Prescription Medicines Authorisation Branch Update

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Assistant Secretary
Department of Health, Disability and Ageing, TGA

Session Overview

- Prescription Medicines Authorisation Branch: what we do
- Recent highlights
- Data in focus
- Reforms program spotlight
- Australian Evaluation Aid

Prescription Medicines Authorisation Branch

What we do

- Administration and evaluation of Prescription Medicines Applications
- Public communications
- Data analytics and reporting
- Innovation to build capability, capacity and efficiency

The last 12 months

Focus presented at 2024 ARCS	Where we are
• Prepare for sustainable growth	• Increased staff by around 25% to reflect growing complexities and volume of work
• Continue improvements to structure, governance, and processes	• Restructured clinical teams and reviewed supporting functions
• Use data to understand our business better	• Captured data to analyse our work and processes
• Deliver key projects, including repurposing program	• Started reforms to the registration process

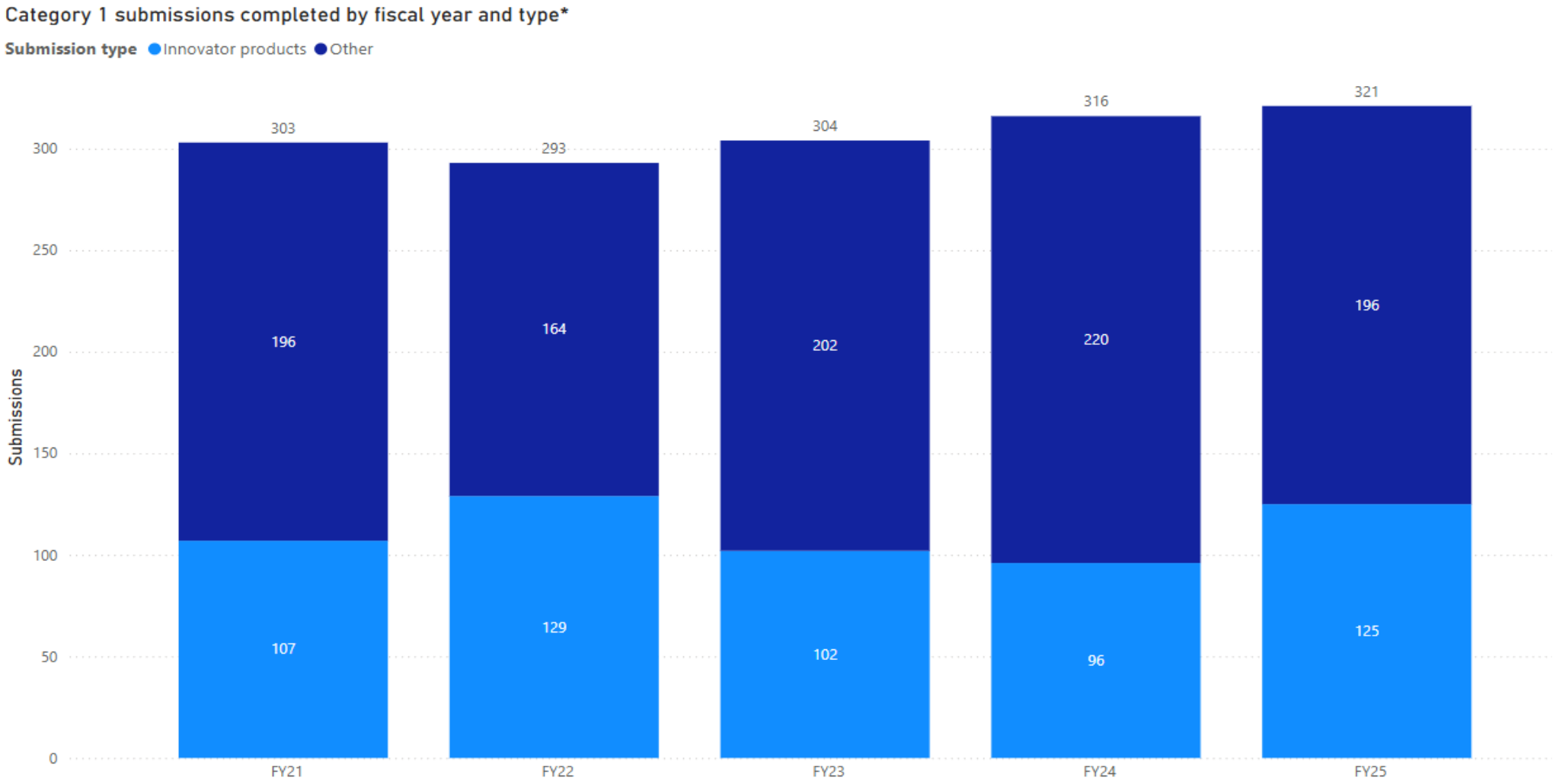
Focus for the next 12 months

- Implement structure and governance changes for supporting functions
- Consult with industry on process reforms
- Improve decision timeliness
- Adoption of AI to support evaluation and decision-making

Recent highlights

New medicines

Submissions completed



*Excludes type new generics and biosimilars. Data was prepared on 23 May 2025 so FY25 is incomplete.

Recent highlights

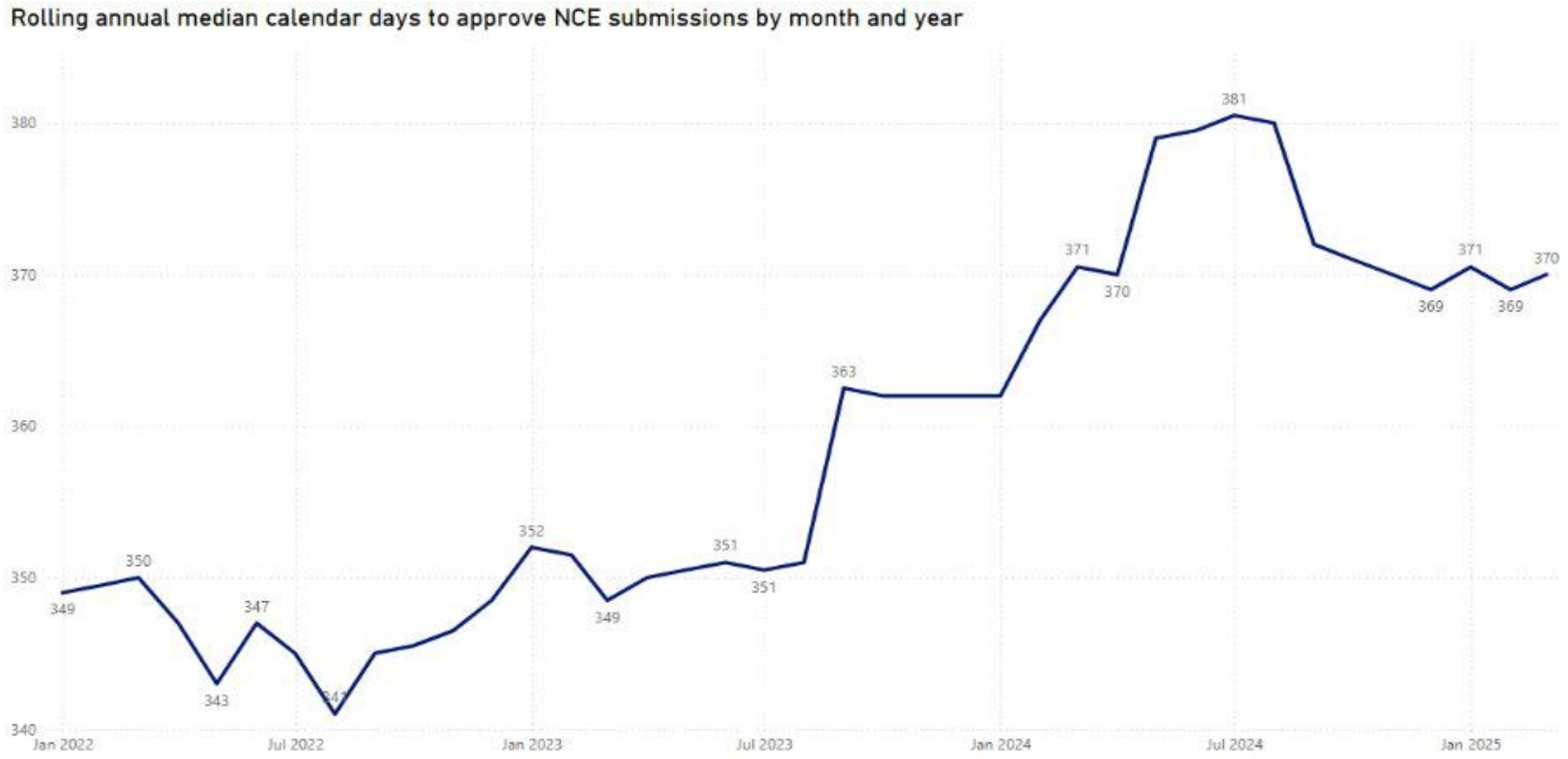
- Increasing international collaborations (ACCESS workshares / Project Orbis)

Significant new medicines

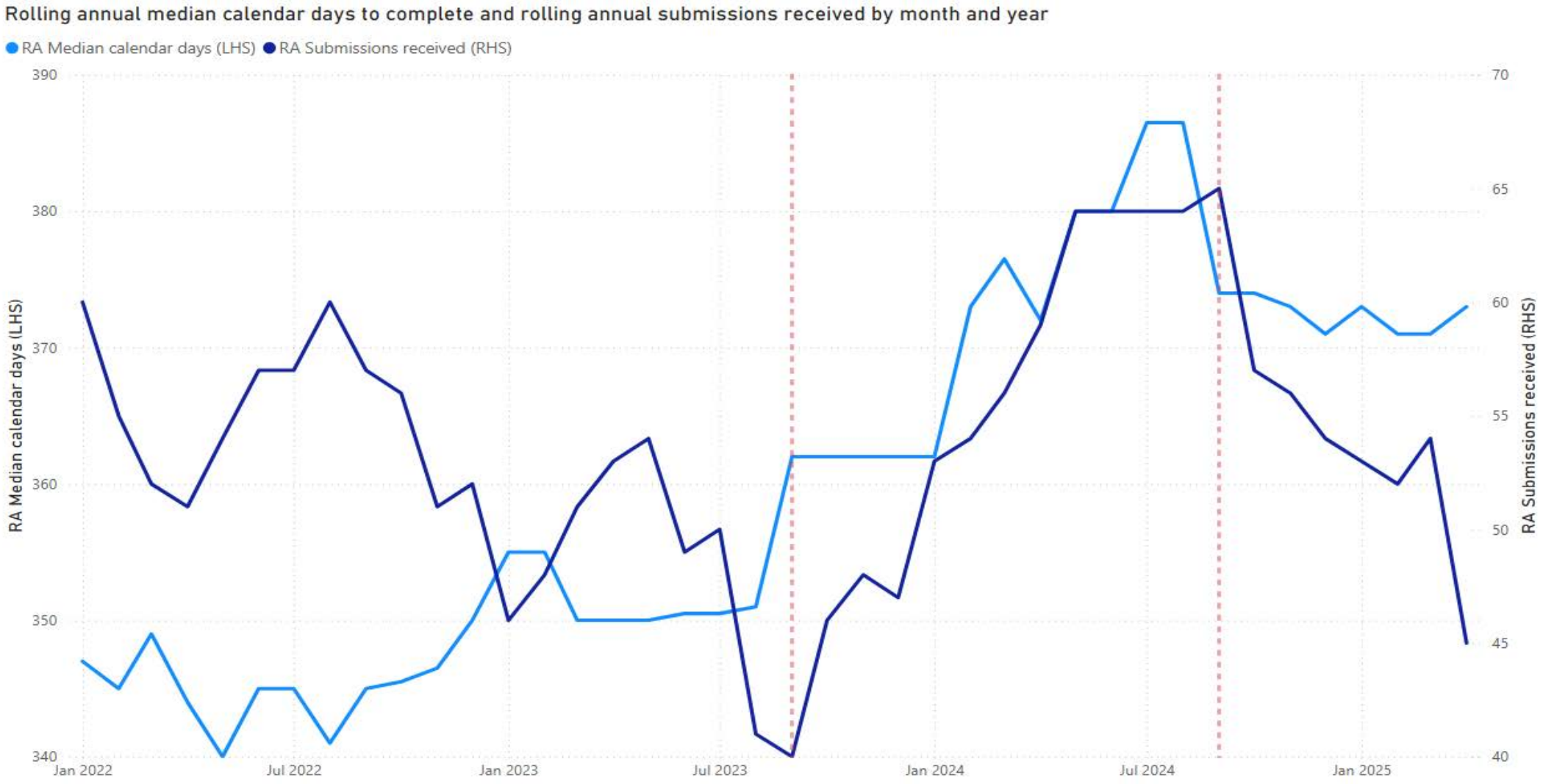
- Alzheimer's disease medicine Donanemab (KISUNLA)
- new medicine for pulmonary arterial hypertension – sotatercept
- first medicine approved for the rare lysosomal storage disease alpha-mannosidosis – velmanase alfa
- new medicine for primary biliary cholangitis - elafibrinor

Data in focus

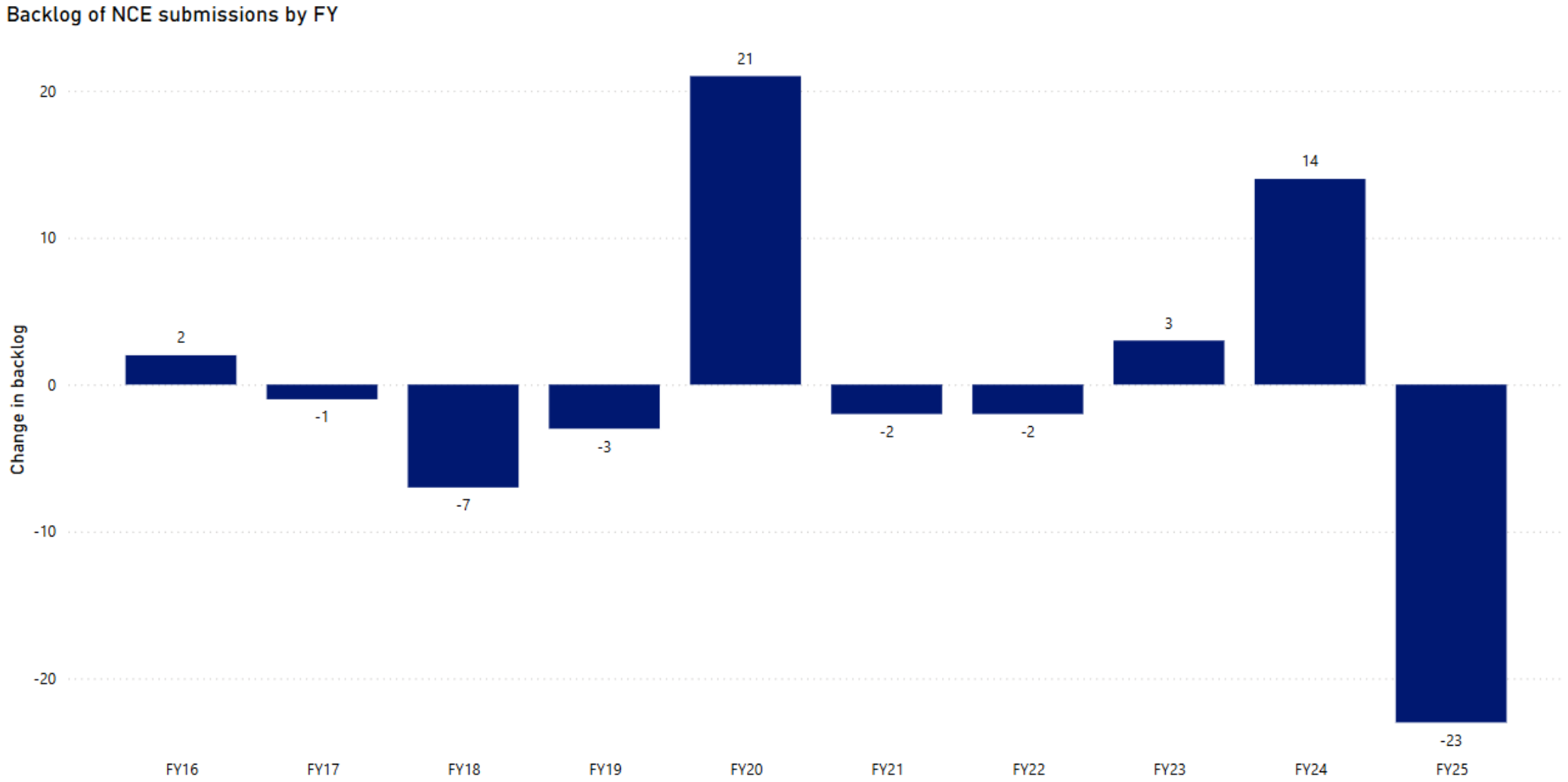
Approval times appear to have peaked in July 2024



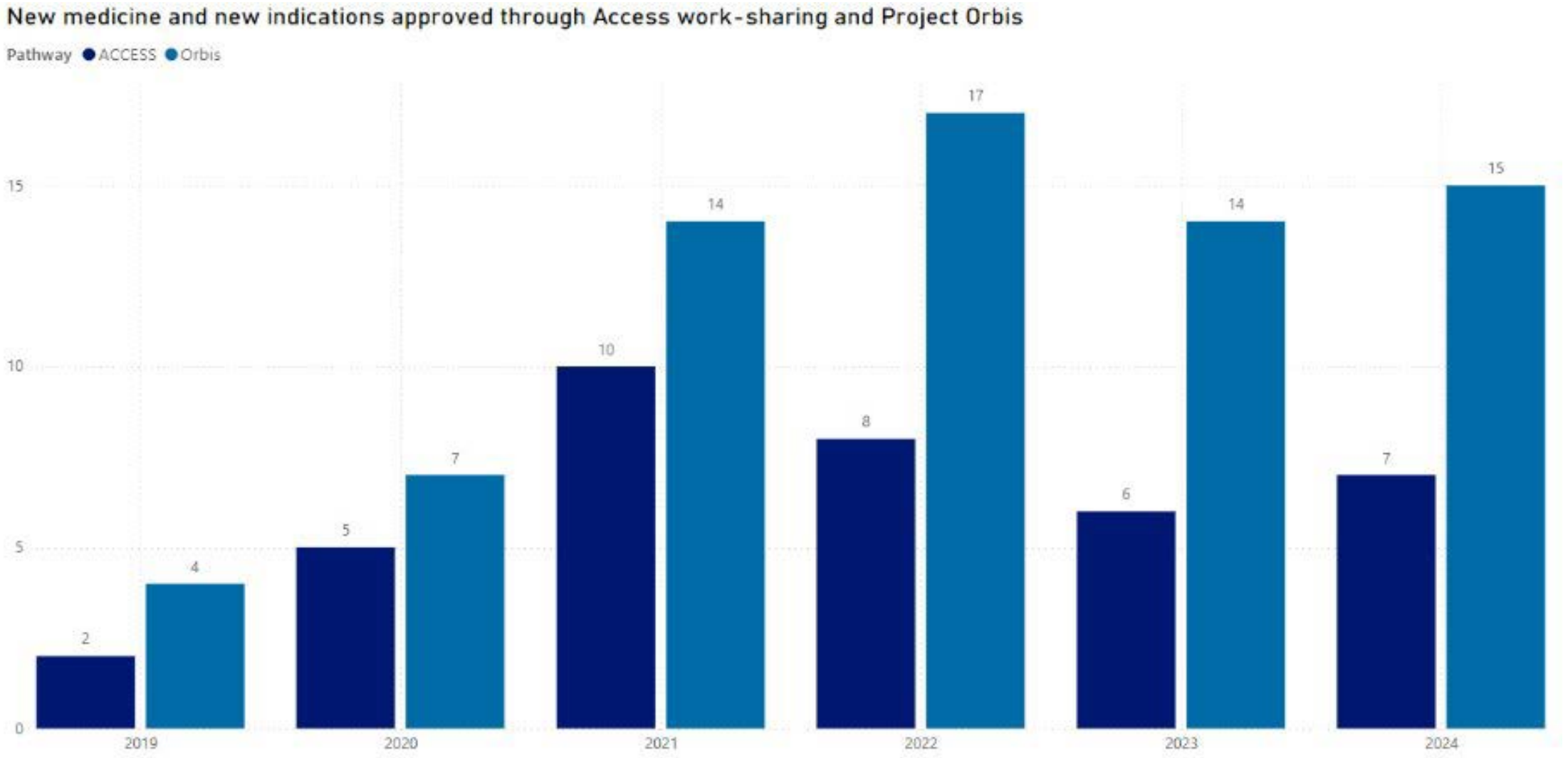
Approval times and new submissions



Improvement in approval times has been driven by a reduction in the backlog of submissions



International collaboration



International collaboration

Project Orbis

- Submissions for new oncology medicines/indications continuing to increase
- Many high-profile submissions:
  - 24% priority, 27% provisional (almost 2/3)
  - 26% orphan
- Benefits in efficiencies to both TGA and sponsors
- TGA is refining how it integrates Project Orbis

ACCESS Consortium

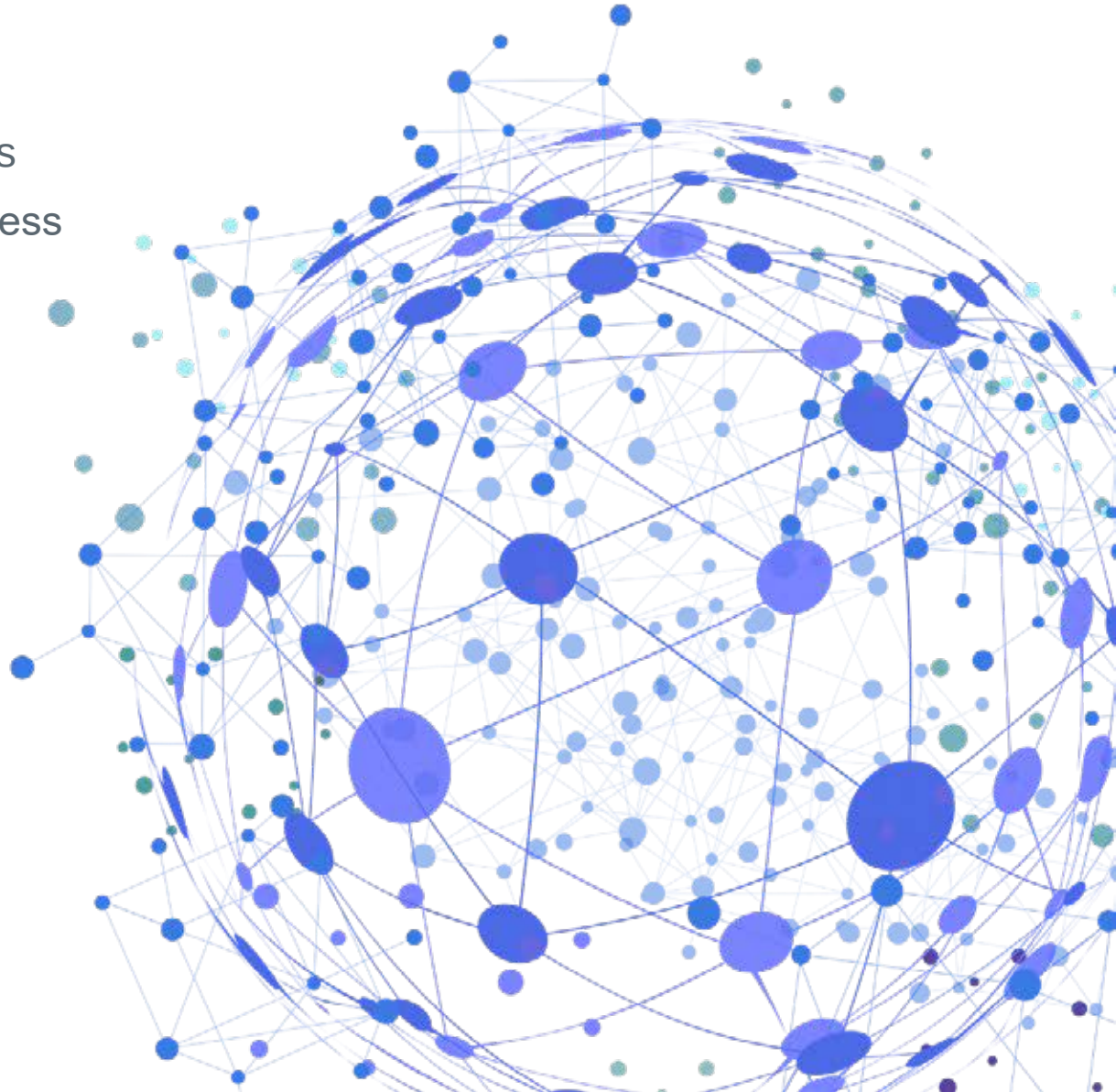
- The TGA received 10 submissions through the ACCESS pathway in 2024. 30% of these submissions were also orphans.
- PMAB has been reviewing the process around ACCESS submissions.

ACCESS Work-sharing operational review

Key benefits

Internal stakeholders and sponsors highlighted strengths

- reduced submission gaps enabling faster patient access
- cross agency partnerships build regulatory expertise
- participation provides early insights into emerging therapies and technologies



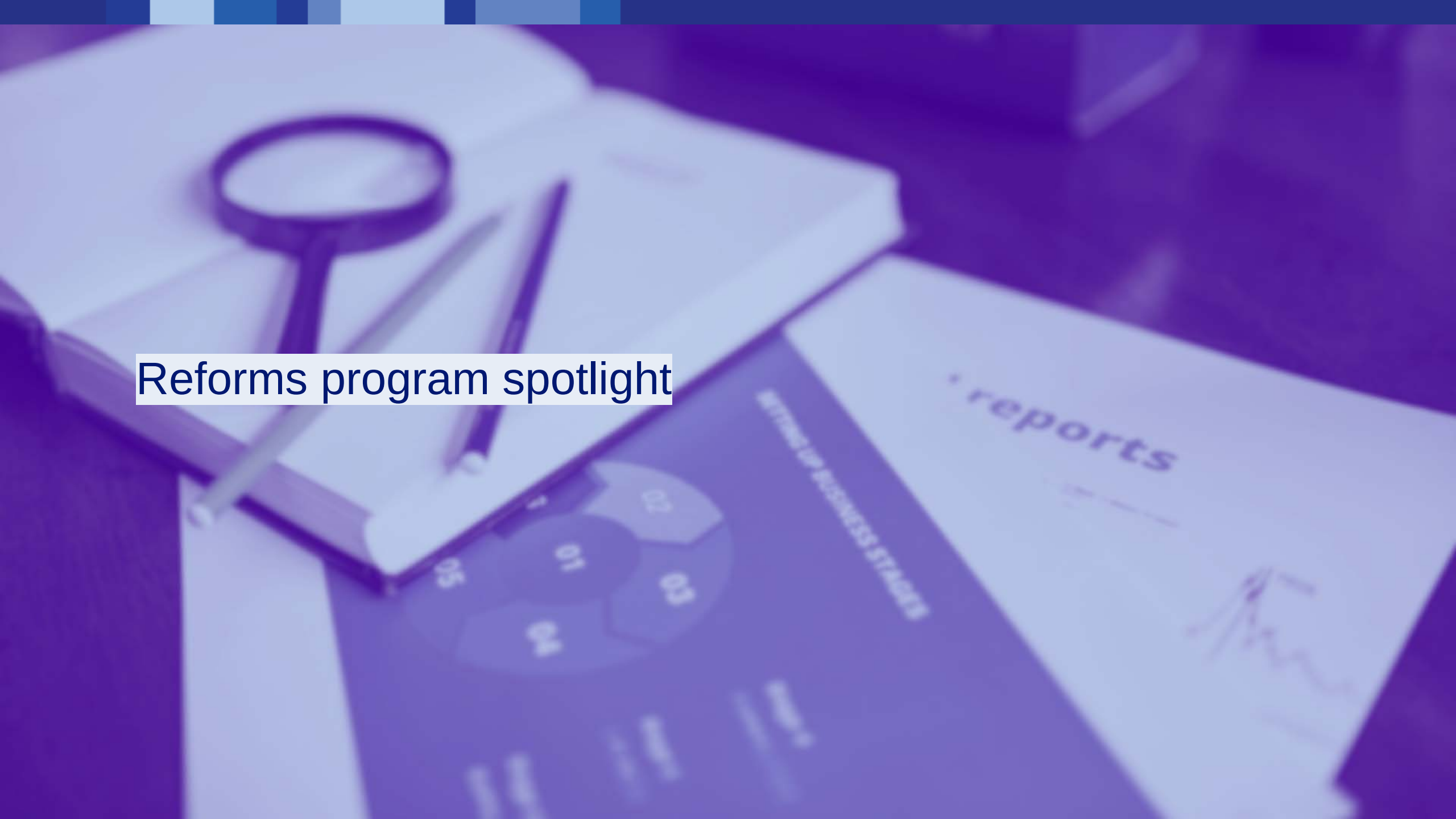
ACCESS Work-sharing operational review

Key recommendations

Formalise an ACCESS Governance and Coordination Group.

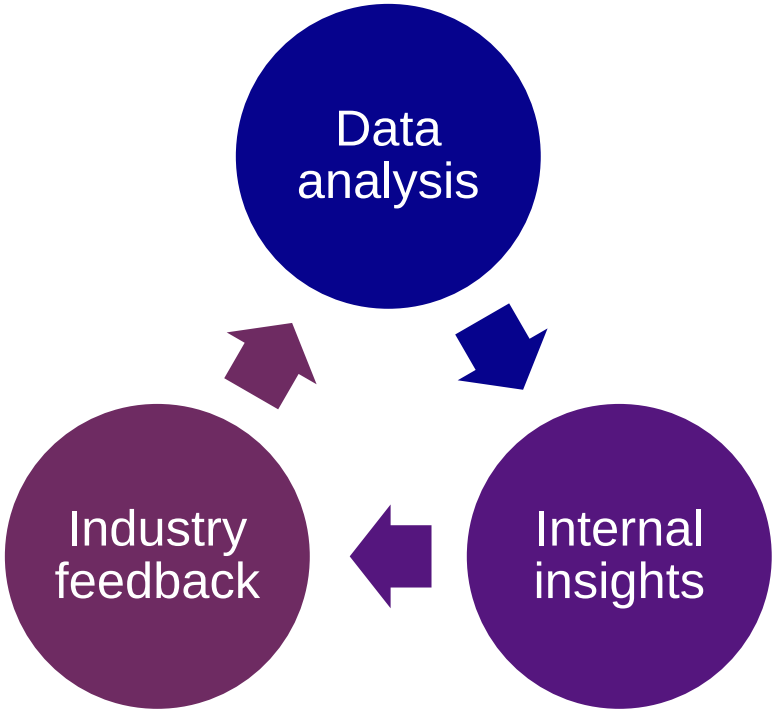
Review practices and align risk tolerances.
Optimise digital tool use.

Increase communication and collaboration between evaluators and delegates, locally and internationally.



Reforms program spotlight

Understanding our current state



Internal analysis

Analysis of data and trends

Review of processes, governance and structure

External feedback

Development of technological capabilities in industry

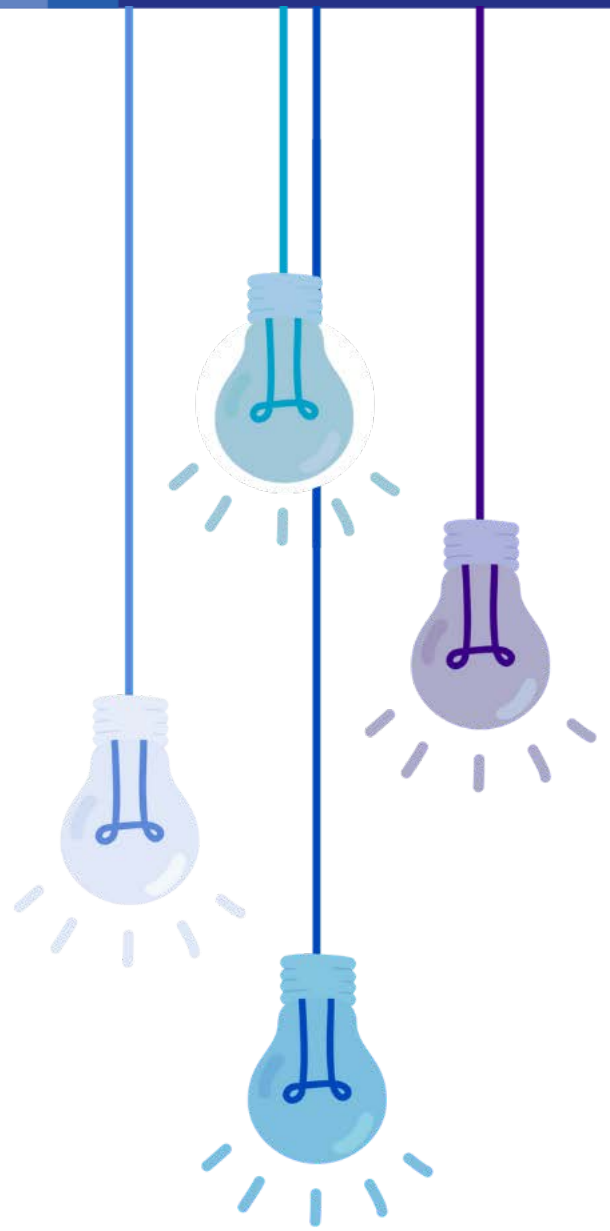
Industry insights

Current projects

PMAB's operational structure

Evaluation phases (MS3 to 7)
- Initial focus on stop clocks

Applications forecasting through AI data mining



Feasibility analysis of use of AI in prescription medicine assessment processes

Submission phase (MS2) review

ACCESS operations

Opportunities for AI in prescription medicine assessment processes

Integrating AI is transforming the pharmaceutical industry's size, efficiency and efficacy.

- The timeframe from drug discovery to submission is decreasing.
- Submission number, complexity and velocity are increasing.

PMAB insights

- Our current processes are highly manual
- There are opportunities to automate and streamline workflows

Australian Evaluation Aid

Dr Andrew Pengilley
Director, Vaccines and Anti-infectives (CES2)
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Current TGA clinical evaluation process

- Clinical evaluator reads, evaluates and drafts a summary of clinical dossier
- Reports are long and contain significant duplication of factual information in the dossiers
- Reports are necessary to inform Delegates for procedurally robust decision making
- Compiling reports is a labour intensive and time consuming, which has implications for cost and timeliness of processing applications

Submission	Type	Total clinical report length (pages)	Commentary (pages)	Factual data (pages)
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PM-2022-01573-1-4	C	125	18	107
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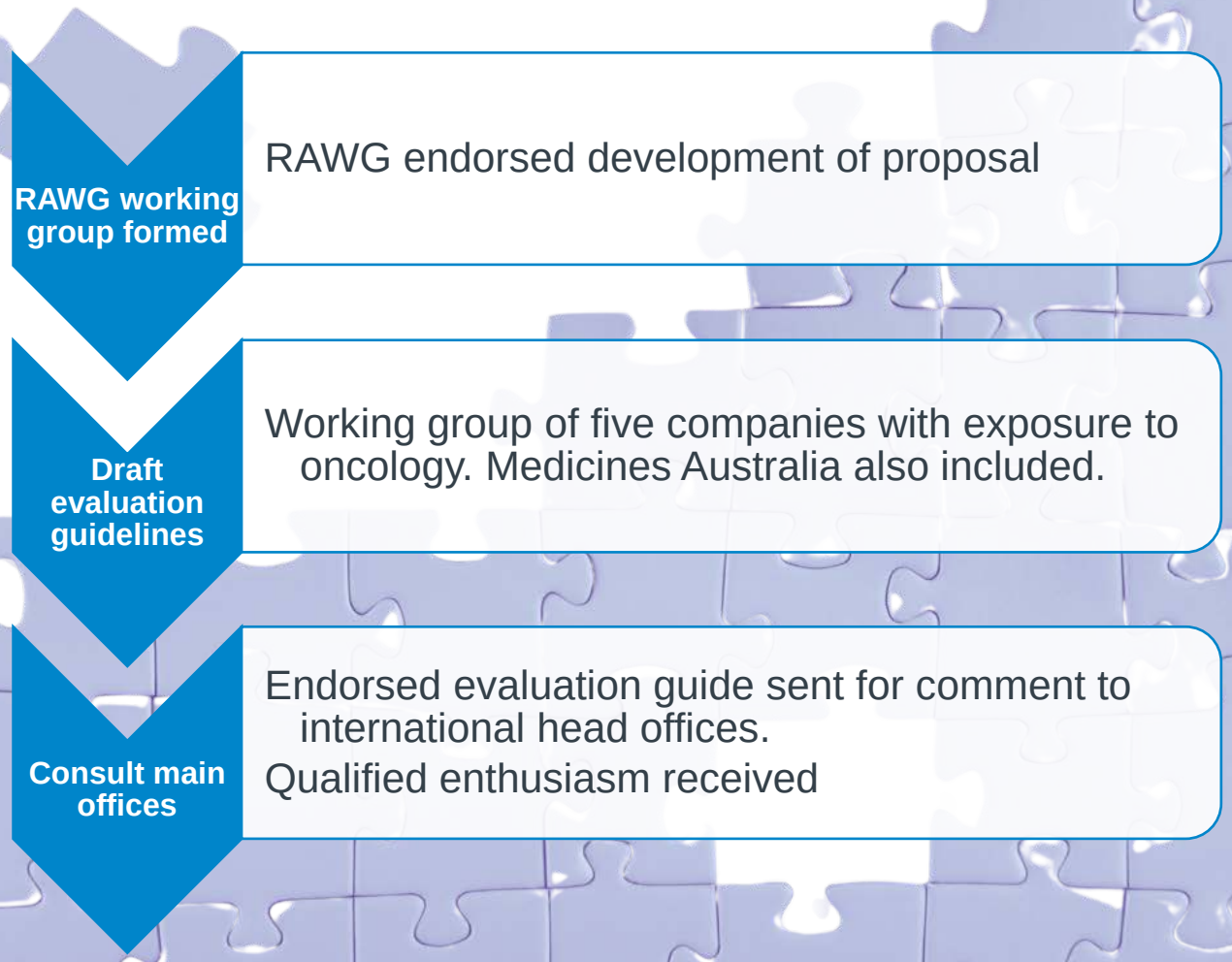
Composition of 8 selected evaluations

Australian Evaluation Aids (AEA) Proposal

- Based on experience with evaluation aids in ORBIS and COR processes
- Similar ideas were being developed in other regulators e.g. EMA
- Increased opportunity for Sponsors to draft documents using AI e.g. trial reports, clinical overview documents
- Better control of quality and/or errors
- Opportunity to improve timelines



Feedback received and a way forward

- Generally considered a reasonable proposal
- Resources limited for Australia-only, would prefer a harmonised process (e.g. ACCESS)
- Could require substantial resources, even with AI, as Sponsors have to authorise documents
- Might lead to delayed submissions
- Use of existing assessment aids, as prepared for the FDA in oncology, was supported

- Whether you feel using an AEA would be a reasonable allocation of resources to preparing a TGA application?
- What amendments might be made to the proposal to make it more attractive for you to use an AEA in preparing a TGA application?
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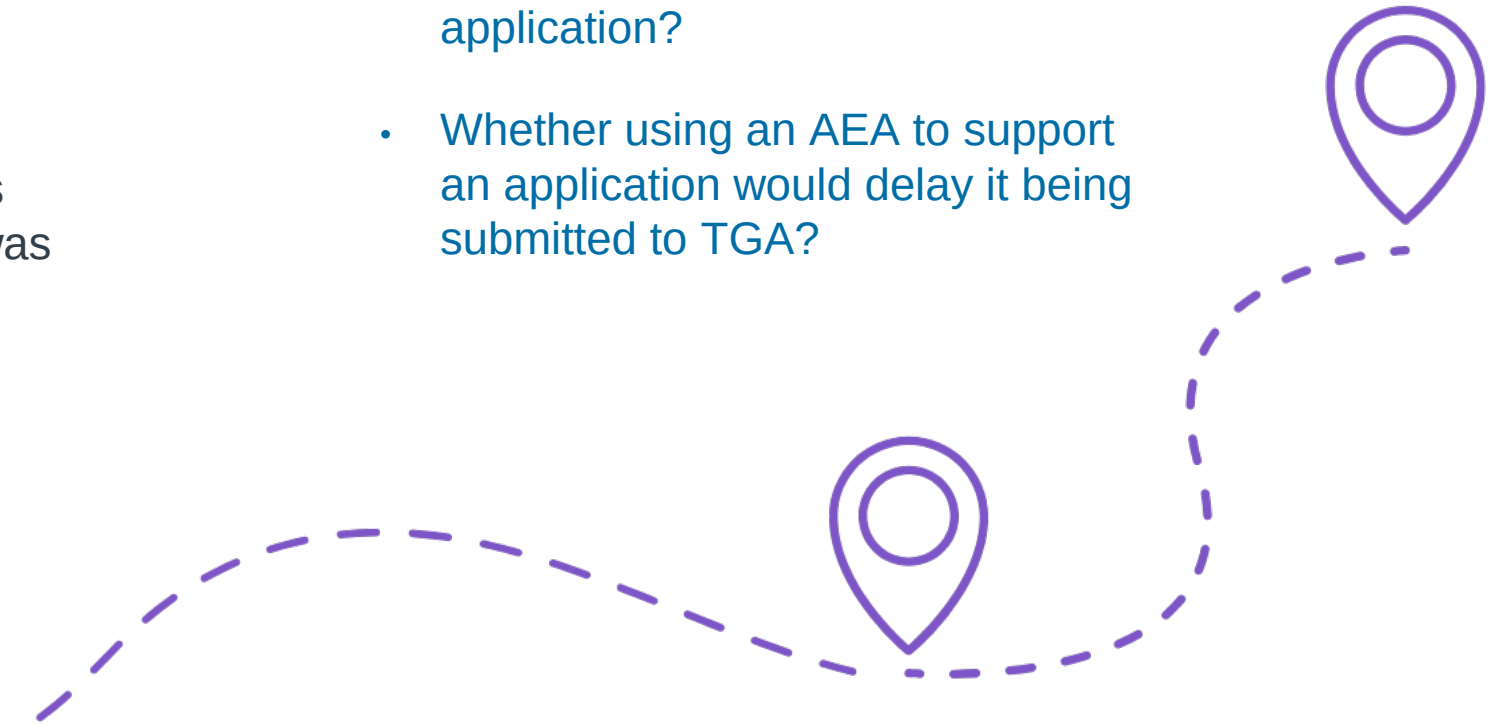

Therapeutic Goods Administration (TGA)

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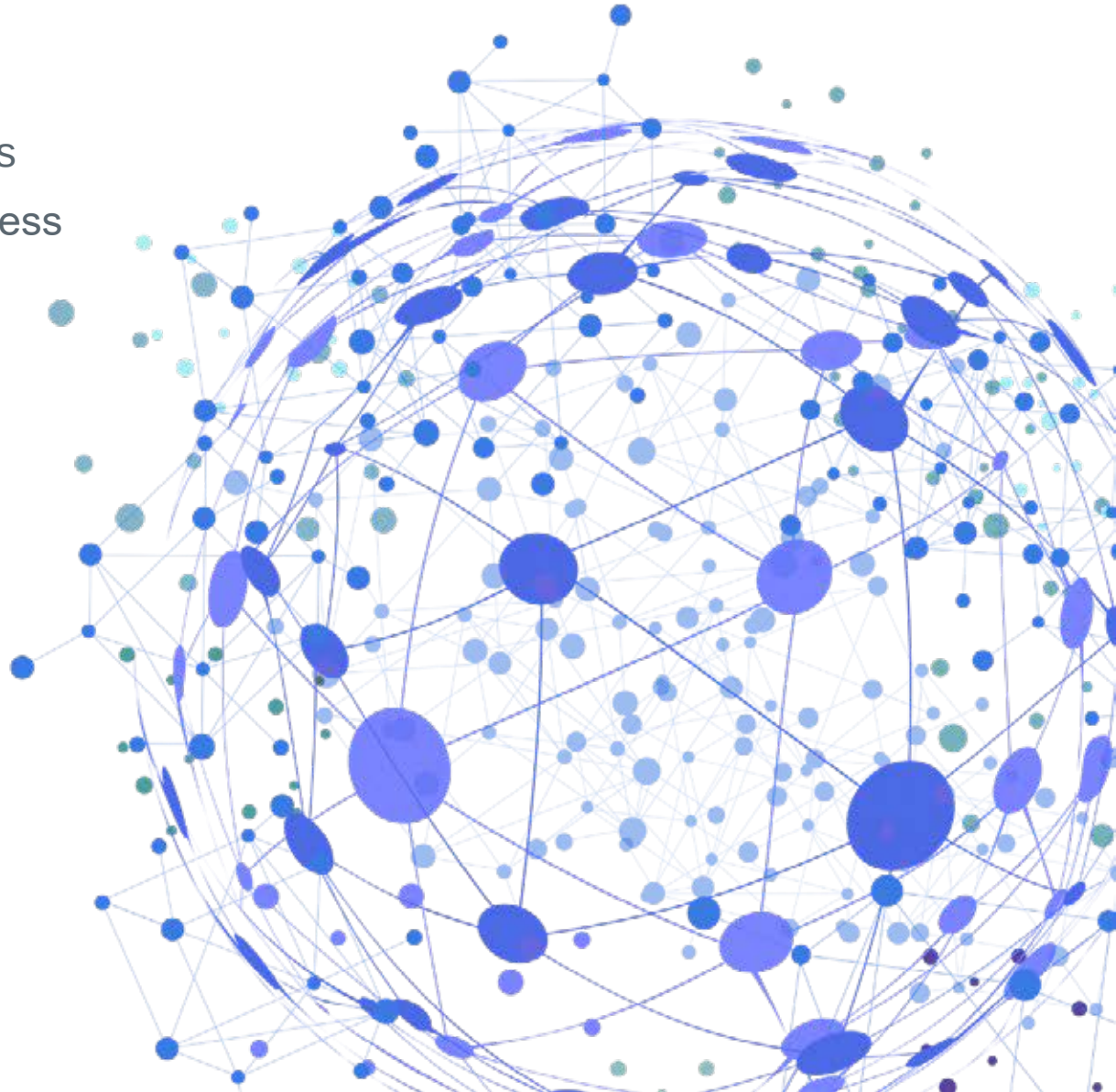

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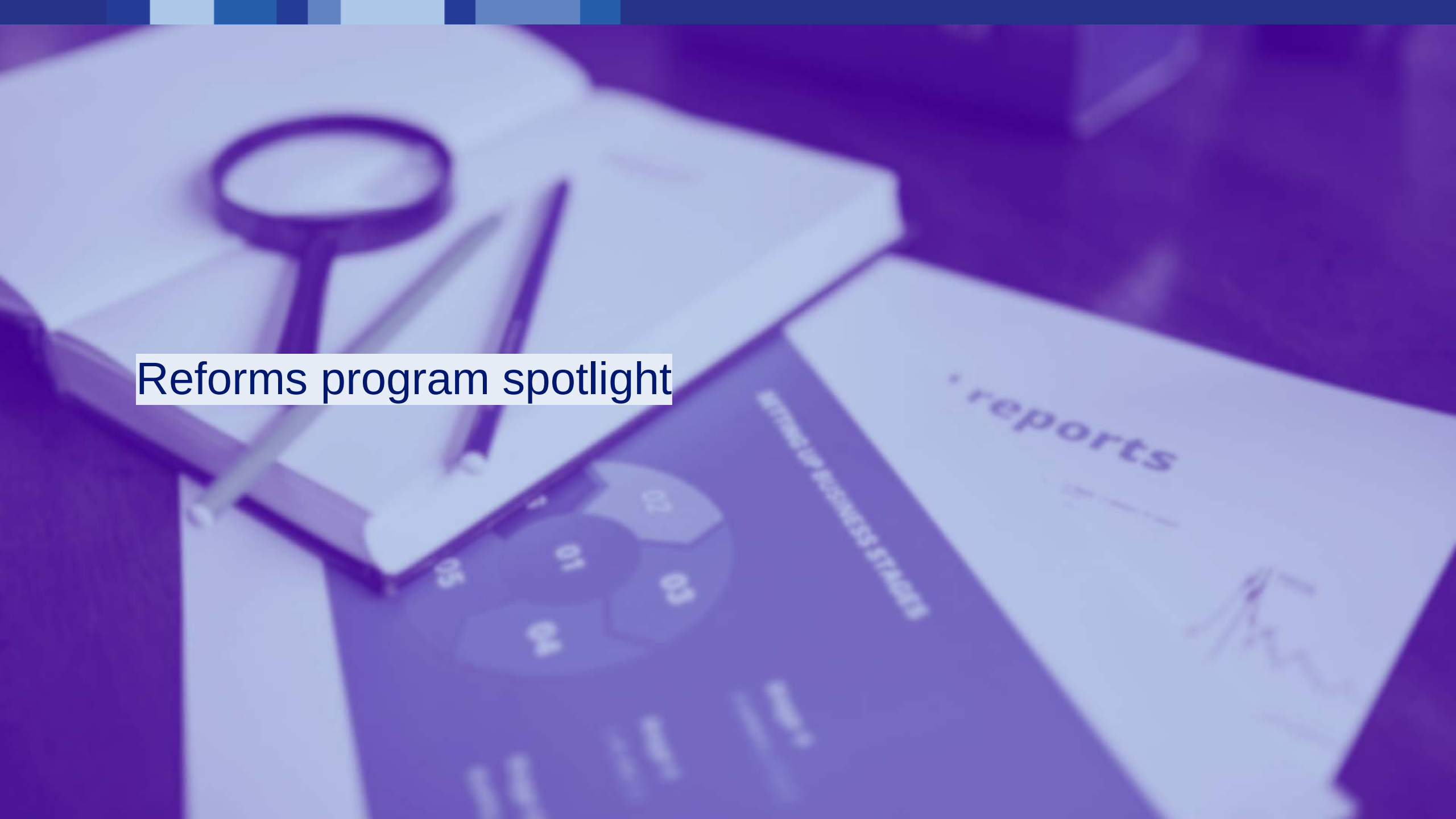

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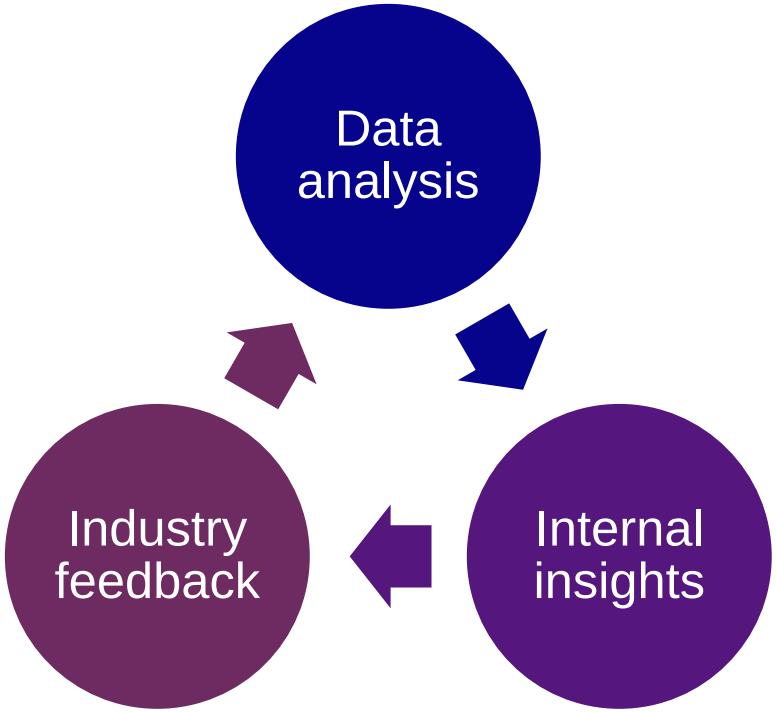

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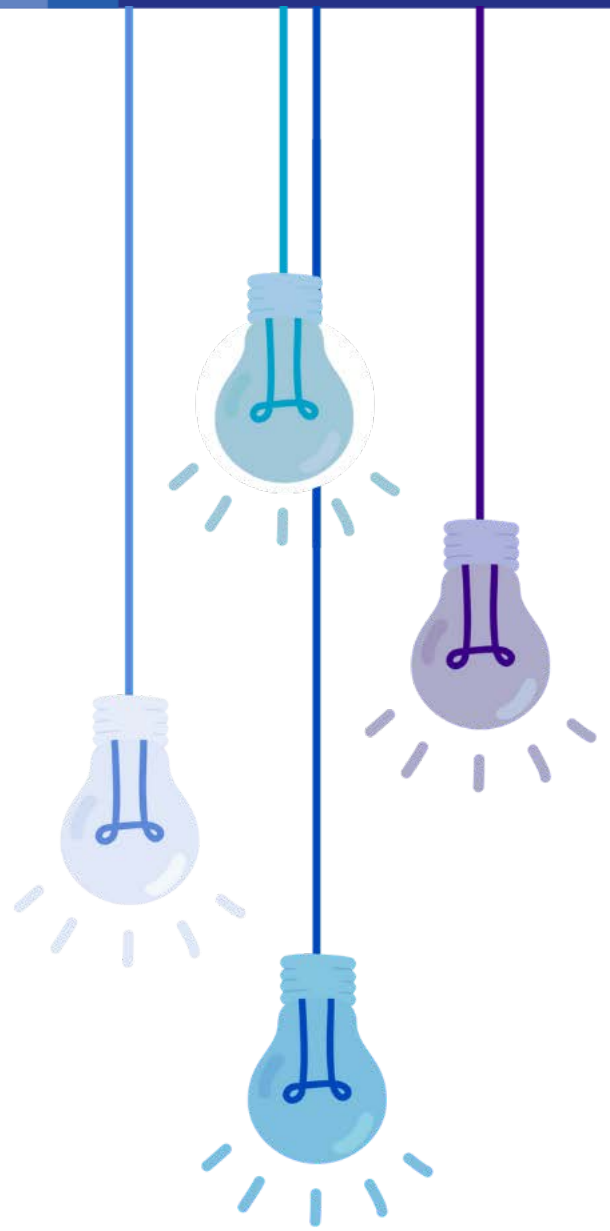

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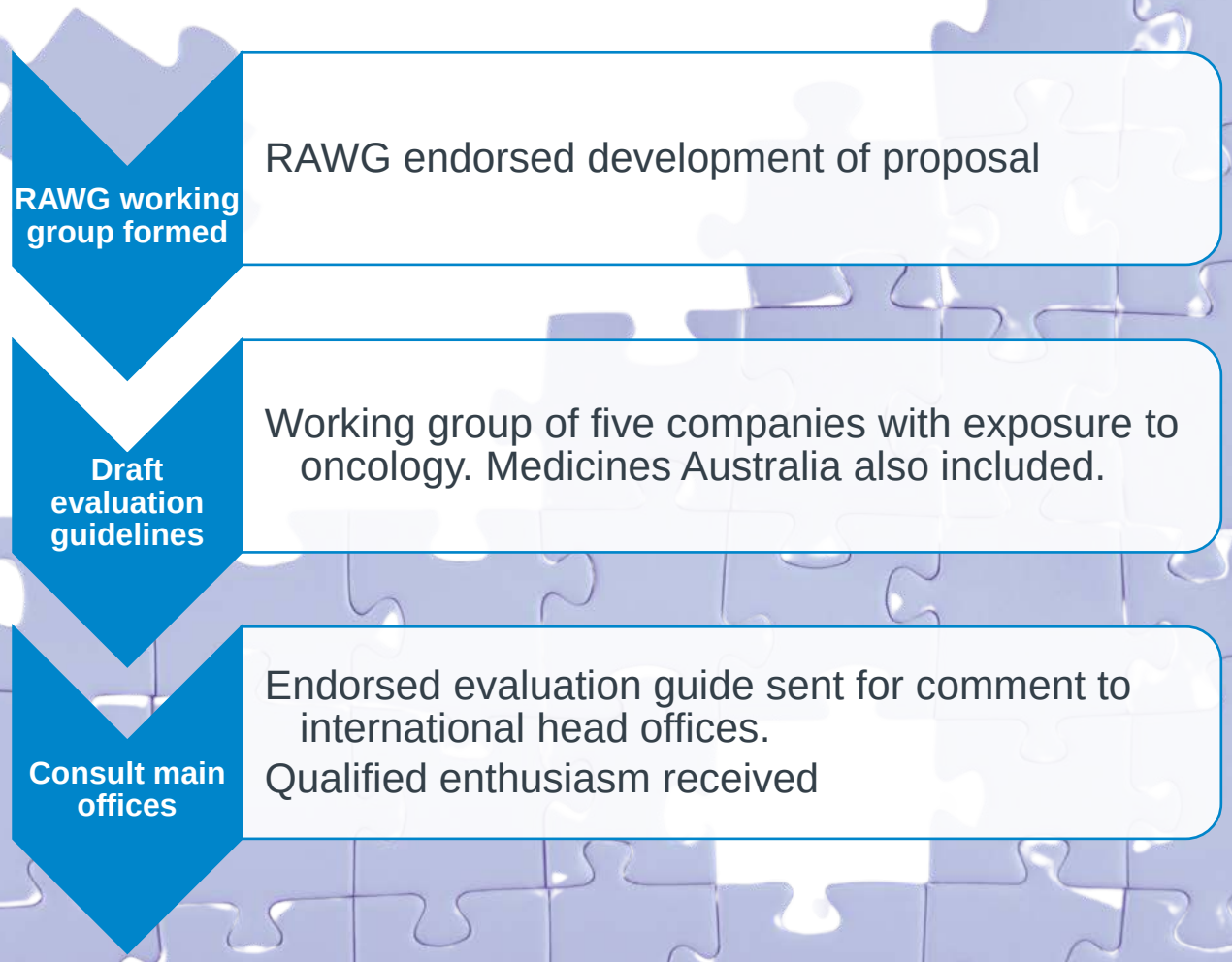

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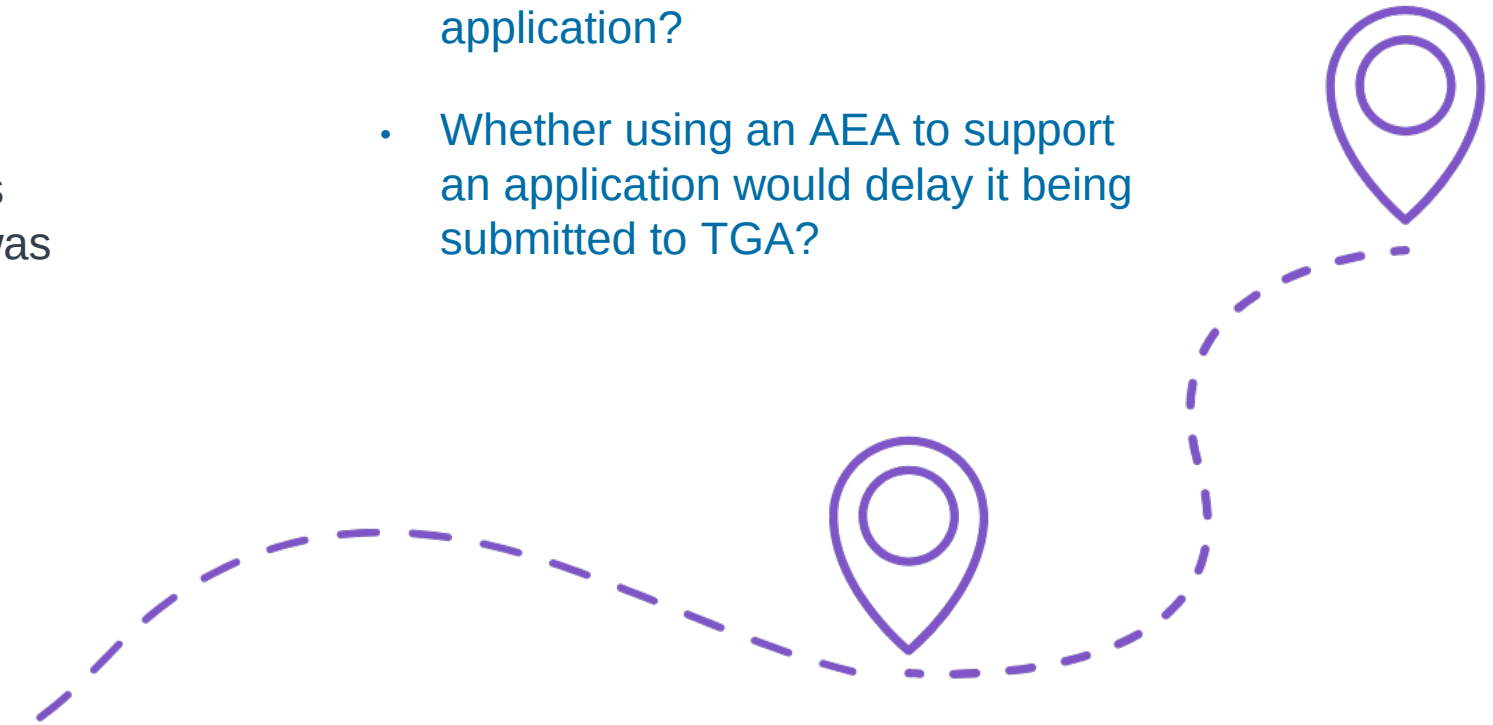

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