Prescription Medicines Authorisation Branch Update

Andrew Simpson
Assistant Secretary
Prescription Medicine Authorisation Branch
Department of Health and Aged Care, TGA

Session Overview

- PMAB: who we are and what we do
- Business improvements
- Recent highlights
- Data in focus
- Other activities

About PMAB

What we do

- Decision-making regarding medicines for the ARTG
- ACM & ACV Secretariat
- AusPARs & Decision Summaries
- Public communications
- eCTD Management

- Manage submissions process
- Guidance on regulatory processes
- Data Analytics & reporting
- Pre-Submission meetings
- Regulation review
- Business systems improvement

Our teams

Advanced Therapies and Biologicals

Dr Tony Gill

Application and Advisory Management

Kaylene Raynes

Application Entry, Support and Export

Elizabeth Santolin

Business Systems Review and Reporting

Phillipa Olrick

Clinical Evaluation Team

Dr Nitin Bagul

Our clinical evaluation sections

Ting Lu

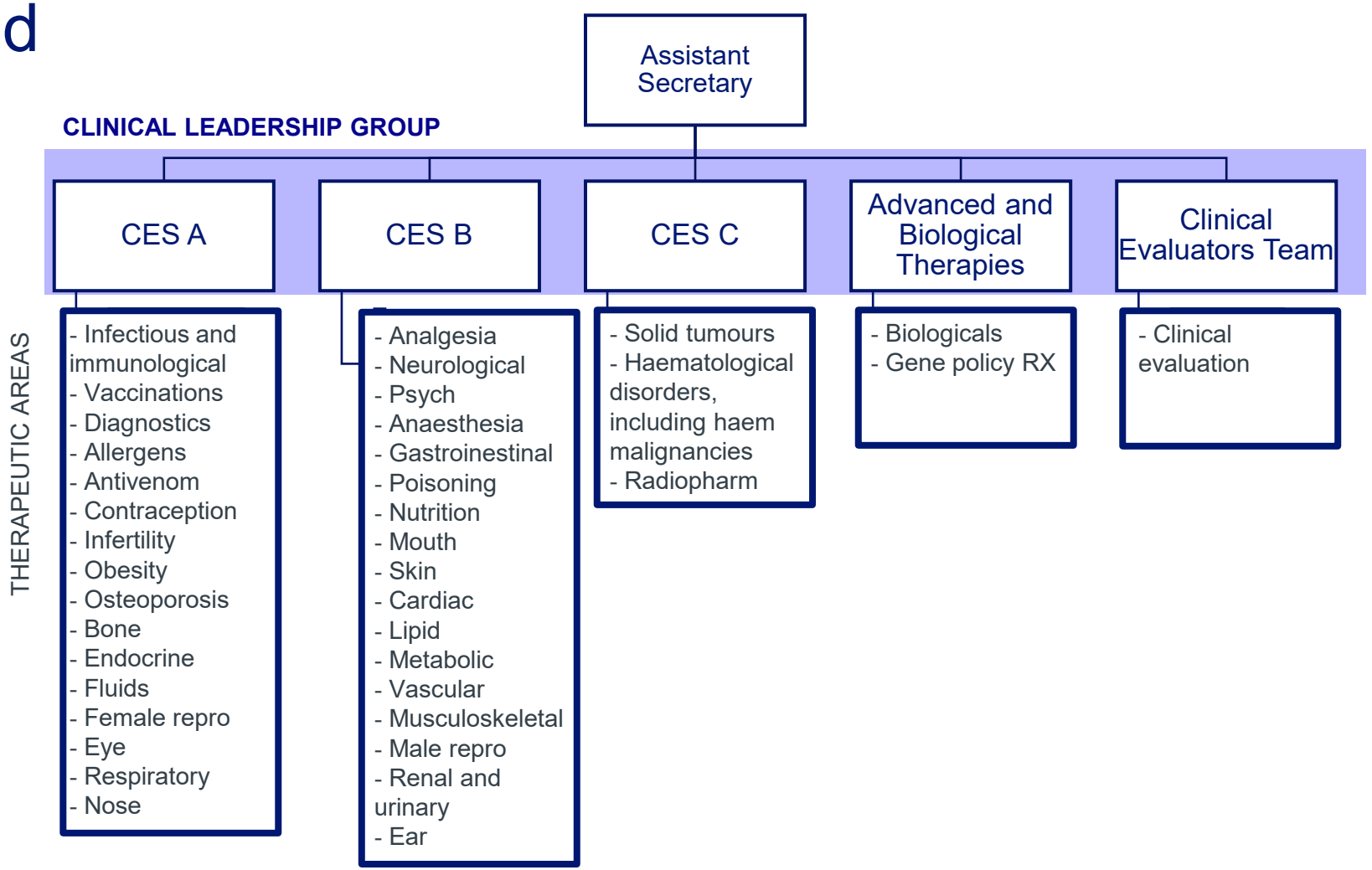
Jason Ferla

Andrew Pengilley

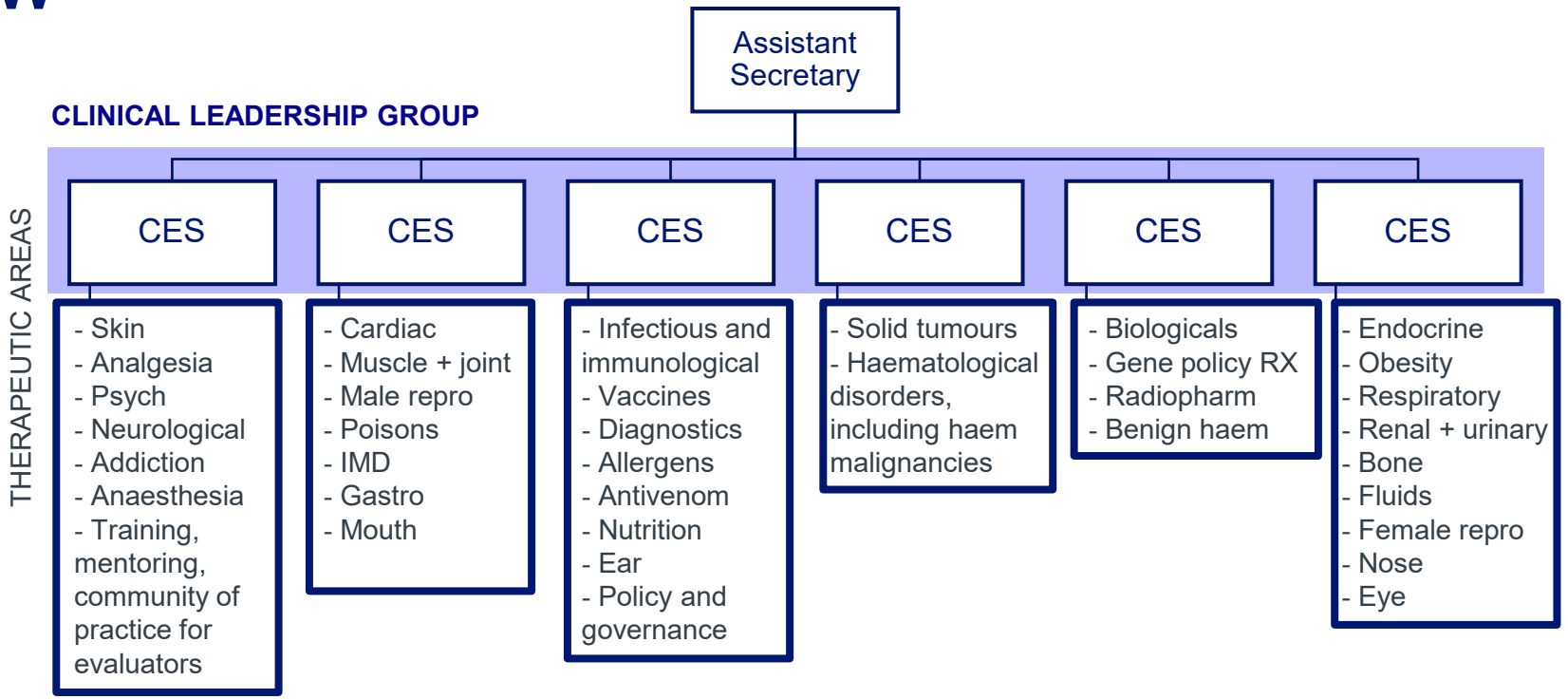
Kaye Robertson

Fiona Turk

The old


Assistant Secretary
CLINICAL LEADERSHIP GROUP
CES A
CES B
CES C
Advanced and Biological Therapies
Clinical Evaluators Team
THERAPEUTIC AREAS
- Infectious and immunological
- Vaccinations
- Diagnostics
- Allergens
- Antivenom
- Contraception
- Infertility
- Obesity
- Osteoporosis
- Bone
- Endocrine
- Fluids
- Female repro
- Eye
- Respiratory
- Nose
- Analgesia
- Neurological
- Psych
- Anaesthesia
- Gastroinestinal
- Poisoning
- Nutrition
- Mouth
- Skin
- Cardiac
- Lipid
- Metabolic
- Vascular
- Musculoskeletal
- Male repro
- Renal and urinary
- Ear
- Solid tumours
- Haematological disorders, including haem malignancies
- Radiopharm
- Biologicals
- Gene policy RX
- Clinical evaluation

The new


Assistant Secretary
CLINICAL LEADERSHIP GROUP
THERAPEUTIC AREAS
CES
CES
CES
CES
CES
CES
- Skin
- Analgesia
- Psych
- Neurological
- Addiction
- Anaesthesia
- Training, mentoring, community of practice for evaluators
- Cardiac
- Muscle + joint
- Male repro
- Poisons
- IMD
- Gastro
- Mouth
- Infectious and immunological
- Vaccines
- Diagnostics
- Allergens
- Antivenom
- Nutrition
- Ear
- Policy and governance
- Solid tumours
- Haematological disorders, including haem malignancies
- Biologicals
- Gene policy RX
- Radiopharm
- Benign haem
- Endocrine
- Obesity
- Respiratory
- Renal + urinary
- Bone
- Fluids
- Female repro
- Nose
- Eye

Focus for the next 12 months

- Prepare for sustainable growth
- Continue improvements to structure, governance, and processes
- Use data to understand our business better
- Deliver key projects, including repurposing program

Recent highlights

Recent highlights

- COVID treatments moving to full registration
- Increasing international collaborations (ACCESS workshares / Project Orbis)
- Multiple first-in-class medicines approved
  - early access to bispecific T-cell engagers for haematological malignancies
  - drug targeting IDH1/2 mutations for glioma and cholangiocarcinoma
  - IgG4 MAb targeting tissue factor pathway inhibitor for haemophilia

COVID Vaccines: Expedited approval for registration transition

Sponsor	Vaccine	Indication (abbrev.)	Approval date
Pfizer Australia Pty Ltd	COMINARTY Original (tozinameran)	Active immunisation to prevent COVID-19 in individuals 6 months and older	13 July 2023
Moderna Australia Pty Ltd	SPIKEVAX Bivalent Original/Omicron BA.4-5 (elasonmeran / davesomeran)	As a booster dose in individuals 12 years and older	14 August 2023
Biocelect Pty Ltd	NUXAXOVID (SARS-CoV-2 rS [NVX-CoV2373])	Active immunisation to prevent COVID-19 in individuals 12 years and older	26 October 2023

COVID Vaccines and Treatments: Ongoing approval

Sponsor	Vaccine	Indication (abbrev.)	Approval date
Pfizer Australia Pty Ltd	COMINARTY Original (tozinameran)	2nd booster dose for individuals 18 years and older	23 August 2023
Moderna Australia Pty Ltd	SPIKEVAX monovalent XBB.1.5 (andusomeran)	To prevent COVID-19 in individuals 12 years and older	6 October 2023
Pfizer Australia Pty Ltd	COMIRNATY bivalent Original/Omicron BA.4-5 (tozinameran/famtozinameran)	Extension of indication to individuals 5 years and older	Provisionally approved 20 December 2023
Biocelect Pty Ltd	NUVAXOVID (SARS-CoV-2 rS [NVX-CoV2373])	Booster dose for individuals 12 to 17 years	31 January 2024

Shout-out: PMAB presentation this afternoon

B25. How to make sense of RNA-based therapeutics

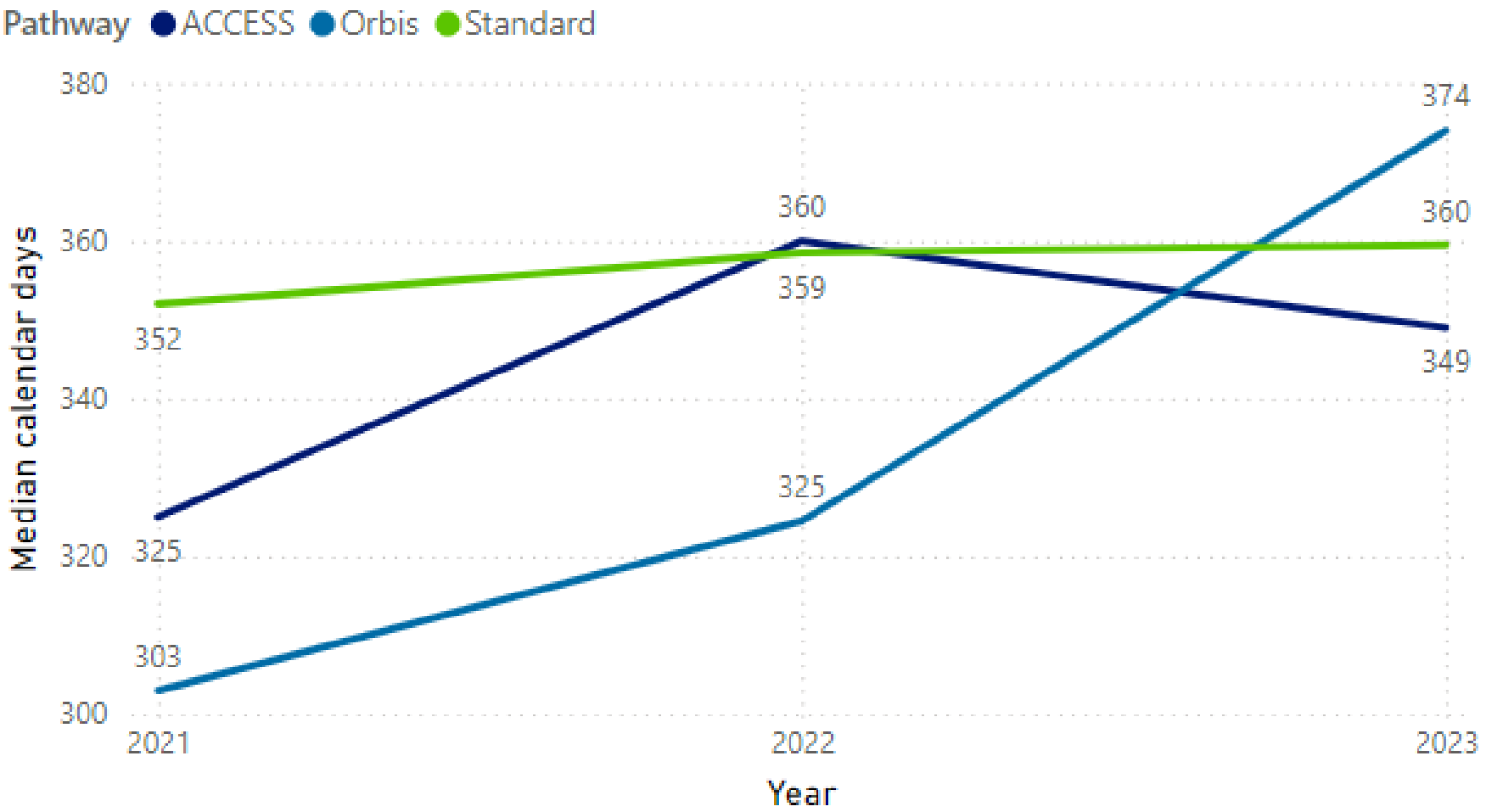
Thursday, June 13, 2024
4:30 PM - 5:30 PM

Dr Mohit Khera
Senior Medical Officer,
Clinical Evaluation section
PMAB, TGA

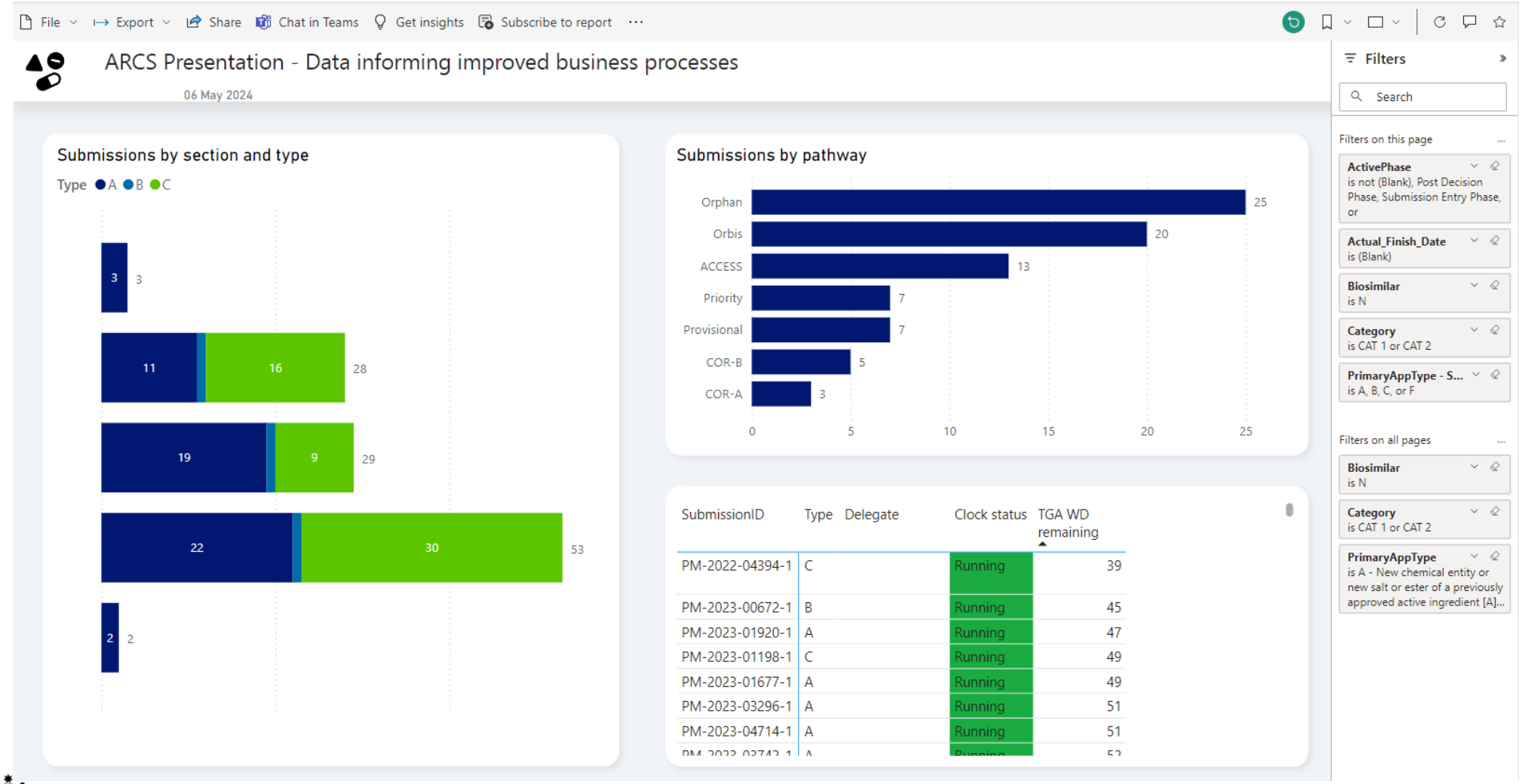
- **Overview of RNA-based therapeutics**
- **Landscape of RNA-based therapeutics development**
- **Regulatory pathways**

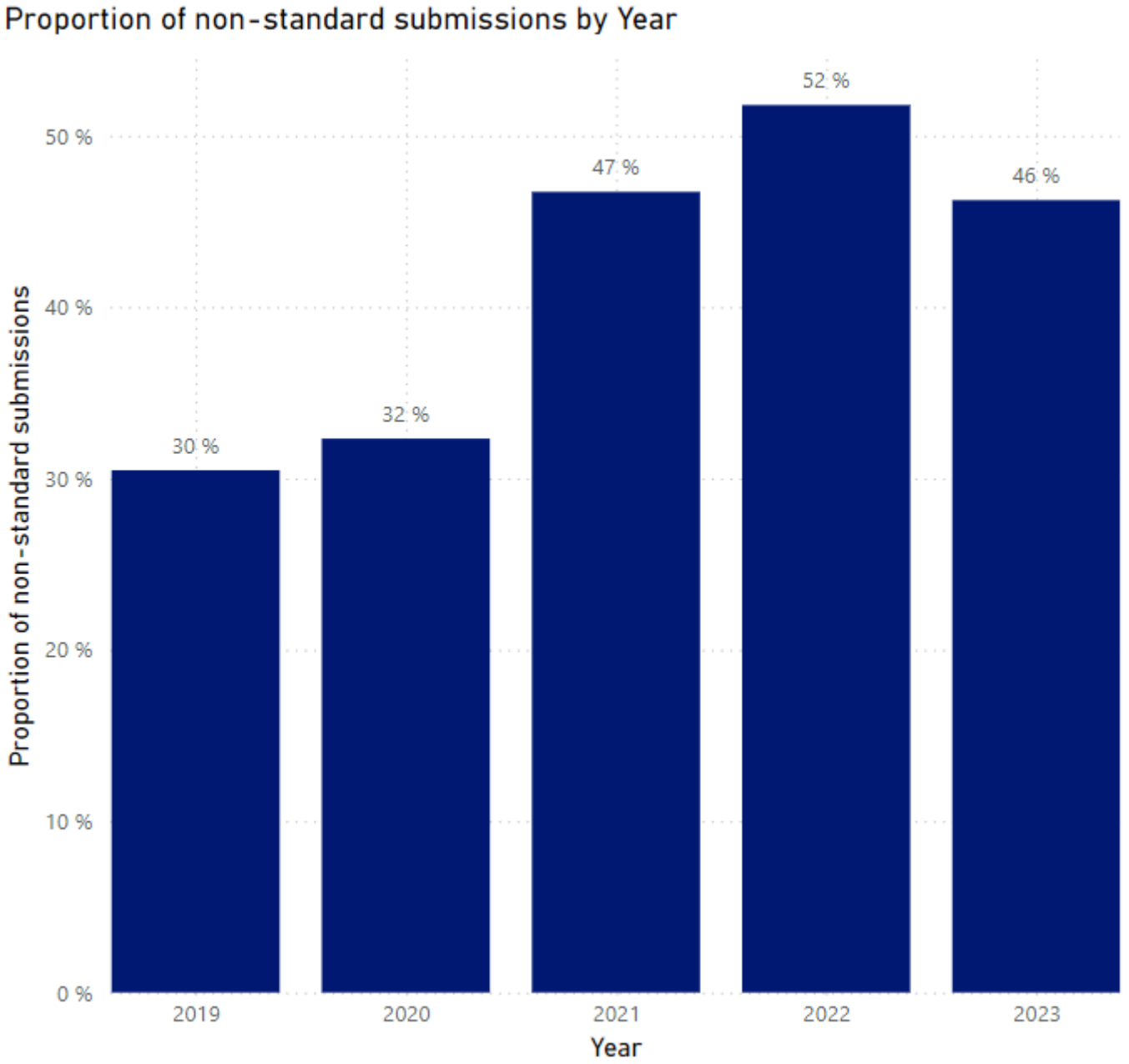
Data in focus

Median calendar days by year and pathway



Improved workflow reporting

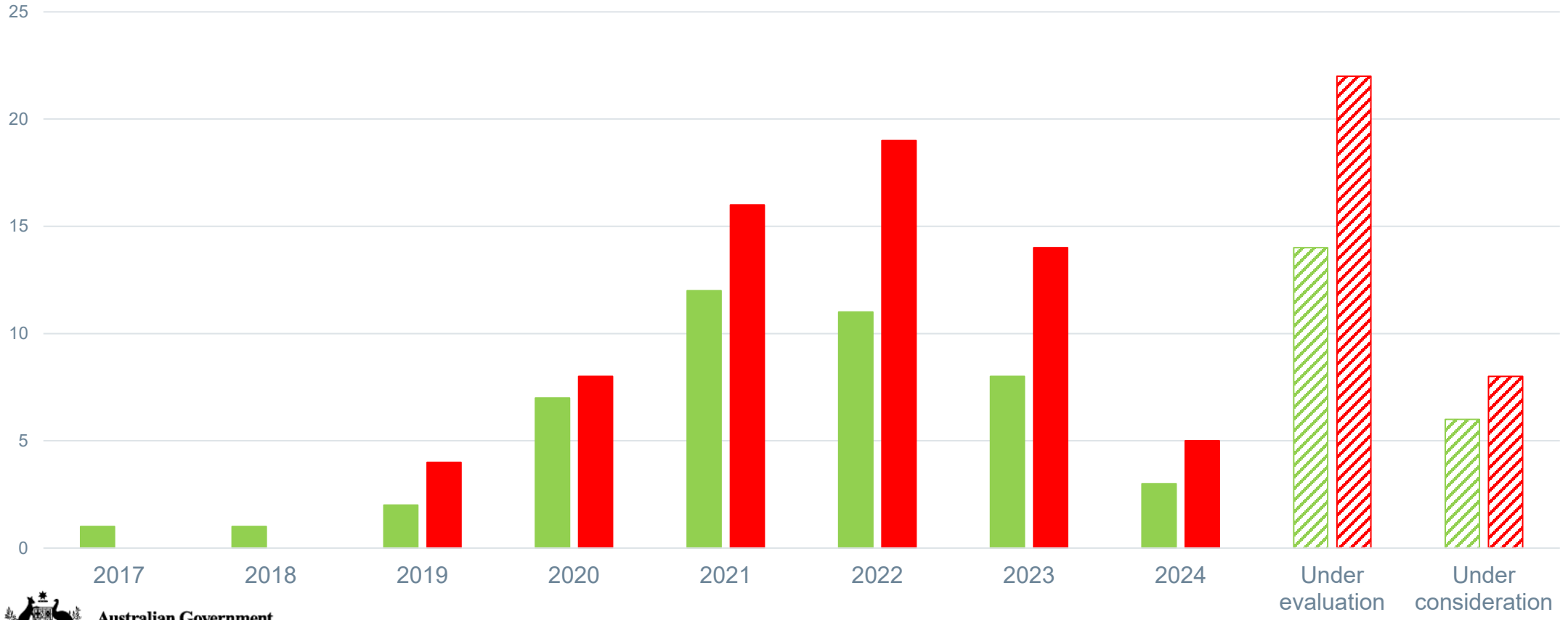



Proportion of non-standard submissions by Year
Proportion of non-standard submissions
50 %
40 %
30 %
20 %
10 %
0 %
30 %
32 %
47 %
52 %
46 %
2019
2020
2021
2022
2023
Year

International collaboration

TGA approvals through Access work-sharing and Project Orbis (as of 29 May 2024)

During 2021-2023: 23% of all new medicines or new indications approved by the TGA were reviewed through Access work-sharing or Project Orbis



International collaboration

Access New Active Substance Work-Sharing Initiative (NASWSI)

- Sponsors interested in submitting through NASWSI, with most submissions being high-profile *
- First priority submission (since the original pilot submission) approved in 2023
- Biosimilars and ATMPs: Welcoming expressions of interest to collaborate (likely via information-sharing)
- Access pipeline meetings: Opportunity for sponsors to meet with the Access partners as a “bloc”
- Promise Pilot Pathway: Streamlining the priority determination stage across the Access partners
- Access partners working to increase harmonisation, standardisation and alignment in processes

* List of all TGA approvals through NASWSI is available at: https://www.tga.gov.au/access-consortium-new-active-substance-nas-work-sharing-initiative

International collaboration

Project Orbis

- Number of submissions for new oncology medicines/indications continuing to increase
- Many high-profile submissions:
  - 29% priority, 32% provisional (almost 2/3)
  - 27% orphan
- Project Orbis offers efficiencies to both TGA and sponsors
- Currently, the TGA's "default" for Orbis collaboration is Type B
- Working towards either standard / priority TGA evaluation plan (unless exceptional clinical significance)
- TGA is refining how it integrates Project Orbis

Other activities

Medicines Repurposing Program

The process of identifying potential new therapeutic uses ('indications') for older medicines through new research and evidence.

The program aims to address barriers and incentivise submissions in supporting sponsors in seeking regulatory approval and subsidy for the new use.

Establishment of the Medicines Repurposing Program – TGA website

eCTD

- Transition to e-CTD Stage 3 complete
- Industry/TGA working group reviewed Module-1 in Oct 2023
- New module 1 v3.2 developed; implementation planned for Feb 2025.
- Preparing our systems and processes for eCTD v4.0 pilot

Website and link references

SME Assist email list	https://www.tga.gov.au/sme-assist-email-list
Clinical trials	https://www.tga.gov.au/clinical-trials
Clinical trials handbook	https://www.tga.gov.au/resource/australian-clinical-trial-handbook
Role of the sponsor	https://www.tga.gov.au/role-sponsor
Priority determination for prescription medicines	https://www.tga.gov.au/publication/priority-determination-eligibility-criteria
Provisional approval for prescription medicines	https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines
ARTG	https://www.tga.gov.au/australian-register-therapeutic-goods
How we regulate medicines	https://www.tga.gov.au/how-we-regulate-medicines
Compliance management	https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management
TGA guidelines email list	https://www.tga.gov.au/tga-guidelines-email-list
TGA business services	https://www.tga.gov.au/tga-business-services
Schedule of fees and charges	https://www.tga.gov.au/schedule-fees-and-charges
SME Assist hub	https://www.tga.gov.au/sme-assist

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration