

# Improving TGA's Services: Modernising Digital Systems

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## GMP FORUM 2024



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

[tga.gov.au](https://tga.gov.au)

# Agenda

- **Digital Health Blueprint**
- Improving the TGA's Digital Services
- [tga.gov.au](http://tga.gov.au)
- Future Innovation
- Upcoming Opportunities to Engage

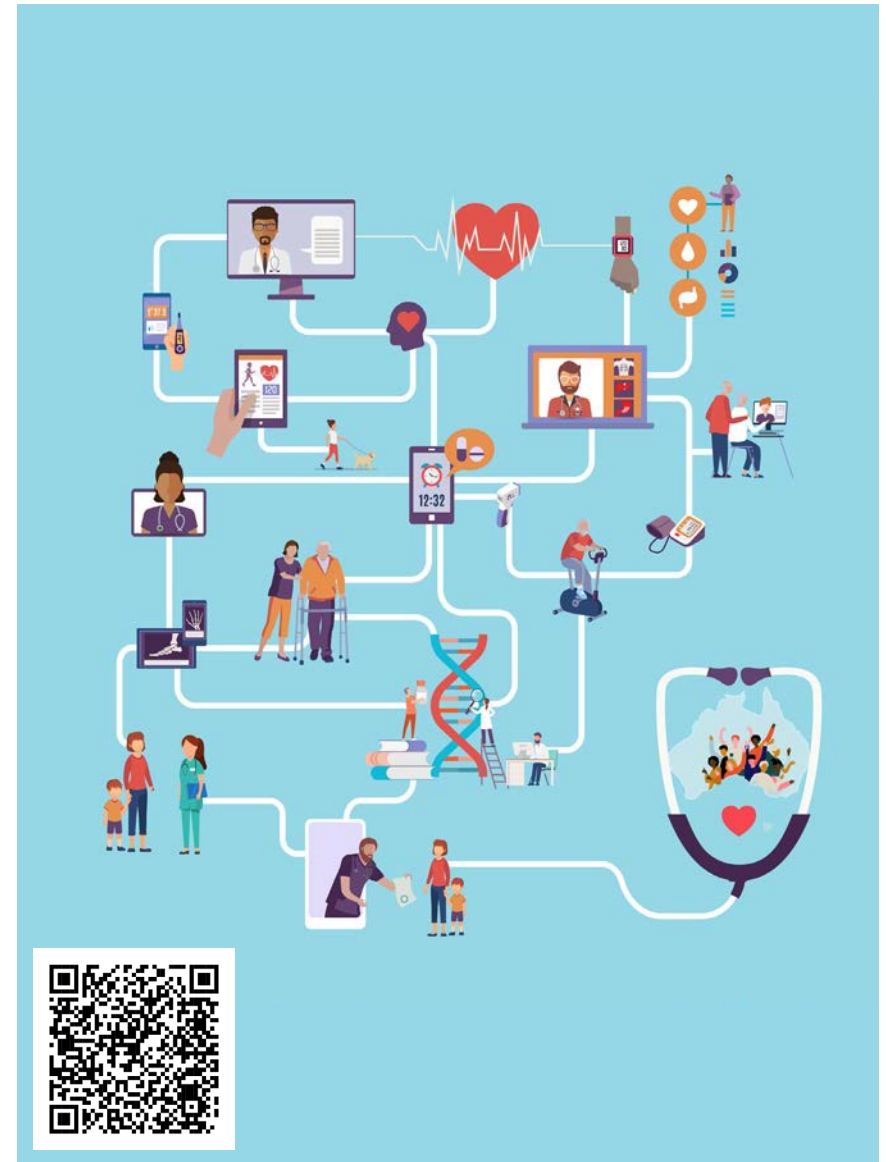
# Digital Health Blueprint 2023-2033

The Blueprint outlines the Australian Government's vision for the role digital health capabilities will play in delivering a more person-centred, connected and sustainable health system by 2033.

“ *Trusted, timely and accessible use of digital and data underpins a personalised and connected health and wellbeing experience for all Australians* ”



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration



# Key priority areas



## National Standards

To support the consistent capture and sharing of health information between health and care settings and across jurisdictional borders.

## Healthcare Identifiers

Unique identifier for patients, healthcare providers and healthcare organisations to enable the accurate matching of patient records from across all parts of the health system.

## National Health Information Sharing Infrastructure

To enable near real-time and seamless information sharing of key patient health information across health and care settings, including to My Health Record, and across jurisdictional borders.

## Legislation

Legislation that will provide the appropriate, nationally consistent consent-based framework for health data to be shared more seamlessly across the health sector.

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# Improving TGA's Digital Business Services

We are working to assist you to meet your regulatory requirements, by providing **intuitive digital services** that make interactions with us easier and more seamless.



## What we hear about current systems

- Not user friendly
- Mixture of digital and paper forms
- Out of date



## Benefits of the new system

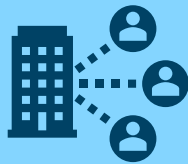
- Intuitive self-serve options that are easy to use
- Contemporary – more integrated, reliable and stable
- Reusing data and information you share to make applications/submissions easier for you
- Easier to make changes and continuously improve

# What's been delivered so far

In **2023-24** the focus was on delivering the first foundations and onboarding the first business processes.



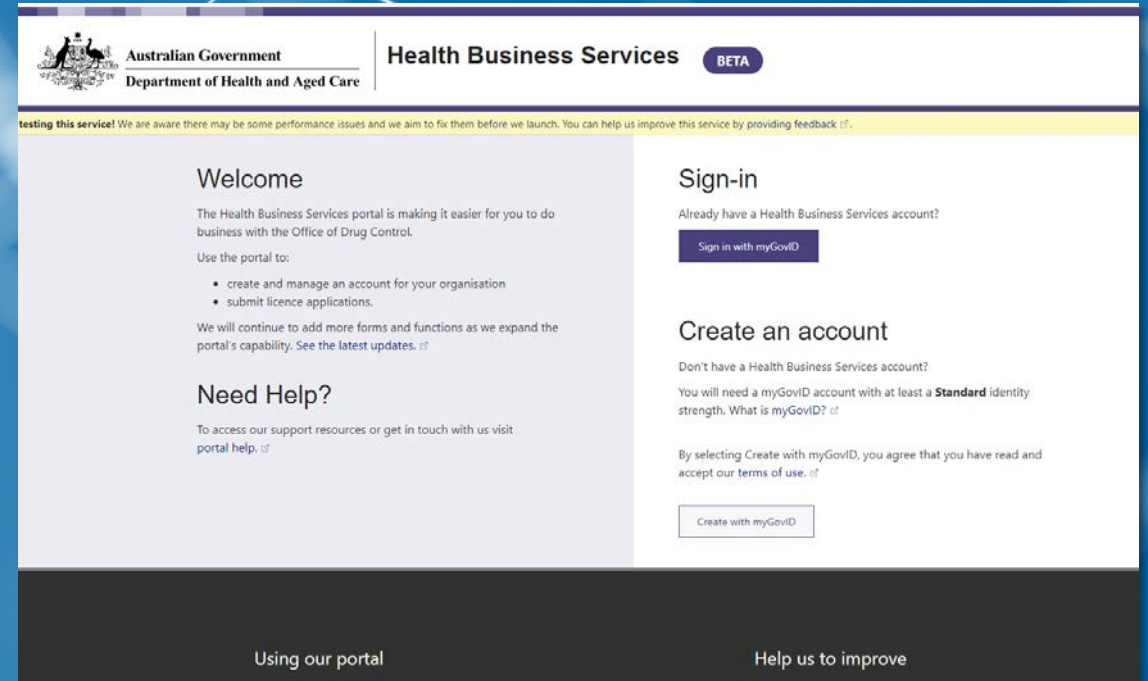
Log in to the new online portal



Create and manage an account for their organisation



Submit licence applications directly to the Office of Drug Control on new digital forms



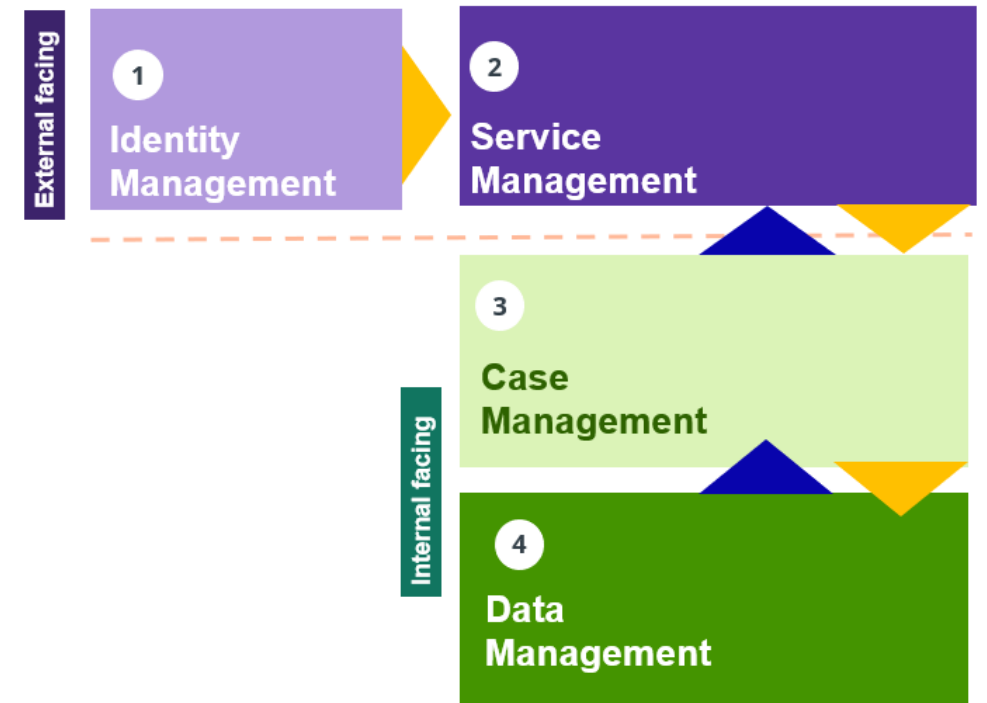
**These are now live**  
<https://businessservices.health.gov.au>

# To be delivered in 2024 and 2025

To progress to the next stage of work, we are building-out four digital pillars:

1. Identity management
2. Service management
3. Case (application) management
4. Data management

From later in 2025, onboarding the first group of TGA users to new solutions and an initial set of services.





External facing

1  
Identity Management

2  
Service Management

Health Business Systems portal

- Progress Tracking
- Sponsor / Interaction History
- Self-Service

User submits an application

Internal facing

3  
Case Management

New Case Management Solution

- Seamless & efficient processes
- Automated Workflow and Task Management

4  
Data Management

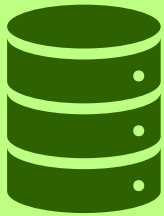
Consolidated Therapeutic Goods Data

- Enhanced Analytics capability
- Consolidated view of information
- Fit for purpose medical devices data

## From later in 2025, we are working to enable the following, for the first group of TGA users

- The ability to view, manage and action invoices.
- The ability to submit a set of applications/notifications to the TGA using new forms for:
  - Pre-submission meetings requests
  - Good Manufacturing Practice clearance application
  - Sponsor Notice for vaping goods
  - Propose a new ingredient names application
- The ability to access other TGA services in older systems through the new portal.
- Sponsor submission of UDI data, including data submission via APIs for electronic data entry.
- Sponsor access to AusUDID from the Health Business Services portal and sponsor notification of data changes (when a device has more than one sponsor).

# Improving shorter-term data analytics, maintaining existing systems



Establishing a **data hub**  
internally to support  
TGA's internal work



Supporting existing  
systems



Preparing to  
decommission older  
systems

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# The TGA website will continue to evolve

2004

2014

2019

2024

# 280+



**People consulted**

## High level summary:

There were 280+ people consulted through:

- 1:1 interviews (industry participants)
- Surveys
- Industry forums
- Meetings with staff

## 181

TGA and ODC website audiences (surveys)

## 2

Industry forums (Reg and Com Tech)

## 11

TGA website users (1:1 interviews with industry)

## 87

TGA and ODC staff (stakeholders and surveys)



# What we heard

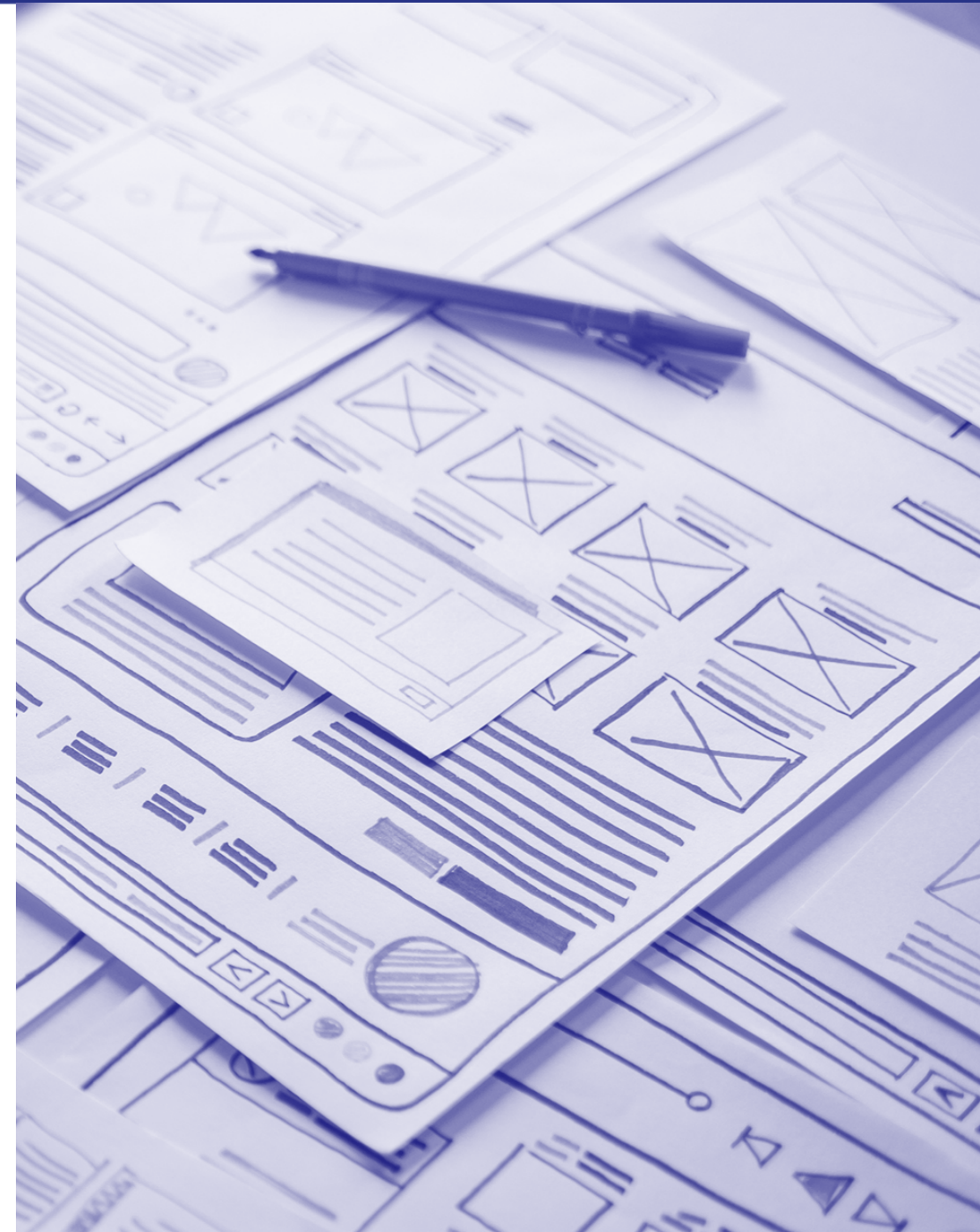
Guidance is heavily used and relied upon.

Opportunities for improvement:

- Version control
- Difficult to find, search and scan
- Single source of truth
- Inconsistent structure
- Accessibility
- Hard to manage

# What's Guidance on the TGA website?

Content that goes to the laws and regulations governing the development, manufacturing, marketing and supply of therapeutic goods in Australia.





# *From*

- Unclear source of truth, inconsistent structure
- Version control issues, unclear
- Accessibility issues
- Difficult to find, search and scan
- Hard to manage

# *To*

- Digital first, structured and consistent content
- Clear, up to date, timely, accurate
- Accessible and user friendly
- Connected content that's easier to navigate
- Easy to maintain

# TGA website changes Guidance project

[www.tga.gov.au/resources/guidance](http://www.tga.gov.au/resources/guidance)

## Guidance

Our Guidance explains the laws and regulations governing the development, manufacturing, marketing, and supply of therapeutic goods in Australia.

We're progressively moving Guidance content from other parts of the website into this new location. In the meantime, if you cannot find what you're looking for, you can search our [Resources](#) or use the site search bar for more results.

[Listen](#) [Print](#) [Share](#) [RSS feed](#)

Use the filters below to narrow your search.

Search guidance

[Open all](#)

139 result(s) found, displaying 1 to 25

### Audience

- Advertisers (33)
- Consumers (15)
- Health professionals (26)
- Manufacturers (98)
- Sponsors (129)

### Product type

### Topic

### Last updated (Year)

#### [Requesting the Minister for Health to reconsider our initial decision](#) Updated

14 October 2024 | Guidance

Guidance about how to request reconsideration of 'reviewable' initial decisions by the Minister for Health.

#### [Special Access Scheme \(SAS\): Guidance for health practitioners accessing unapproved therapeutic goods](#) Updated

1 October 2024 | Guidance

This guidance is to assist health practitioners understand their requirements when prescribing 'unapproved' therapeutic goods for an individual patient using the Special Access Scheme (SAS).

#### [Understanding requirements for unapproved therapeutic vaping devices and accessories in Australia](#) New

1 October 2024 | Guidance

This guidance helps sponsors and manufacturers of 'unapproved' therapeutic vapes understand quality and safety requirements, under the Therapeutic Goods (Medical Device Standard —Therapeutic Vaping Devices) Amendment Order 2024.

#### [Understanding product standards for unapproved therapeutic vapes in Australia](#) New

1 October 2024 | Guidance

Guidance on the quality and labelling requirements of Therapeutic Goods Legislation Amendment (Standard for Therapeutic Vaping Goods) (TGO 110) Instrument 2024.

# New features make Guidance clearer and more accessible

Clear list of related legislation on each page



Visual indicators to flag updates

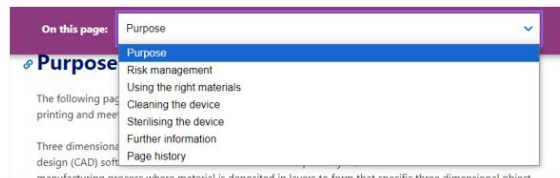
on individual Guidance pages



Clear list of changes over time



'Sticky' navigation makes it easy to move through long pages



Detailed table of contents for Guidance with many headings

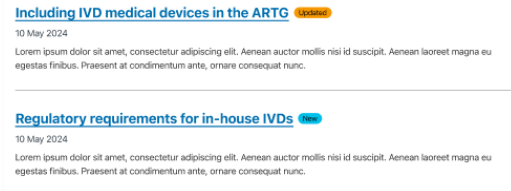
Show detailed table of contents



Published: 21 June 2022

Last updated: 25 January 2024

on Guidance listing page



Bookmarkable headings for easy sharing

 Purpose

'Save as PDF' function

 Listen  Print  Share  Save as PDF

# Next steps

- We want **your views** – please take our survey and tell us what you think of the new features.
- If you notice any errors in Guidance, you can report to us:
  - use ‘Is there anything wrong with this page’ link at the bottom of the page, or
  - email to [tga.website@tga.gov.au](mailto:tga.website@tga.gov.au).
- We plan to **work with TGA staff** in future to:
  - improve Guidance content to make it easier to understand and reduce duplication
  - re-home content that is no longer considered Guidance under the new definition.



Scan the QR code for  
the Guidance survey

Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

[News and Community](#) [About us](#)

Search this website

[Products we regulate](#) [Product safety](#) [How we regulate](#) [Guidance and resources](#)

## Therapeutic Goods Administration (TGA)

We are Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. We regulate medicines, medical devices and biologicals to help Australians stay healthy and safe.



If you'd like to be involved in **user testing**, scan the QR code to sign up for our user research group

# TGA website changes

## Information architecture review

November 2024 to June 2025

Information architecture refers to:

- how we organise content
- relationships between each piece of content
- how content is visibly displayed on the website's navigation – logical headings and pathways mean that users can easily find what they need.

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# Our digital uplift is also paving the way for future innovation

- AI tools present *new* and innovative opportunities.
- Trust, governance, care and risk management will be critical.
- As a government agency, our approach will be guided by broader Government and Commonwealth setting, including advice from Digital Transformation Agency (DTA) and the Department of Industry, Science and Resources
- We will be mindful of
  - The sensitive nature of the information we hold and ensuring its security
  - Alignment with Australia's 8 Artificial Intelligence (AI) Ethics Principles, and the [DTA's Policy for Responsible Use of AI in Government](#), to ensure AI is safe, secure and reliable.

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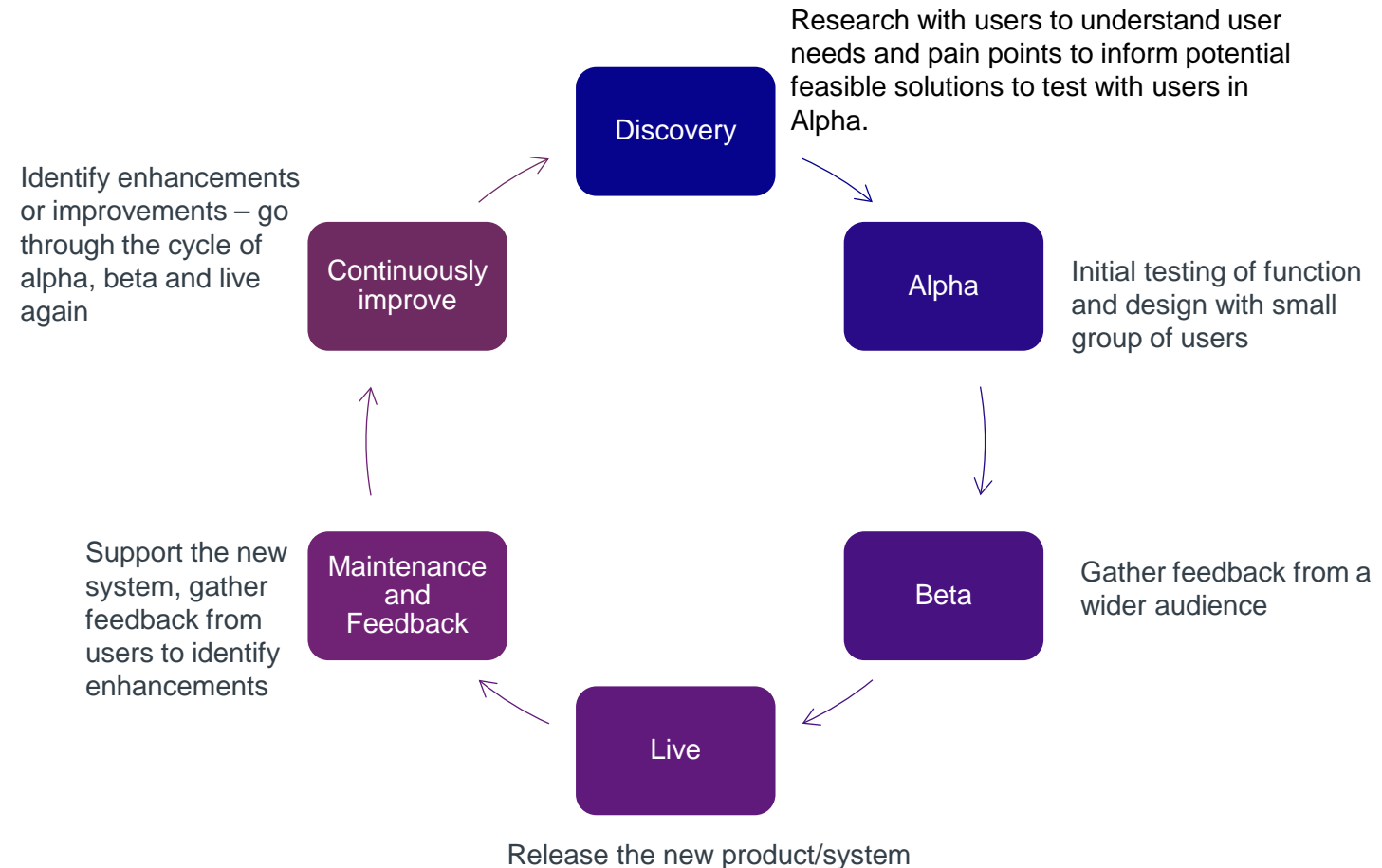
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# Modernising TGA systems will continue to occur in stages

TGA systems are many and complex  
– we need to build and move to new systems in stages to ensure

- We fully understand user needs
- We are building the right system to meet those needs
- We are building a system that can adapt and continually improve



# How to engage with us

We will continue to engage and consult with stakeholders, particularly industry, health providers, health professionals and consumers to understand their needs and issues to build a better experience for everyone.



## Get in touch

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You can reach out to our team with questions or suggestions.

[www.tga.gov.au](http://www.tga.gov.au)



## Learn more

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You can join our mailing distribution list for regular Program updates.

[tgatp@health.gov.au](mailto:tgatp@health.gov.au)



## Future testing & feedback

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If you'd like to contribute to this work, you can sign up for our user research group.



# Questions?



Scan this QR code with your device to submit a question



# GMP FORUM 2024



**Australian Government**

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