Australian Government
Department of Health
Therapeutic Goods Administration

Unique Device Identification Webinar 10

Accessing and using the Australian UDI database 'Sandpit'

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TGA Health Safety Regulation

21 June 2022

Welcome

- This webinar is being recorded
- Webinar will be made available in the upcoming weeks
- Any relevant links will be broadcasted via the slido app
- Questions will be open midway in the session using slido
- A live Q&A session will take place after the presentation
- Live poll – please let us know how we went

Difficulties hearing from computer?

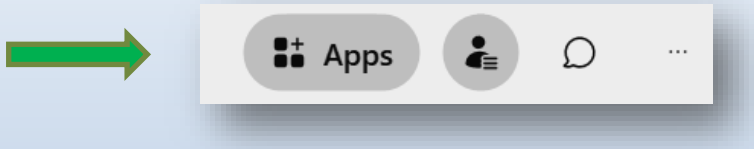
Check your settings located under "**Audio & Video"** tab located top of your screen:

OR

Dial: +61-2-9338-2221 | **Access code:** 2653 324 7391

How to ask questions...

Slido App

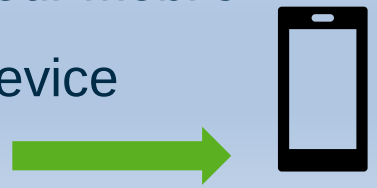


- Click on Apps+ icon
- Select "Slido"
- Open "Q&A" tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device



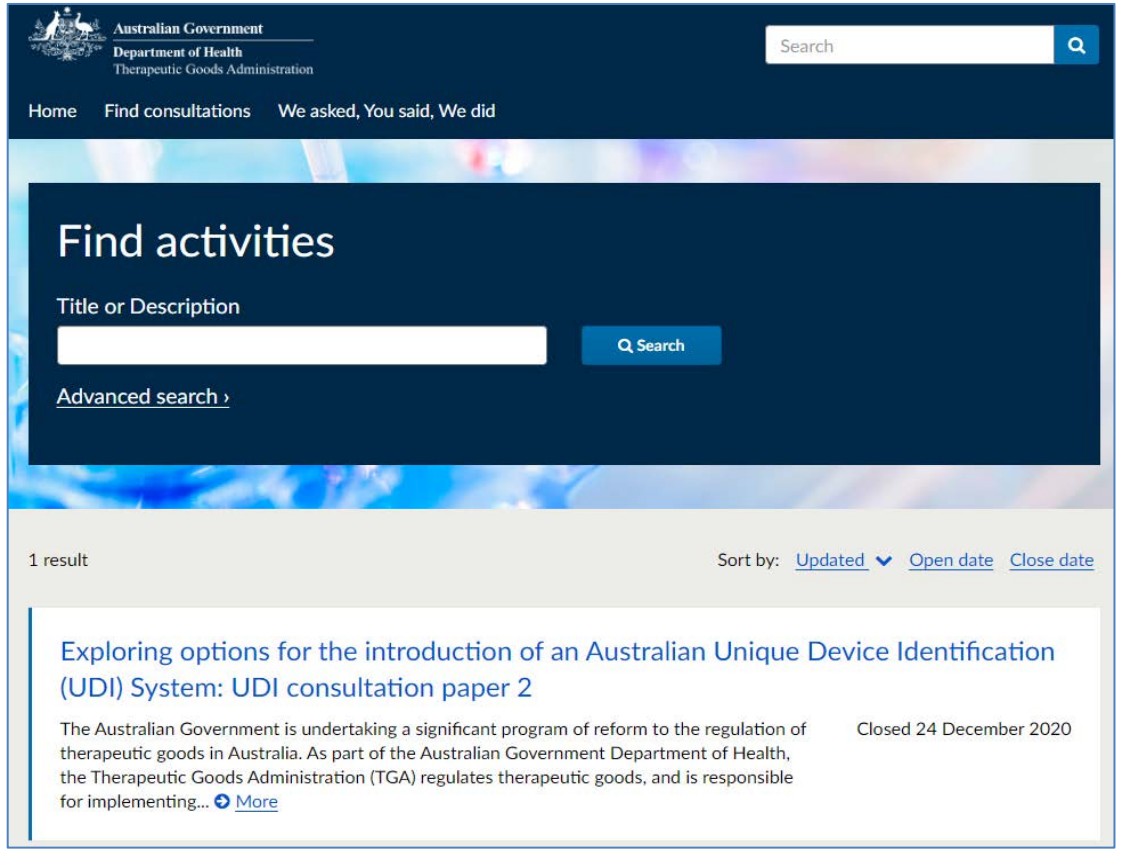
Agenda

- UDI Consultation Paper 3
- AusUDID Sandpit
- Questions and answers

To inform the regulatory framework

- Third UDI consultation
- Feedback will help inform Government decisions on UDI regulations
- Subject to feedback, no further consultations planned before voluntary compliance (planned for early 2023)

- Will be published as an online survey on the TGA consultation hub
- 6 weeks to provide feedback
- Likely timing for publishing end June/July
- Notifications to existing sponsors and UDI contact list
- To be included on the UDI mailing list please advise us at udi@health.gov.au



https://consultations.tga.gov.au/

Key areas of focus are likely to include

- Impacts of accepting both U.S. FDA and EU compliant labels
- Transition approach
- Provision of data and data elements
- Exempt devices
- Fees and charges (from July 2024)
- Adoption and use
- Labelling

Agenda

- UDI Consultation Paper 3
- **AusUDID Sandpit**
- Questions and answers

Gary Pascoe – UDI Product Owner

Gary Pascoe
UDI Product Owner
Therapeutic Goods Administration

Gary has been a member of the UDI team since November 2020 with responsibility for development of the Australian UDI database.

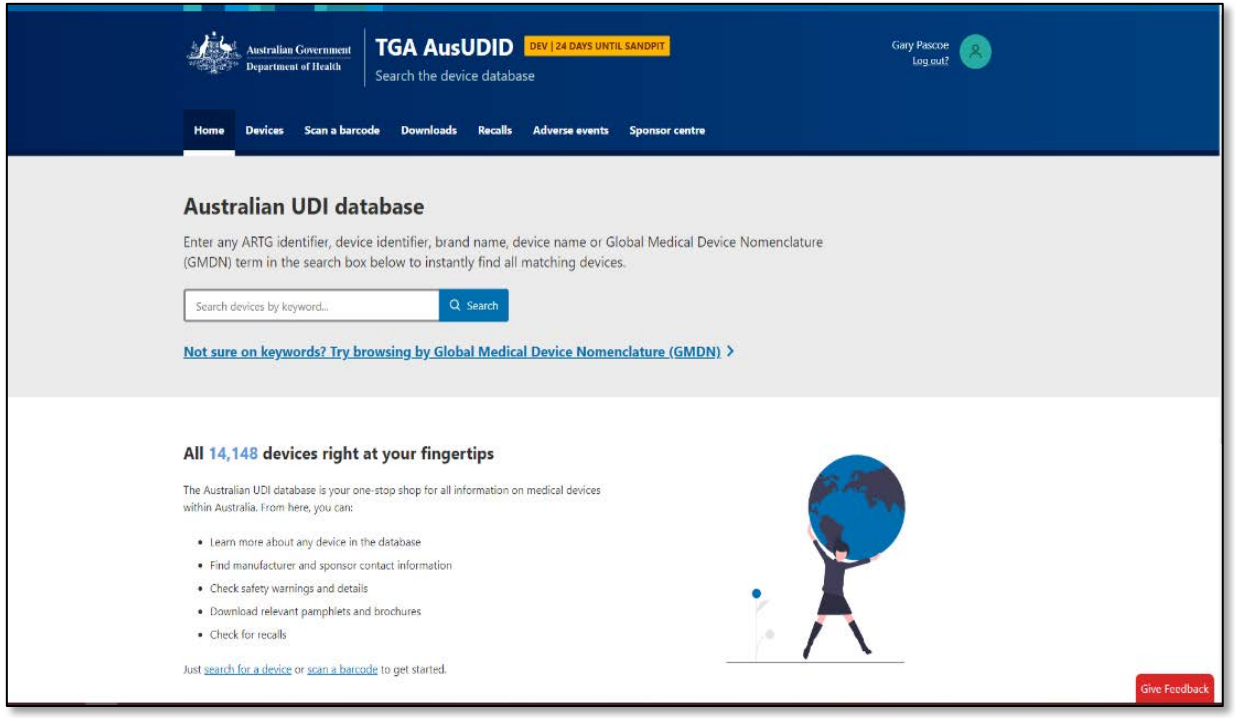
He is a highly experienced product owner with over 20 years in lead roles for the design and implementation of business and IT services in government and the private sector.

Gary is a strong advocate for close engagement and collaboration with all stakeholders and he is very excited to have the Sandpit create these opportunities for AusUDID.

AusUDID ‘Sandpit’ - Objectives

An early release of the AusUDID specifically to:

- Provide the opportunity for users to provide feedback on its usability and features prior to the voluntary compliance release planned for early 2023
- Support stakeholder considerations for Consultation Paper 3



As an early release expect:

- The data to be test data
- Features that change (to incorporate user feedback, additional capabilities and refinements in the rules)

Sandpit scope

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

- Manage UDI record and device status
- Verify integrity of UDI data
- TGA Staff Centre (access operational statistics, manage and release reference data)
- Manage reference data sets

Features (1 of 2)

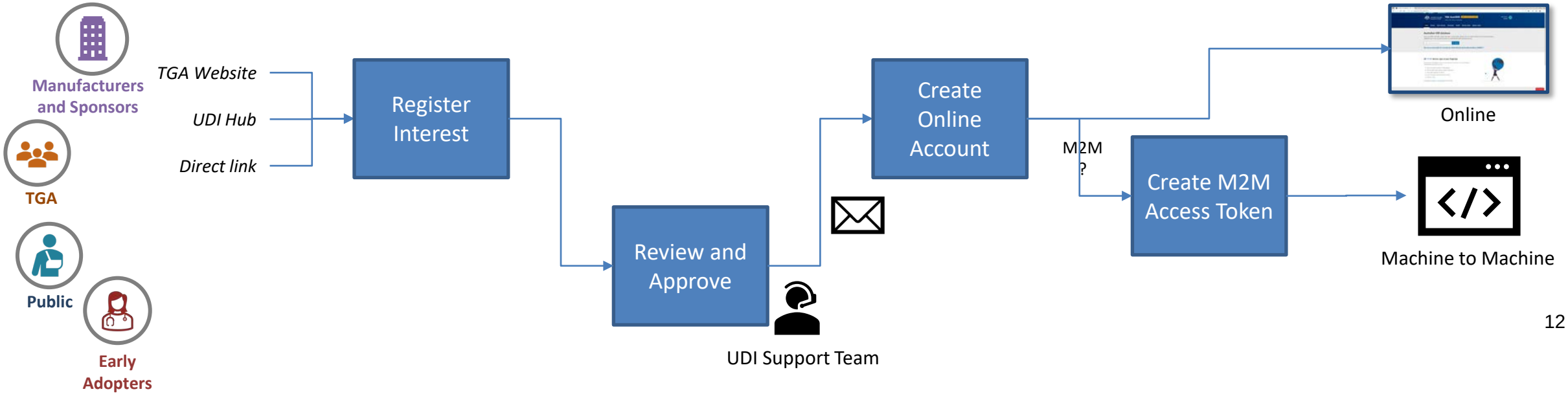
Feature	Sandpit	Future considerations
Create, Read, Update UDI Data	• Create, read, update and store UDI records, including validation of all relevant fields (based on USFDA data and basic validation rules) • Create UDI records by using existing UDI records as a template • UDI record "quick" editing with simple validation • Basic “trigger” rules that initiate a new UDI when significant data is changed • Sponsors and manufacturers view and manage their UDI records	• Changes to data elements following stakeholder feedback (Sandpit and Consultation Paper 3) • Catering for corrections to UDI record including use of a “Grace Period” • Confirmation of manufacturer and sponsors roles, including multiple sponsors
Search and View UDI Data	• Search all devices by keyword with keyword highlighting in search results • Search and browse devices by GMDN terms and collective terms • Medical term dictionary support ‘hover’ explanations in GMDN and Device Description	• Updates to search and view experience from feedback
Receive UDI Data	• UDI data via bulk upload, National Product Catalogue and the standard adopted by the USFDA for GUDID (HL7 SPL) • Bulk linkage of UDI to the Australian Register of Therapeutic Goods, including a sample template • Ability to accept data from manufacturers without an Australian presence	• Refinement to HL7 SPL and NPC integrations, bulk upload features • Additional data feeds, subject to stakeholder feedback (e.g. EU HL7 format, HL7 FHIR, GS1 Global Data Synchronisation Network (GDSN))
Provide UDI Data	• Export and download all device records, selected records, or search results (using CSV, JSON and XML formats) • Bulk download of all UDI records (using JSON format)	• Extensions to export and download of UDI data following stakeholder feedback • Machine to machine provision of UDI data (standards to be confirmed)

Features (2 of 2)

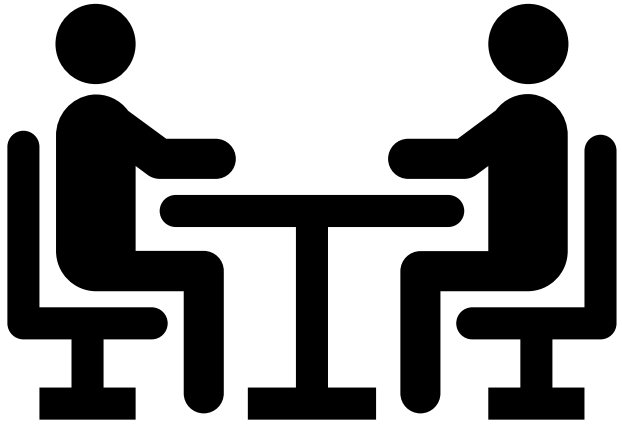
Feature	Sandpit	Future considerations
Manage Device Lifecycle	• Full device history and audit trail to display changes to a record • Draft-to-publish workflow for UDI records, including capability to auto publish on a future date	• Device versioning across all channels • UDI Triggers: Recording information on device changes and reason for change • Advanced linkage of devices and device relationships
Manage links to other device data	• Basic links to the Australian Register of Therapeutic Goods (ARTG) allowing one or more ARTG entries to be linked to a UDI record • Displaying the ARTG Public Summary, status, manufacturer, Global Medical Device Nomenclature (GMDN) term • Link to GMDN Codes	• Extended integration with ARTG including validation and sharing of data • Linkages to Recalls, Adverse Events, Prostheses List / Billing Codes • Management of changes to GMDN codes across UDI and ARTG
Attach Documents to UDI Record	• Attach files to UDI record and ability to tag document as Patient Information Leaflet (PIL) and restrict public access • Support for external links with click-through	• Extensions to file attachments following stakeholder feedback
Scan Barcodes and Device Labels	• Scan a UDI barcode (1D or 2D / Data Matrix) with a camera and display device details, including translation of the UDI-Production Identifier (UDI-PI) • Manually enter a barcode (via text entry) to look up a device	

User registration and accounts

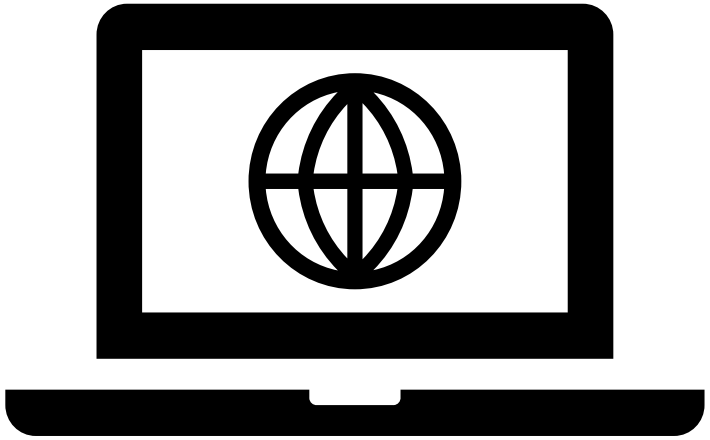
User Registration and accounts	• Role-based access system for secure access by all users • All users will require an account, and create own account and manage password; including authentication for HL7 SPL data exchange • TGA Staff Admin manage and approve all access, ability to approve and remove any user's access • TGA may progressively introduce different users / user groups over first weeks • All will be required to accept a Terms of Use before account is created	• Addition of agents



Demonstration / Key concepts



Registration



AusUDID Portal

Jasmin Hyatt –UDI Support Manager

Jasmin Hyatt
UDI Support Manager
Therapeutic Goods Administration

Jasmin Hyatt has worked at the TGA for many years in various customer facing roles.

She has a passion for customer service and business process design, and is excited to be part of the AusUDID project.

She looks forward to getting to know you and helping you with your UDI requirements.

Please reach out to Jasmin's team should you have any questions.

Support and feedback

- Dedicated UDI support team
- Contact
  - Email: udi@health.gov.au
  - Phone: +61 2 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.

- Sandpit onboarding and rollout approach from 4 July
- Upcoming FAQs on UDI Hub: Unique Device Identification system | Therapeutic Goods Administration (TGA)

Agenda

- UDI Consultation Paper 3
- AusUDID Sandpit
- **Questions and answers**

How did we go?

LIVE POLL

The team is currently reading over your submitted questions.

We'll be back shortly for Q&A

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

Questions?

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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

Contact us

UDI Project

udi@health.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration