Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar 11

Accessing and providing feedback on the Australian UDI database ‘Sandpit’

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TGA Health Safety Regulation

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Agenda

- **Progress update**
- Demonstration
  - User registration and creating an account
  - Bulk data upload
- Answers to previous questions
- Questions and answers

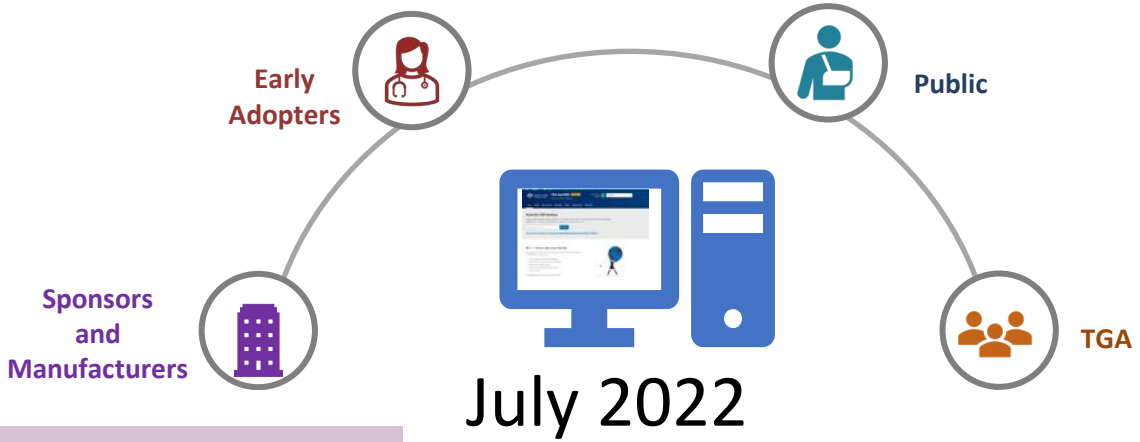
AusUDID Sandpit

Early Adopters

- View and download UDI data, full device versions, history and relationships (CSV and M2M (HL7))
- Scan labels and barcodes
- Device data (based on GUDID) to support agreed Projects

Public

- View and download UDI data, full device versions, history and relationships (CSV)
- Scan labels and barcodes



Sponsors and Manufacturers

- Create, update and delete UDI records via the Portal
- Create, update, delete UDI records via M2M (beta NPC and other systems using HL7)
- Bulk upload of new UDI records
- Link UDI to ARTG
- Sponsor access and authentication
- Manufacturer access and authentication
- Attach documents to UDI records
- Support clean-up of ARTG data and alignment / integrity with UDI

TGA Engagement and Operations Team

- Manage access permissions
- Manage UDI record and device status
- Verify integrity of UDI data
- TGA Support Centre (access issues, operational statistics, manage and release reference data)
- Provide guidance, templates and documentation support

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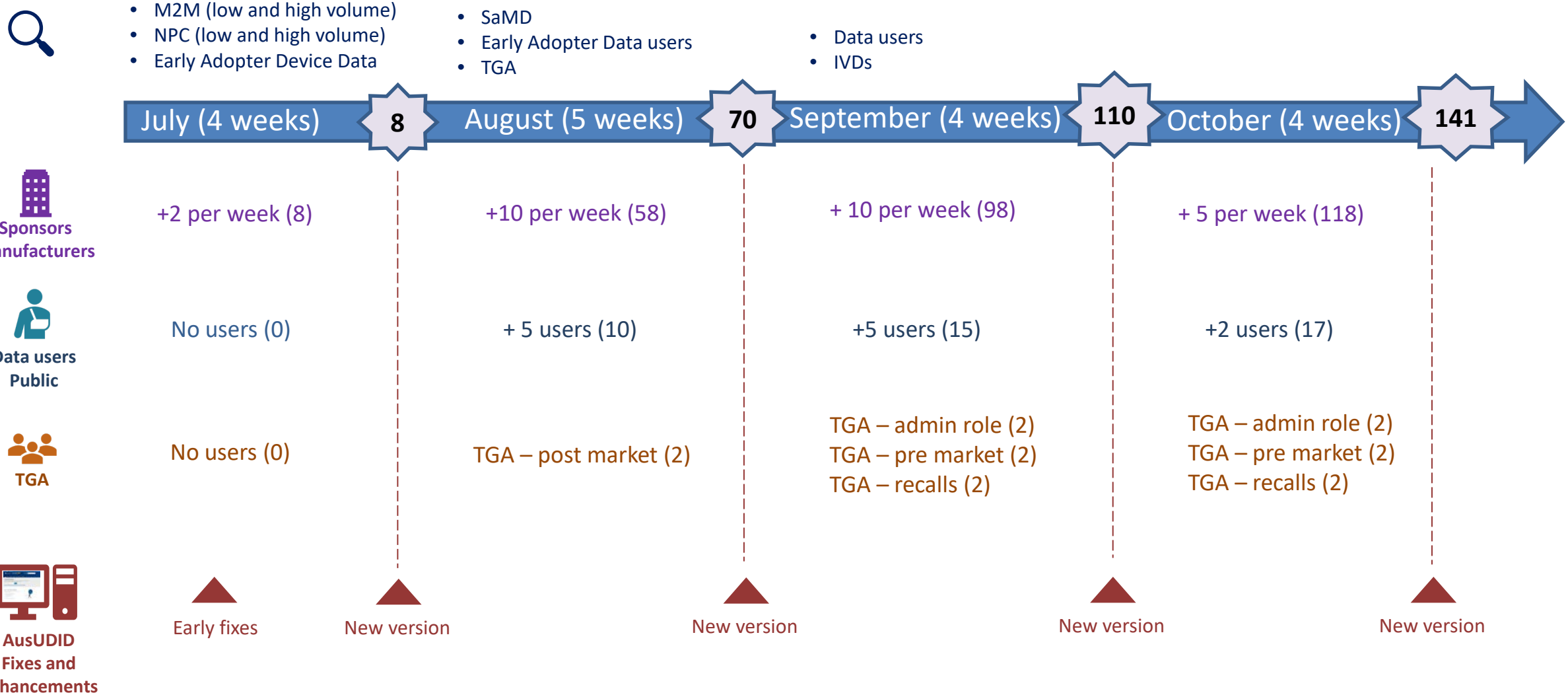
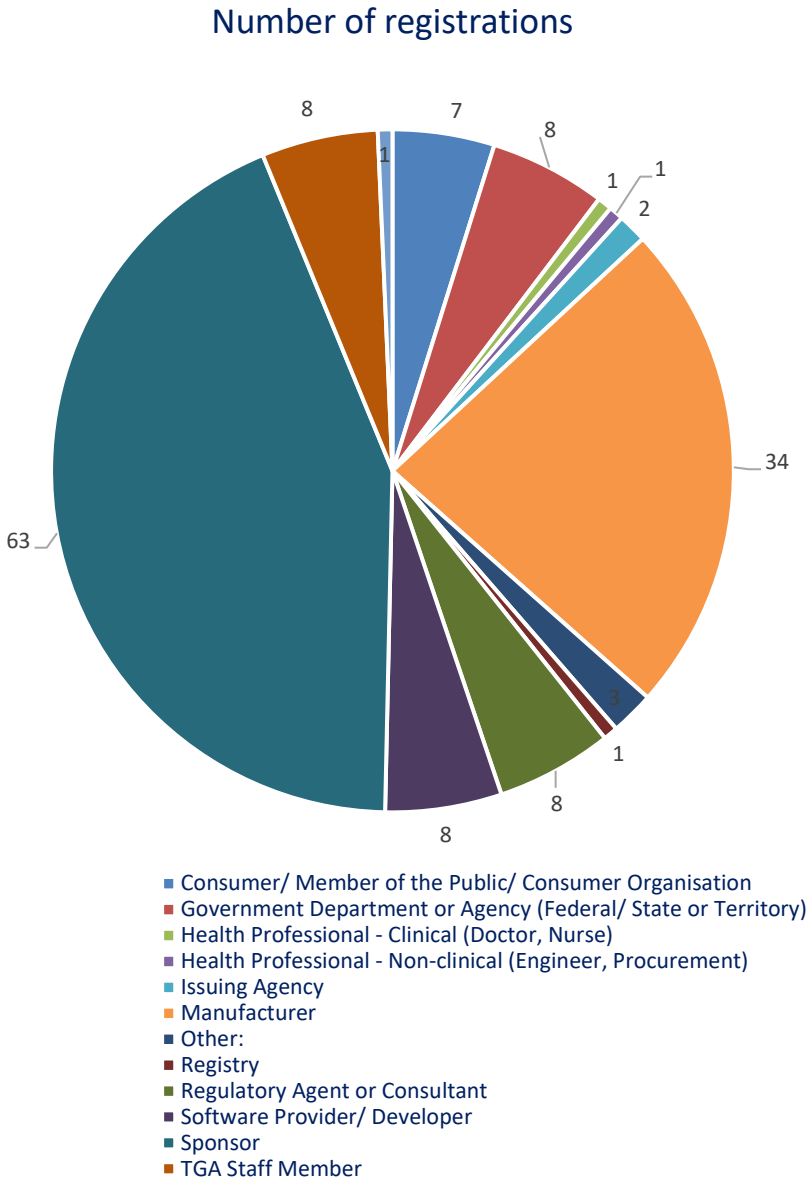
AusUDID Sandpit – Indicative Roadmap

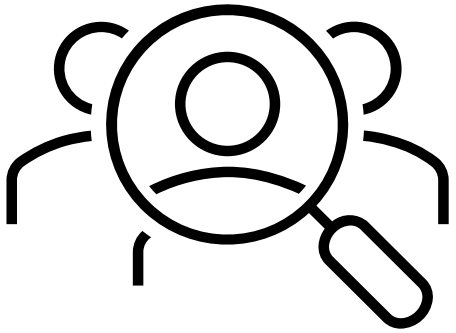


Progress update

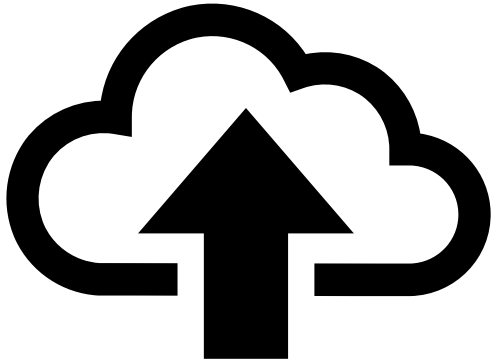
- Registrations opened 27 June 2022
- Sandpit opened on 4 July 2022
- Received 145 received as at 15 July, approximately 67% of registrations are manufacturers and sponsors
- 38 sponsors and manufacturers from 11 organisations have access
- Preparing to receive data via machine to machine Health Level 7 Structured Product Labelling (HL7 SPL) connection
- Finalising National Product Catalogue (NPC) connection with GS1, followed by phased introduction of NPC data
- Some minor updates have been implemented



Sandpit demonstration

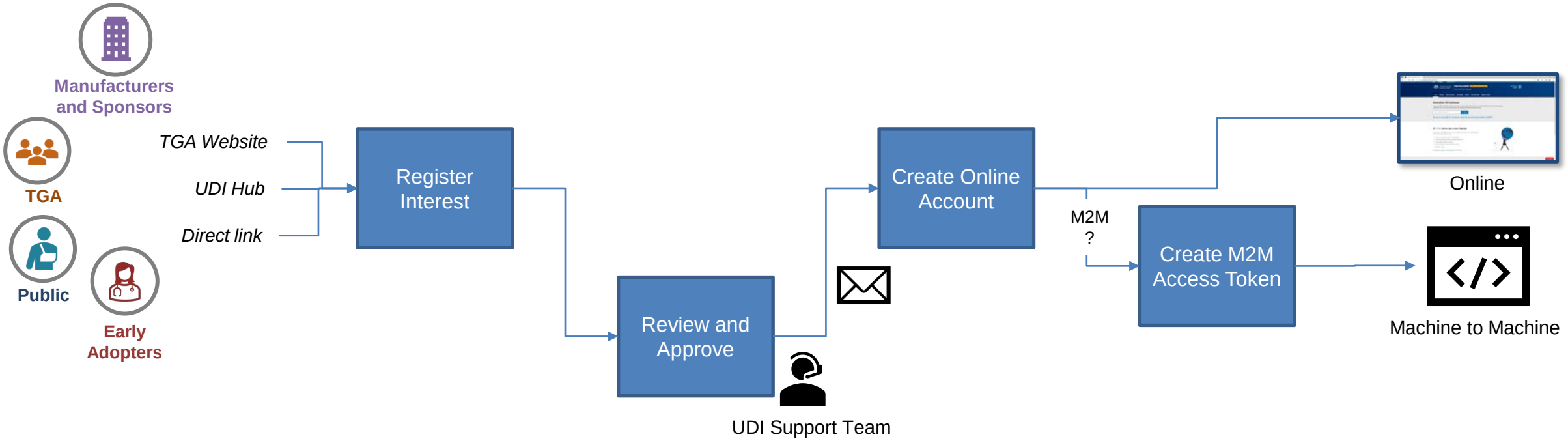


Account Creation



Bulk Uploads

User registration and account creation



Support and feedback

- Dedicated UDI Engagement and Operations team
- Contact
  - Email: udi@health.gov.au
  - Phone: 02 6289 8557 | International: +612 6289 8557
- We welcome all feedback while testing the application

> We'd love to hear your thoughts. Please submit any comments you have using the Give Feedback button located at the bottom right corner of the page.

Answers to previous questions

How and when can I access the Sandpit?

Complete the AusUDID Sandpit Registration of Interest form found on the UDI Hub at Unique Device Identification system | Therapeutic Goods Administration (TGA).

Access to the Sandpit will be granted to users in 'rollout phases'

When will the Sandpit be open and for how long?

The Sandpit opened on 4 July 2022 and is planned to be open until December 2022 (for feedback purposes).

It is planned to have a permanent Sandpit in place from early next year

Is the Sandpit account linked to our current TGA Business Services (TBS) TGA account?

The Sandpit will not link with your TBS account and is a separate log-in.

Who can I contact if I have technical issues with the Sandpit or need support?

Contact the UDI Engagement and Operations team 9am-5pm (AEST) Monday-Friday

Phone: 02 6289 8557 | International: +612 6289 8557 | Email: UDI@health.gov.au

Answers to previous questions

Will there be a template provided for uploading data in to Sandpit?

Yes, an excel spreadsheet template is available for bulk data uploads.

Sponsor/ Manufacturer users can download the template from the "Bulk Edit UDIs" tab.

What is the proposed timeline for the Australian UDID (AusUDID)?

Indicative timelines -

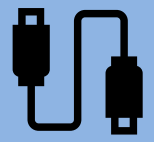
July 2022	Sandpit available for feedback
January 2023	Voluntary compliance for high-risk devices (Class II, III, AIMD)
July 2024	Mandatory compliance for allocation of UDIs, UDIs on labelling, and provision of data for implantable devices

Is the data used in Sandpit live data and is it linked to the ARTG?

Medical device data provided by sponsors and manufacturers is classed as ‘test’ data, and is only for the purpose of using this data in the context of the Sandpit.

While registered users will be able to access any data provided to the Sandpit, this data is not intended for use except in relation to the Sandpit and should be treated as confidential.

Answers to previous questions



Will the sandpit support machine-to-machine for receiving UDI data, or will it be user interface upload of HL7 SPL?

The current Sandpit M2M connection supports the submission of data using the U.S. FDA's HL7 SPL message format.

Interested sponsors and manufacturers are being progressively introduced into the M2M capability (to help us manage initial data volumes).

Please register your interest using the Registration process and indicate your interest in using the M2M connection. A member of the AusUDID team will then be in touch.

Will it be mandatory for all classes of device to have UDI records in the AusUDID?

We are in the planning stages for the Australian implementation and have not yet defined the new regulations, including the scope of devices that will require UDIs

We plan to publish our third consultation soon, which will seek feedback on the operational requirements of Australia's UDI system

Other questions and feedback

Please reach out to the UDI Engagement and Operations team:

Phone: 02 6289 8557 | International: +612 6289 8557 | Email: UDI@health.gov.au

More information

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

Questions?

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Jasmin Hyatt
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Website and link references

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

Contact us

UDI Engagement and Operations Team

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