Australian Government
Department of Health
Therapeutic Goods Administration

Joint IMDRF / DITTA Workshop
Australian UDI presentation

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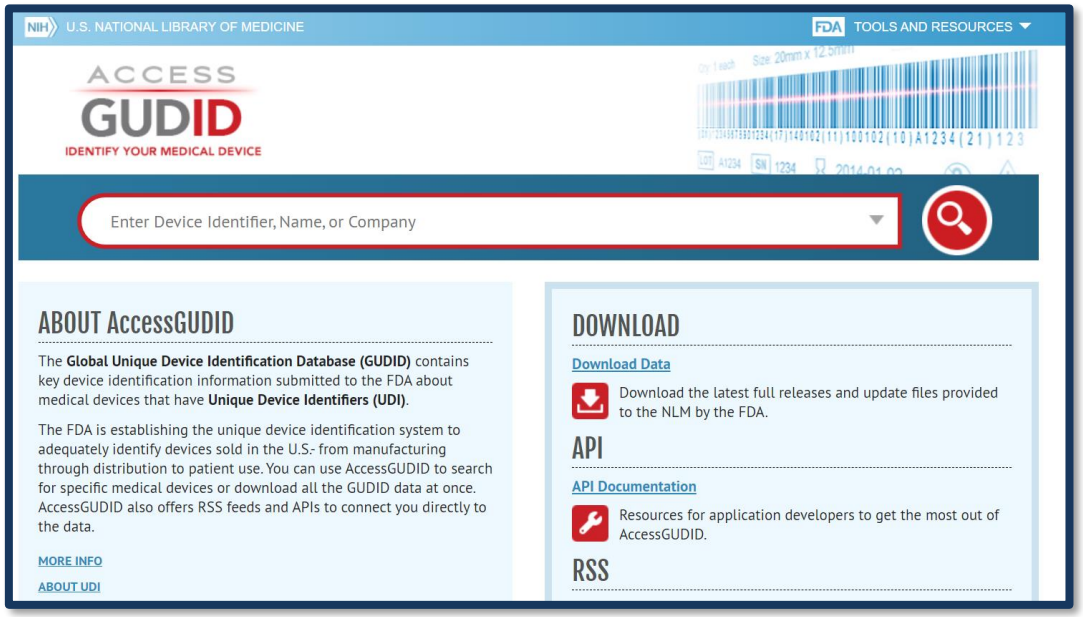
TGA Health Safety Regulation

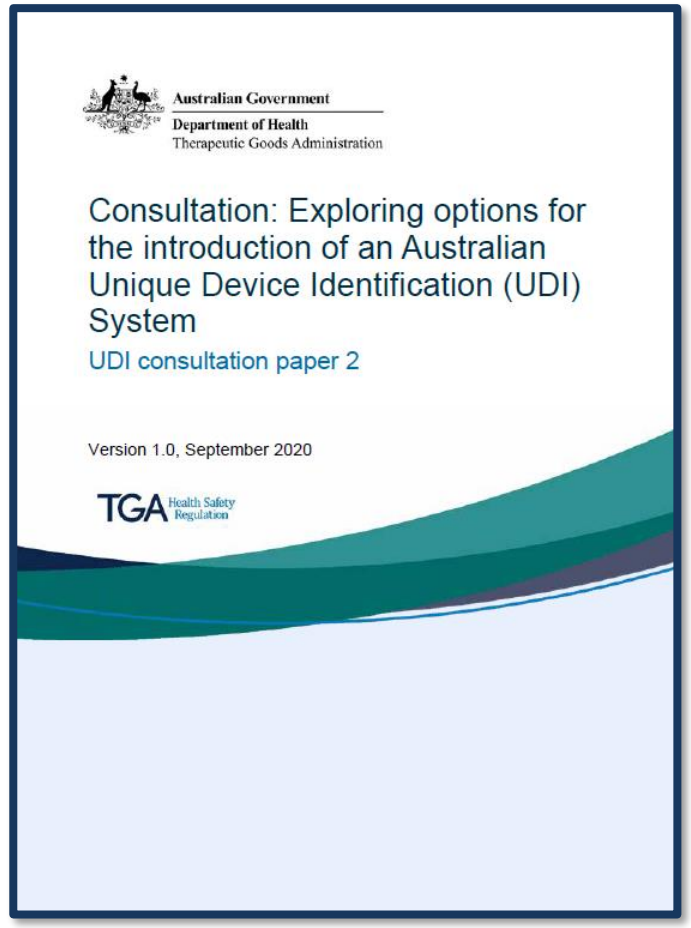
International alignment

- Member of the 2019 UDI Working Group
- In principle aligned with IMDRF Guidance
- Feedback from the second consultation paper on the possibility of leveraging the U.S. data. Exploring how we might use/leverage this generally, and especially for early adopter projects
- Exploring differences and similarities between IMDRF, USA and EU



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
- Two public consultations
- Established regular meetings with key stakeholders
- Engaged a technical delivery partner to build the technical components



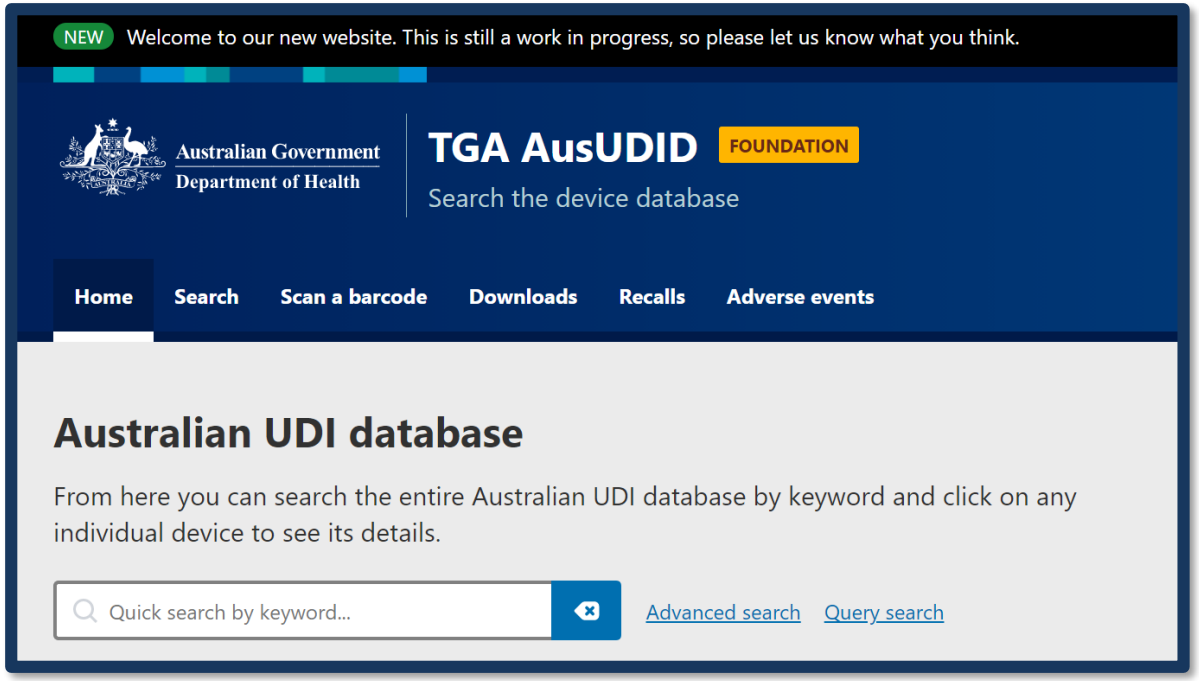
Who do we need to engage with?

- 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

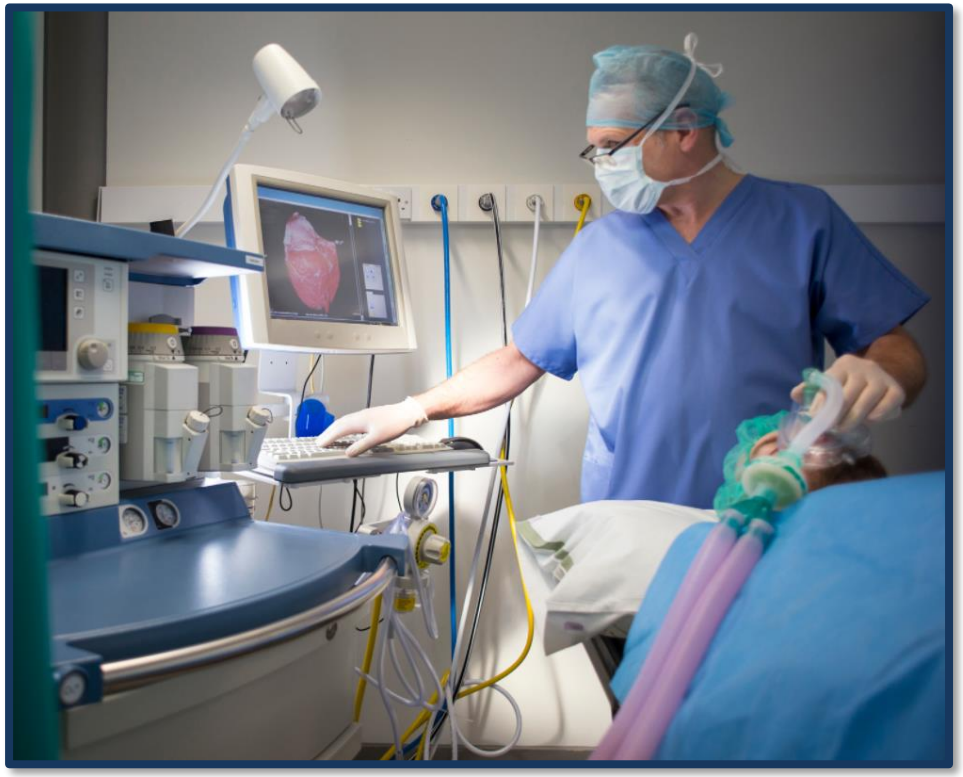
Collaboration, communication and co-design

- Extensive and regular engagement with key stakeholders across the health ecosystem – leverage learnings
- TGA UDI web hub
- Regular webinars including “guest presenters”
- “Sandpit” UDI environment now built, including an app
- First working group being established



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)

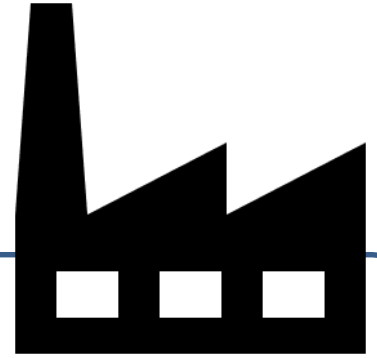


Benefits

- ✓ 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))

Considerations

- Alignment and regulatory burden on manufacturers who supply to multiple UDI markets with differing UDI requirements
- Speed of uptake in broader health care system
- High-volume devices such as contacts, spectacle lenses
- Supply chain v health care requirements



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U.S. FOOD & DRUG ADMINISTRATION

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