger’.

When this happens:

- The device must be issued a new UDI-DI
- A new UDI record must be submitted to the AusUDID.

Some UDI Triggers relate to the device, such as MRI Safety Status or whether the device is supplied sterile.

Others relate to how the device is supplied, such as Brand Name or how many devices are supplied in the box.

UDI Trigger rules can mean we have multiple UDI records for what ‘seems to be’ the same model of device.

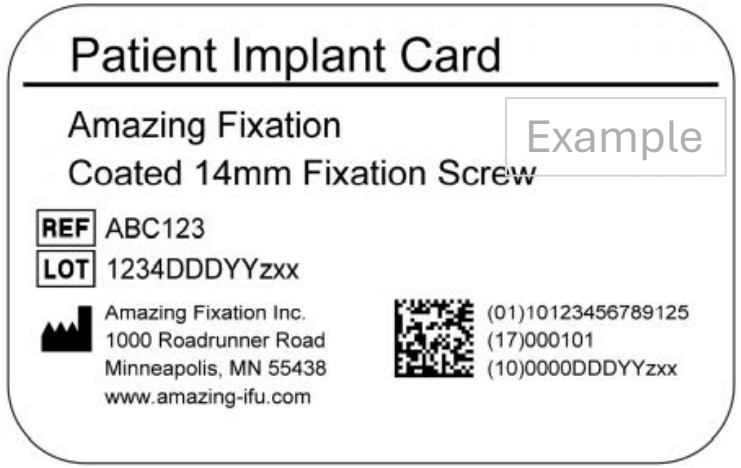
Australian Trigger Data Elements

- Labelled as single use
- If the restricted number of reuses changes
- Packaged sterile
- Need for sterilisation before use
- Critical warnings or contraindications:
  - Contains latex
  - MRI safety status *
- Clinical size (including volume, length, gauge, diameter) *
- Brand name
- Device version or model (including software add/change of features that result in change to intended purpose / a new major version number)
- Quantity of devices provided in a base package (device count)

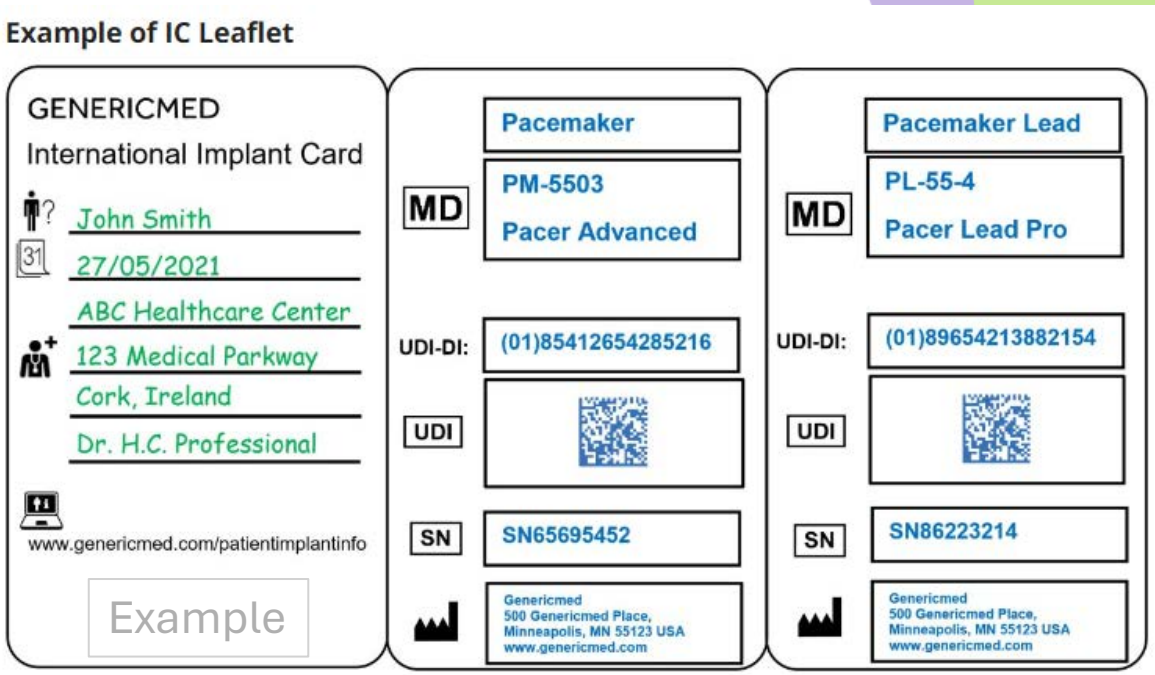
UDI requirements

When available, UDI is to be included on:

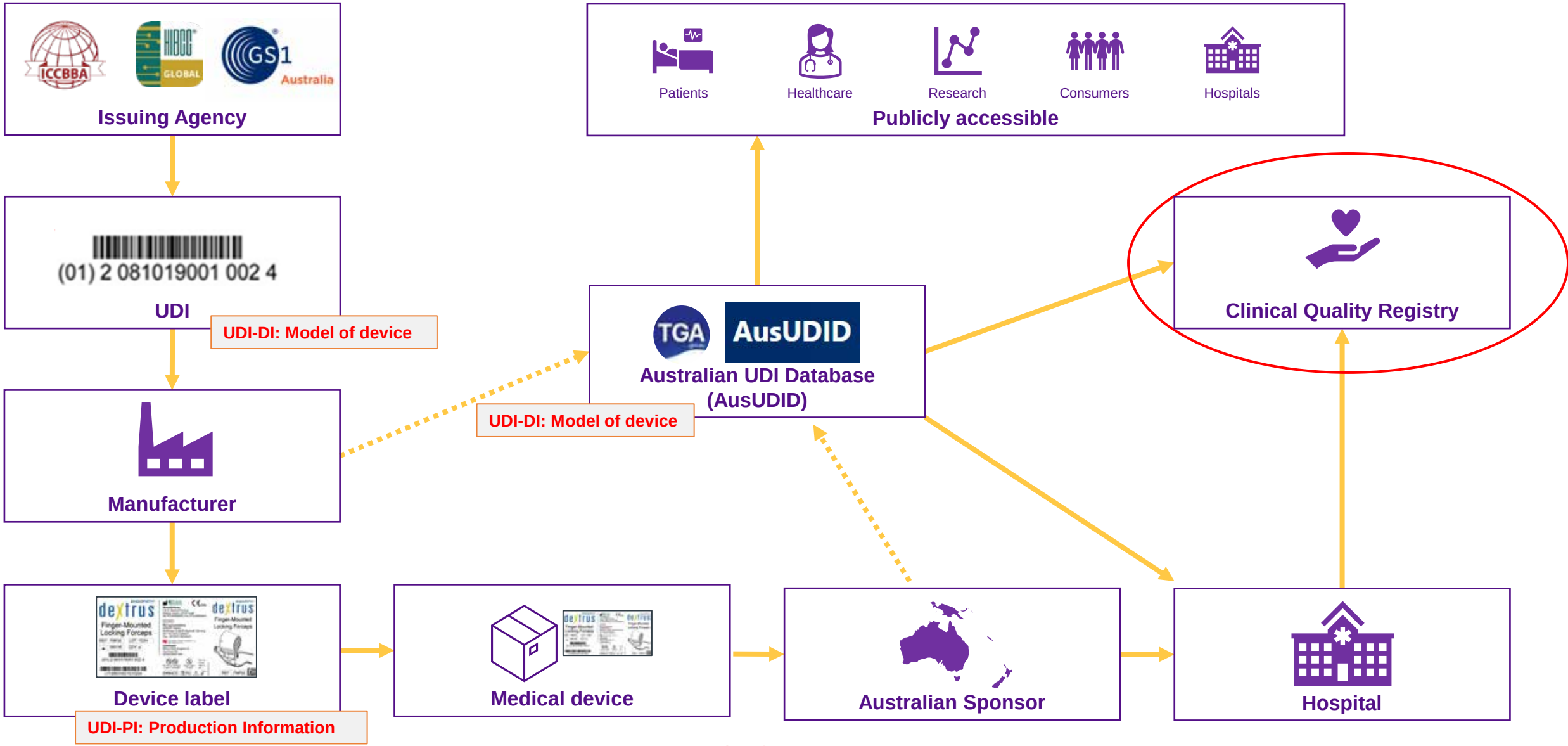
- Patient Implant Cards
- Adverse Events and Device Incident Reports
- Market actions, such as recalls, alerts, corrections



Example of IC Leaflet



How UDI can help



Expected challenges for UDI and Registries

Data Capture and Visibility

Inconsistent capture of device usage at the point of care, combined with limited access to up-to-date device data, reduces overall data accuracy and completeness

Digital Capability

Variation in digital maturity across hospitals and healthcare creates uneven capacity to collect, manage, and integrate device data effectively

Data Sharing and Governance

Complexity in establishing data-sharing agreement limits seamless information exchange

Timeliness and Process Efficiency

Reliance on manual submission methods (mailed sticker sheets) impacts the timeliness of registry data.

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AusUDID live demonstration

UDI helps Registries overcome challenges

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Find more information on the UDI Hub or contact the UDI Support Team

TGA UDI Hub

UDI Support Team: UDI@health.gov.au

ausudid.tga.gov.au

Questions?

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration