

## **Executive Summary**

The Therapeutic Goods Administration (TGA), Australia's regulatory authority for therapeutic goods, embarked on a transformative initiative to implement a Unique Device Identification (UDI) system for use across the national healthcare system. This initiative, known as the Australian Unique Identification (UDI) Project, aimed to enhance traceability, safety, and regulatory compliance for medical devices. Akkodis was engaged as the technology partner, developing and delivering the Australian UDI Database (AusUDID) since 2021. Today Akkodis are providing application support and continuous improvement after the AusUDID went live in March 2025.

# **Project Objectives**

- Establish a national UDI system and the Australian UDI database (AusUDID) to improve traceability and recall efficiency of medical devices
- Educate and increase awareness of the UDI compliance obligations for medical device manufacturers and sponsors
- Support the manufacturers' and sponsors' transition to meeting the UDI requirements through to 2030
- Support the use of UDI in the healthcare ecosystem, including hospitals, supply chains, and registries.

## Scope and Approach

The project was structured around three core pillars:

- Regulatory Framework Definition
  Collaborative design with global and local stakeholders to align with international standards (e.g., International Medical Device Regulators Forum (IMDRF), GMDN, GS1, HL7) and Australian legislation.
- Technology Delivery

  Akkodis led the design, development, and deployment of the AusUDID application, integrating it with:
  - The Australian Register of Therapeutic Goods (ARTG)
  - National Product Catalogue (GS1)
  - The Department of Health, Disability and Ageing's enterprise IT services and data environment (for shared user access and data interoperability).
- Stakeholder Engagement
  Extensive consultation with government agencies, manufacturers and sponsors,
  hospitals, and industry groups to ensure awareness, adoption and compliance readiness.



## **Key Achievements**

Successful delivery of the UDI regulations and AusUDID in March 2025.

- Integration of AusUDID with national systems using Microsoft Azure, Cosmos DB, Redis, and HL7-compliant APIs
- On-time and within-budget delivery over a 4-year timeline, with a team of 16 including 9 Akkodis consultants
- System go live achieved successfully in March 2025
- Well received and Akkodis acknowledgement for solution delivery at the Regulations and Technical Consultative Forum in May 2025.

## **Challenges and Mitigations**

- Complex Stakeholder Landscape:
   Managed via structured working groups and early adopter programs.
- Technical Complexity:
  - Overcome by leveraging a DevOps model and continuous improvement cycles.
- Developing a solution while regulations are evolving:
   Continuous engagement with key delivery personnel ensured quality delivery.

## **Outcomes and Impact**

- Better regulatory oversight and compliance transparency for medical devices
- Established foundation for full UDI compliance by 2030
- Improved patient safety outcomes through medical device tracking and tracing capabilities
  across the health ecosystem within Australia and globally through improved information sharing
  between the international medical device regulators.

#### **Lessons Learned**

- Cross-sector collaboration is critical for regulatory change
- Early investment in data integrity pays dividends in system reliability and stakeholder trust
- Agile delivery models are essential for managing evolving regulatory and technical requirements.

#### **About Akkodis**

Akkodis is a global digital engineering company and Smart Industry leader. We enable clients to advance in their digital transformation with Consulting, Solutions, Talent, and Academy services. Headquartered in Switzerland and part of the Adecco Group, Akkodis is a trusted tech partner to the world's industries.

We co-create and pioneer solutions that help to solve major challenges, from accelerating the clean energy transition and green mobility, to improving user and patient centricity. Empowered by a culture of inclusion and diversity, our 50,000+tech experts across 30 countries combine best-in-class technologies and cross-industry knowledge to drive purposeful innovation for a more sustainable tomorrow. We are passionate about Engineering a Smarter Future Together.

#### Find out more

If you are interested in learning more about Akkodis and how we can help, please reach out today:

Amanda Fisher
Account Director
ACT Consulting, Akkodis Australia
E: amanda.duffell@akkodisgroup.com

Carol Gobby
VP Sales and Growth
Akkodis Australia
E: carol.gobby@akkodis.com

