Clinical Trials and Good Clinical Practice

Dr Iga Policinska
Director

Romana Cecchele
Assistant Director

Pharmacovigilance Branch
Department of Health, Disability and Ageing, TGA

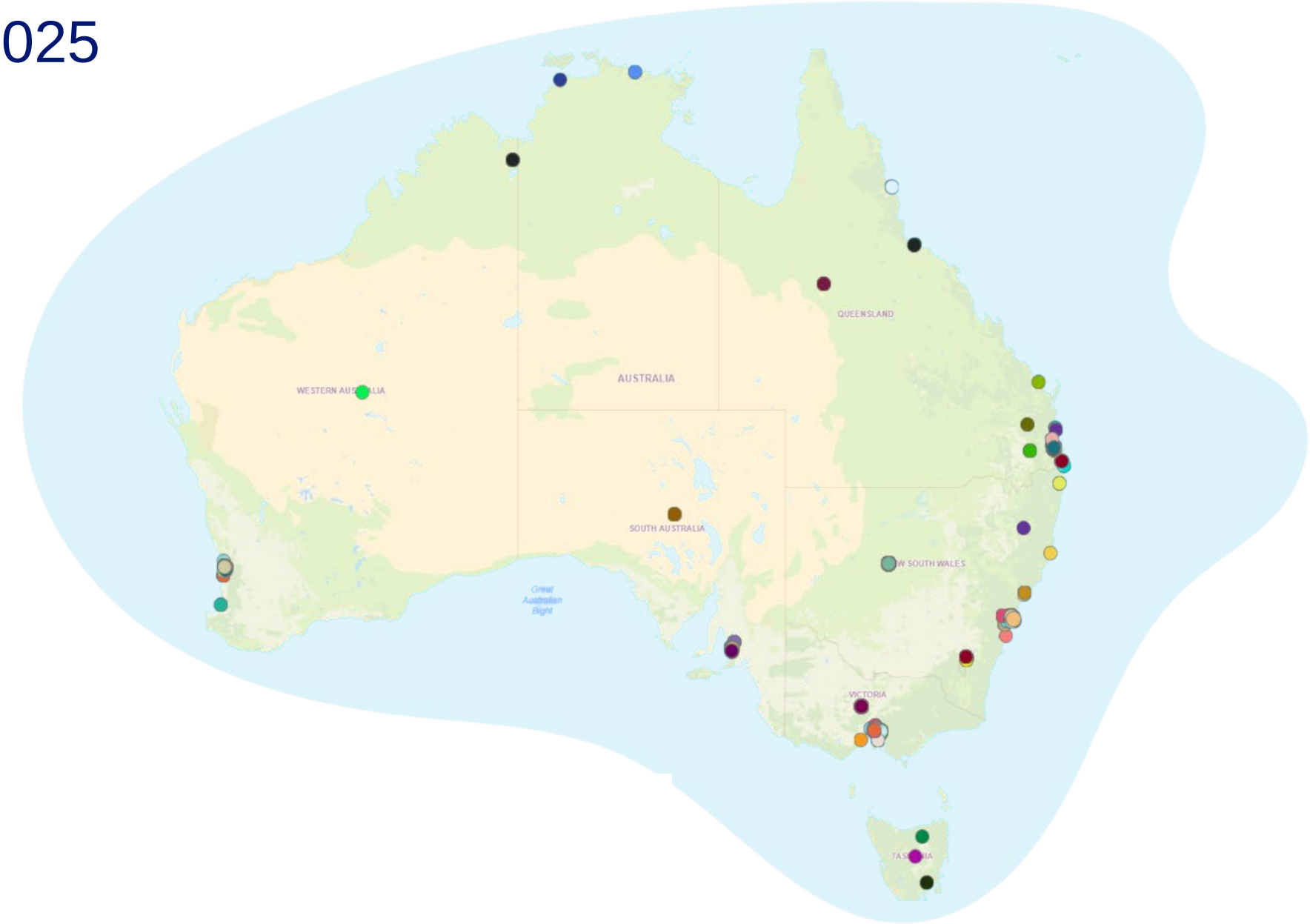
TGA initiatives

- Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes - numbers and trends
- Good Clinical Practice (GCP) Inspection Program
    - Good Clinical Practice (GCP) Inspection Program Metrics 2025 Report
    - ICH GCP E6(R3) adoption
    - ISO 14155:2026 update
    - GCP education eLearning
- Review of the CTA Scheme
- The Australian Clinical Trial Handbook
- HREC and TGA Clinical Trials Discussion Forum

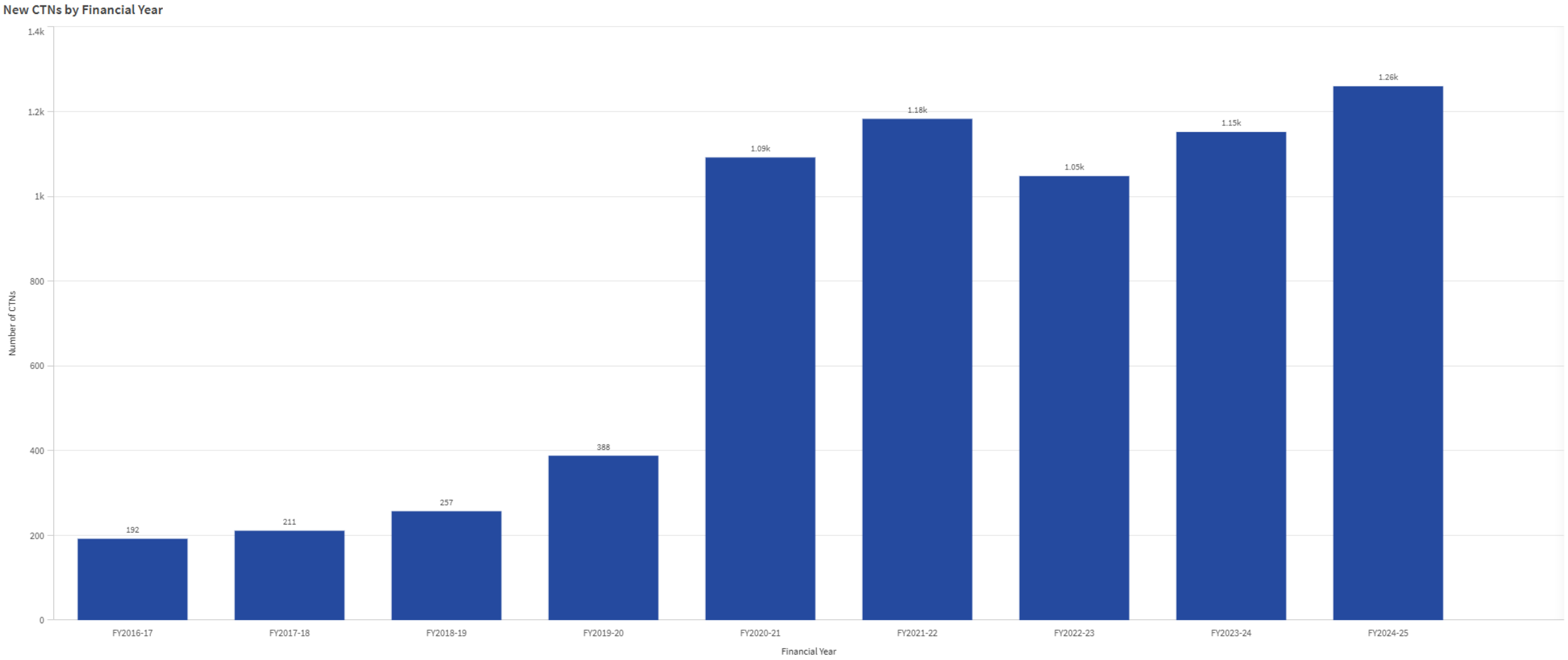
Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes

Numbers and trends

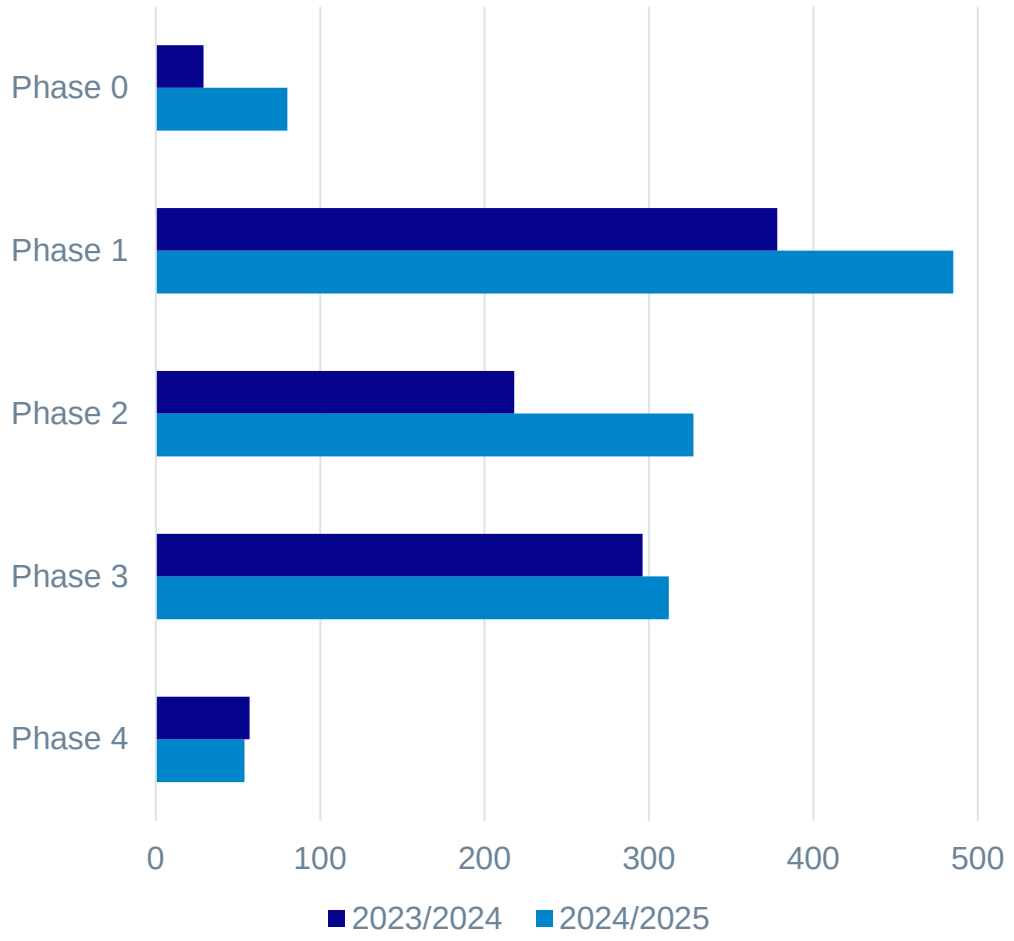
CTNs 2025

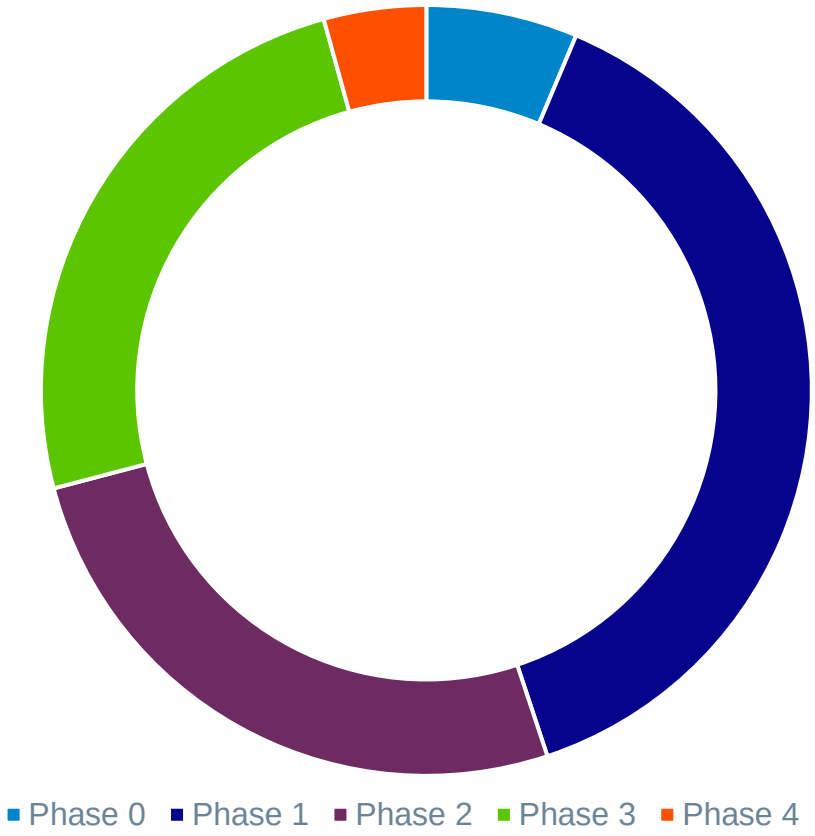

QUEENSLAND
AUSTRALIA
SOUTH AUSTRALIA
VICTORIA
Great Australian Bight

New CTNs

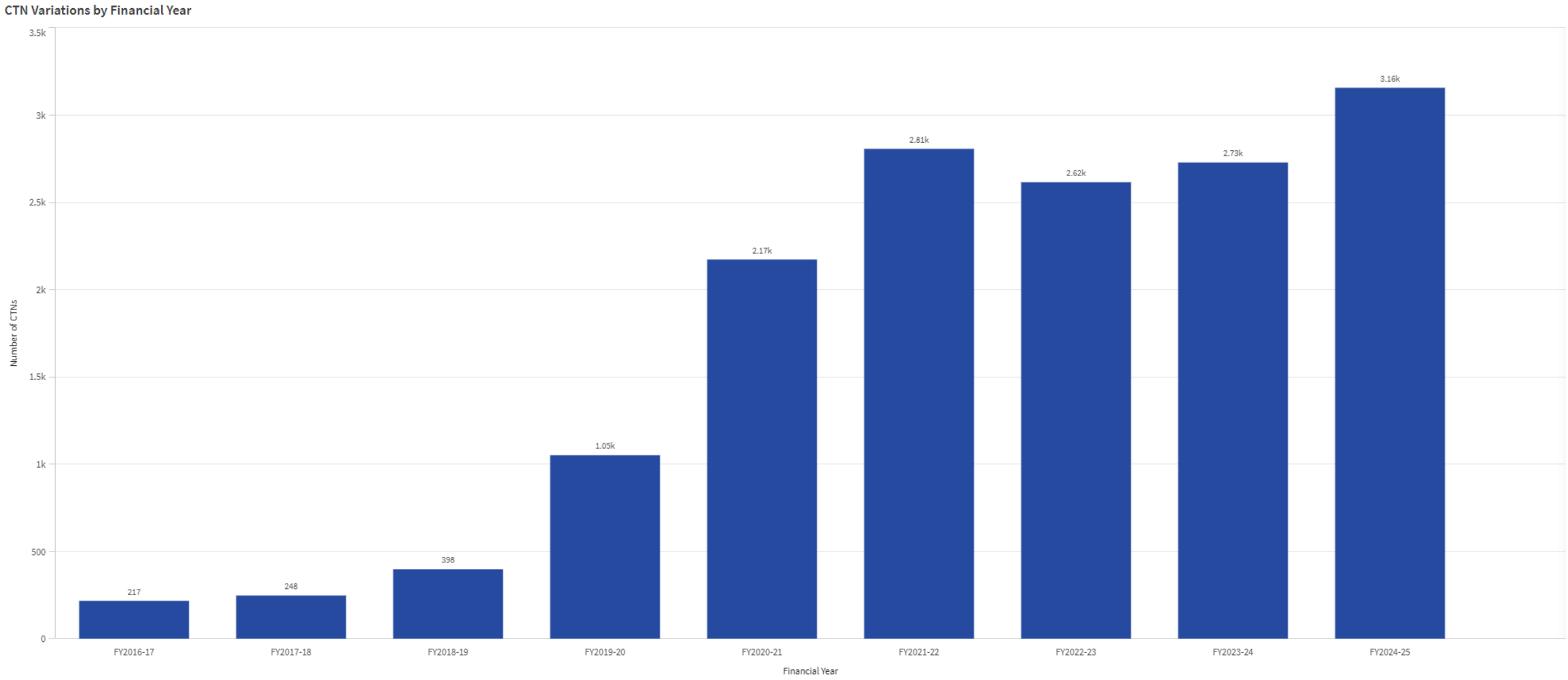

New CTNs by Financial Year
1.4k
1.2k
1k
800
600
400
200
0
Number of CTNs
192
211
257
388
1.09k
1.18k
1.05k
1.15k
1.26k
FY2016-17
FY2017-18
FY2018-19
FY2019-20
FY2020-21
FY2021-22
FY2022-23
FY2023-24
FY2024-25
Financial Year

CTNs by trial phase





CTN variations



Common issues with CTNs

Dosage and frequency

Site start date

No investigational product

Site address

Multiple strengths

Trial type

Common issues with CTNs

1. Medicine / Biological Dosage and Frequency

- Dosage regimen is missing or incomplete
  - Dosage amount is missing
  - Frequency of supply is missing

- Dosage range is missing the upper limit

Common issues with CTNs

2. Trial Site Start Date

- Date entered into the start date field is before the CTN submission date

Common issues with CTNs

3. No Investigational Product listed

- The IP is mentioned in the Title of Study, but it is not listed as the IP in the CTN sub-form

- The IP has been mentioned in the Title of Study, but it is not included in the CTN sub-form

Common issues with CTNs

4. Trial Site Address

- Physical address is missing or incomplete
- Multiple addresses are listed in single site sub-form

Common issues with CTNs

5. Medicine / Biological Formulation Multiple Strengths

- Multiple strengths of the same good are listed in the same CTN sub-form

Common issues with CTNs

6. Trial Phase

- ‘Trial Type’ field does not match the trial phase in the Title of Study
- No phase is selected in the ‘Trial Type’ field

New CTAs

- 2 trials were approved last year under the CTA scheme

- We received several enquiries about the CTA scheme. More information at which clinical trial exemption can you use and class 4 biologicals.

Good Clinical Practice (GCP) Inspection Program

Explaining Good Clinical Practice (GCP)

- Good Clinical Practice (GCP) is an international, ethical, scientific and quality standard for the conduct of trials that involve human participants.

- Clinical trials conducted in accordance with GCP provide assurance that the rights, safety, and well-being of trial participants are protected, that the trial data generated are reliable, and promotes the mutual acceptance of trial data internationally.

We recognise the following internationally accepted GCP guidelines:

- ICH GCP E6 (medicines & biologicals)
- ISO 14155 (medical devices)

The objective of the GCP Inspection Program

GCP Inspections

The GCP Inspection Program aims to strengthen the TGA's monitoring activities and protect the safety and wellbeing of clinical trial participants.

Education

In addition to verifying you are meeting your compliance obligations, GCP inspections allow us to provide education and work with you to ensure you have effective systems in place aligning with Australian legislation and the relevant GCP guideline(s).

CTN and CTA trials are within GCP Inspection Program scope

Within scope

- ✓ All Australian clinical trial sites involved in CTN and CTA trials of medicines, biologicals and devices.
- ✓ commercially sponsored trials, investigator-led or academic trials
- ✓ All phases (first in human, phase 1 through to 4) and stages of the trial (ongoing, completed)

Out of scope

- × HREC
- × Approving Authority/ Research Governance Office (RGO)
- × Clinical trial sponsor

GCP Inspection Program inspection focus

Main categories

- Protection of Participants
- Protocol Compliance
- Documentation
- Therapeutic Good/Investigational Product (IP)
- Trial Management

Main category	No.	Sub-category
Protection of participants	1.1	Informed consent – Presence of informed consent
	1.2	Informed consent – Informed consent process
	1.3	Informed consent – Informed consent form content
	1.4	HREC/Approving authority – Favourable opinion
	1.5	HREC/Approving authority – Opinion, amendments, notifications
	1.6	HREC/Approving authority – Composition, functions, operations
	1.7	Participant protection – Personal data protection
	1.8	Participant protection – Safeguarding safety and well-being
Protocol compliance	2.1	Eligibility criteria
	2.2	Assessment of efficacy
	2.3	Safety reporting
	2.4	Non-compliance with safety reporting to HREC/ Approving authority /TGA
	2.5	Reporting in case report form/diary as specified in the protocol
	2.6	Other protocol non-compliance not listed above
Documentation	3.1	Essential documents
	3.2	Source documentation
	3.3	Qualification and training
	3.4	Standard operating procedures
	3.5	Organisation and personnel
	3.6	Facilities and equipment
	3.7	Randomization, blinding and codes of therapeutic good
	3.8	Direct access to data
	3.9	Contracts and agreements, including PI oversight of contractors/site-hired third-party vendors
Therapeutic Good / Investigational Product	4.1	Therapeutic Good / Investigational Product (IP) accountability at site
	4.2	Supplying, storage, retrieving and destruction
	4.3	Prescription, administration and compliance
Trial management	5.1	Non-compliance with local regulatory requirements (other than safety reporting)
	5.2	Sponsor-investigator responsibilities

NEW
Update!

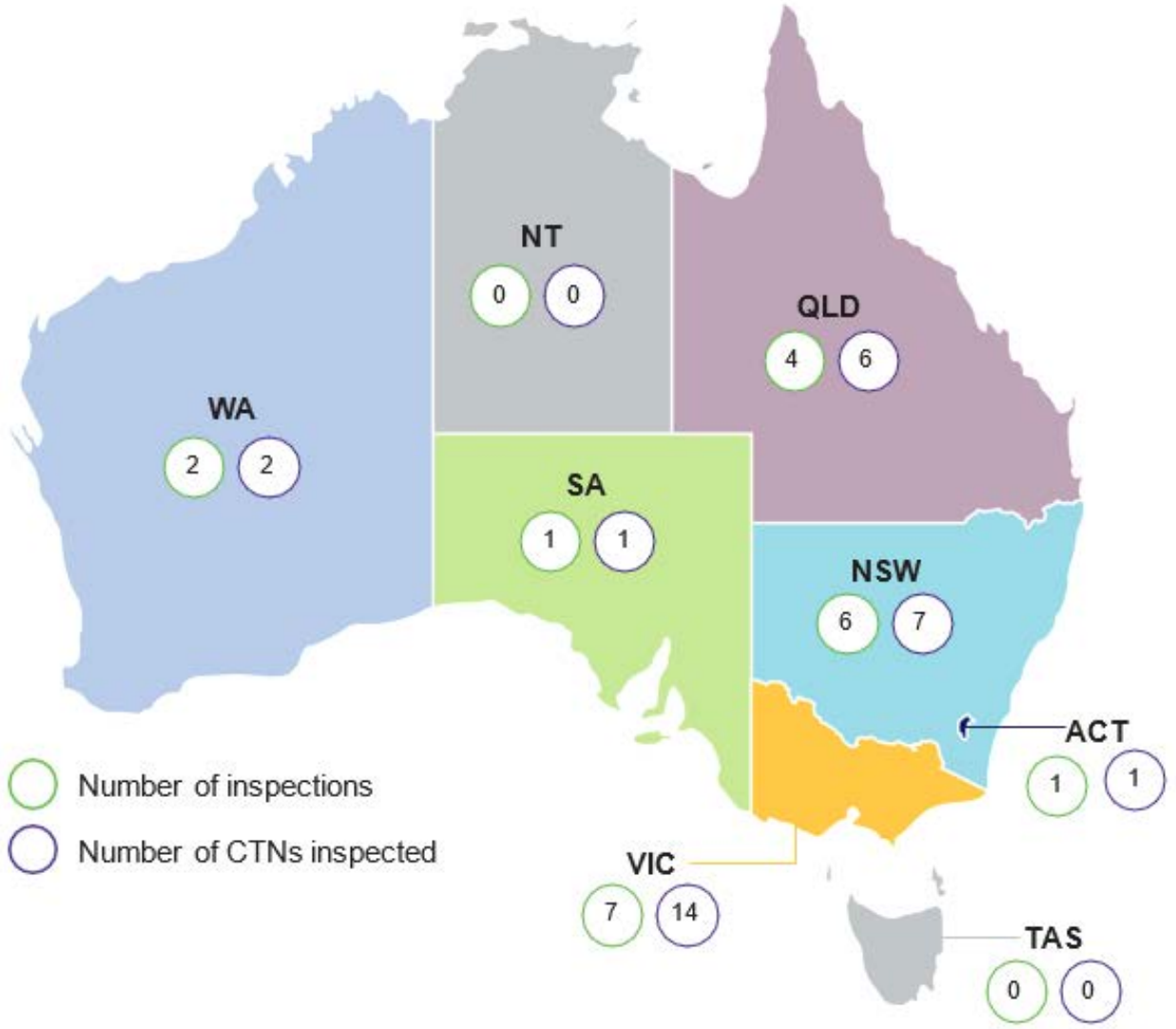
GCP Inspection Program Metrics 2025 Report

Insights

- number & types of inspections conducted
- areas of compliance and non-compliance
- examples of major deficiencies identified through GCP inspections
- de-identified data

We conducted 21 inspections in 2025

- 20 announced routine inspection
- 1 announced re-inspection
- A total of 31 CTNs
- No CTAs



GCP inspections conducted in 2025

Therapeutic good (TG) / Investigational product (IP)			
Medicine	Biological	Device	Combination*

Trial phase				
Phase 1	Phase 1/2	Phase 2	Phase 3	Device

Recruitment status		
Active, recruiting	Active, not recruiting	Closed

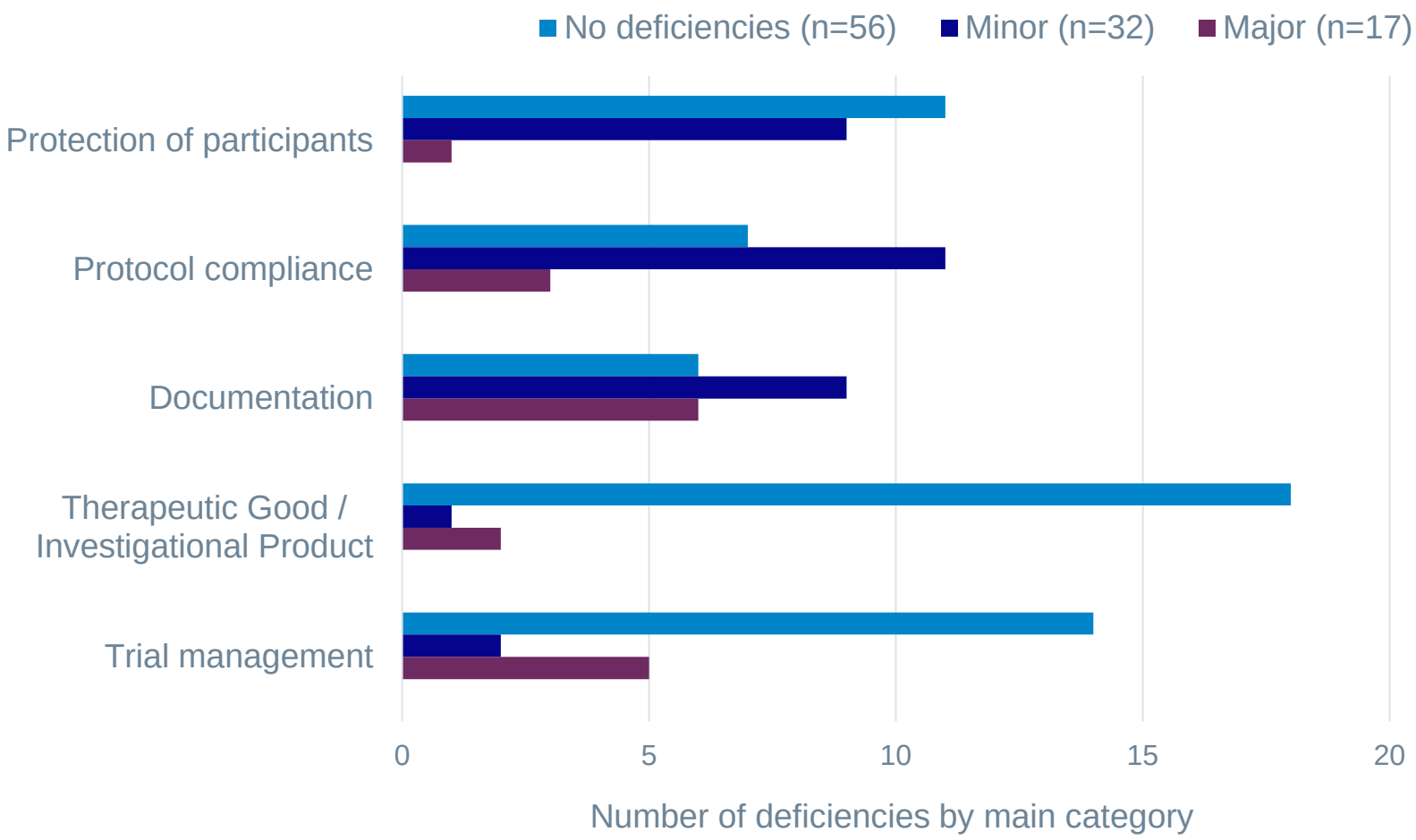
Sponsor type	
Commercial	Non-commercial including investigator-initiated trials (IITs)

*Combination included a medicine and/or biological and/or device

Summary of inspection outcomes

- Overall, inspection outcomes demonstrated a high level of compliance:
  - No deficiencies were identified in 3 inspections
  - No critical deficiencies were identified
- The highest level of compliance was observed in the ‘Therapeutic Good / Investigational Product’ category
- The highest level of non-compliance was observed in the ‘Documentation’ category
- At least one major deficiency was reported in each main category

Summary of main category deficiencies in 2025 inspections



ICH GCP E6(R3) update

We asked

- Feedback on proposed TGA comments
- transition period

You said

- We received 50 submissions
  - 58% organisations
  - 42% individuals
- Broad representation from
  - government
  - industry
  - researchers
  - HREC/RGO

We did

- Adoption on **13 January 2026** with **TGA comments**
- **12-month transition period**

The process

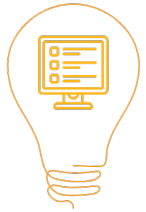

Internal consultation
Public consultation
Outcomes published
12 month transition
Full Implementation

A 12-month transition period to support implementation

- The transition period allows sponsors, trial sites and other stakeholders time to update processes, documentation, and training to meet the updated requirements

- Clinical trials of medicines and biologicals regulated under the CTN and CTA schemes must comply with either ICH GCP E6(R2) or E6(R3)

Clinical trial sites should:



Review ICH GCP E6(R3) and TGA comments and perform a gap analysis

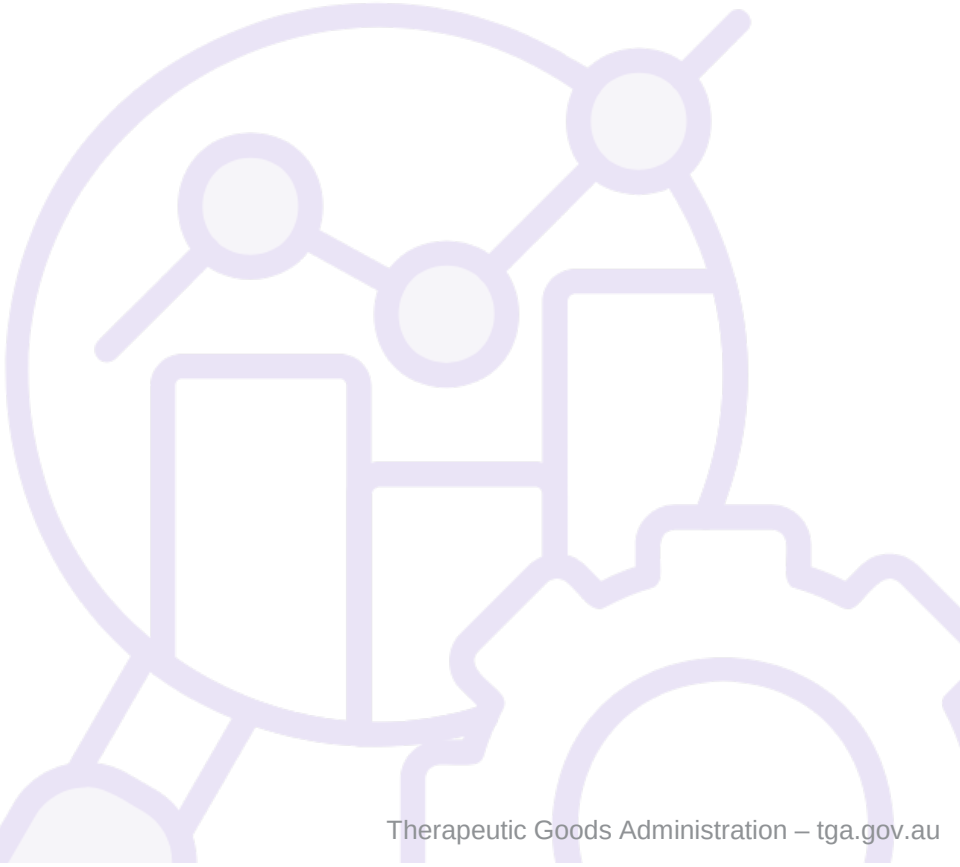
Develop a plan to address gaps and document updates

Undertake training and maintain training records

ISO 14155:2026

- Published by the International Organization for Standardization (ISO) in March 2026
- Updates reflects current international regulatory expectations and clinical investigation practices for medical devices
- For device trials conducted under ISO 14155, sites should:
  - review the updated standard
  - perform a gap analysis, and
  - document, with appropriate justification, risk proportionate decisions on applying the updated standard.

- Transition period is 12 months - from March 2026 publication



NEW
Update!

GCP e-learning module

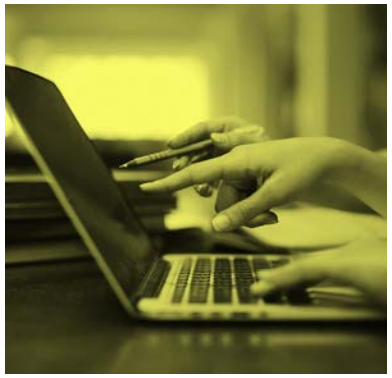
New TGA e-learning modules coming soon!

Explore four new modules!

- Getting started: therapeutic goods in Australia
- Getting started: therapeutic goods sponsors
- Getting started: advertising therapeutic goods in Australia
- Getting started: TGA's Good Clinical Practice (GCP) Inspection Program

The modules extend website and webinar content, providing interactive learning to help you build regulatory capability at your own pace.

GCP Inspection Program focus for 2026/2027



Education and collaboration

- Collaboration with external stakeholders
- Practical implementation of ICH GCP E6(R3)
- Guidance updates & metric reports
- Webinar

GCP inspections

- Ongoing GCP inspections
- Encouraging ongoing feedback from inspected sites

Clinical Trial Approval (CTA)

Review of the Clinical Trial Approval (CTA) Scheme

Objectives

1	Streamlined process for CTA applications
2	Increased collaboration with HRECs
3	Clear guidance, including timeframes and data requirements
4	Supports decisions about which pathway to use – CTN vs CTA

Coming soon…

- Updated forms
- Clear CTA application dossier guidance

Review of the Clinical Trial Approval (CTA) Scheme

We are currently in the process of reviewing the Clinical Trial Approval (CTA) Scheme.

Last updated: 1 September 2024

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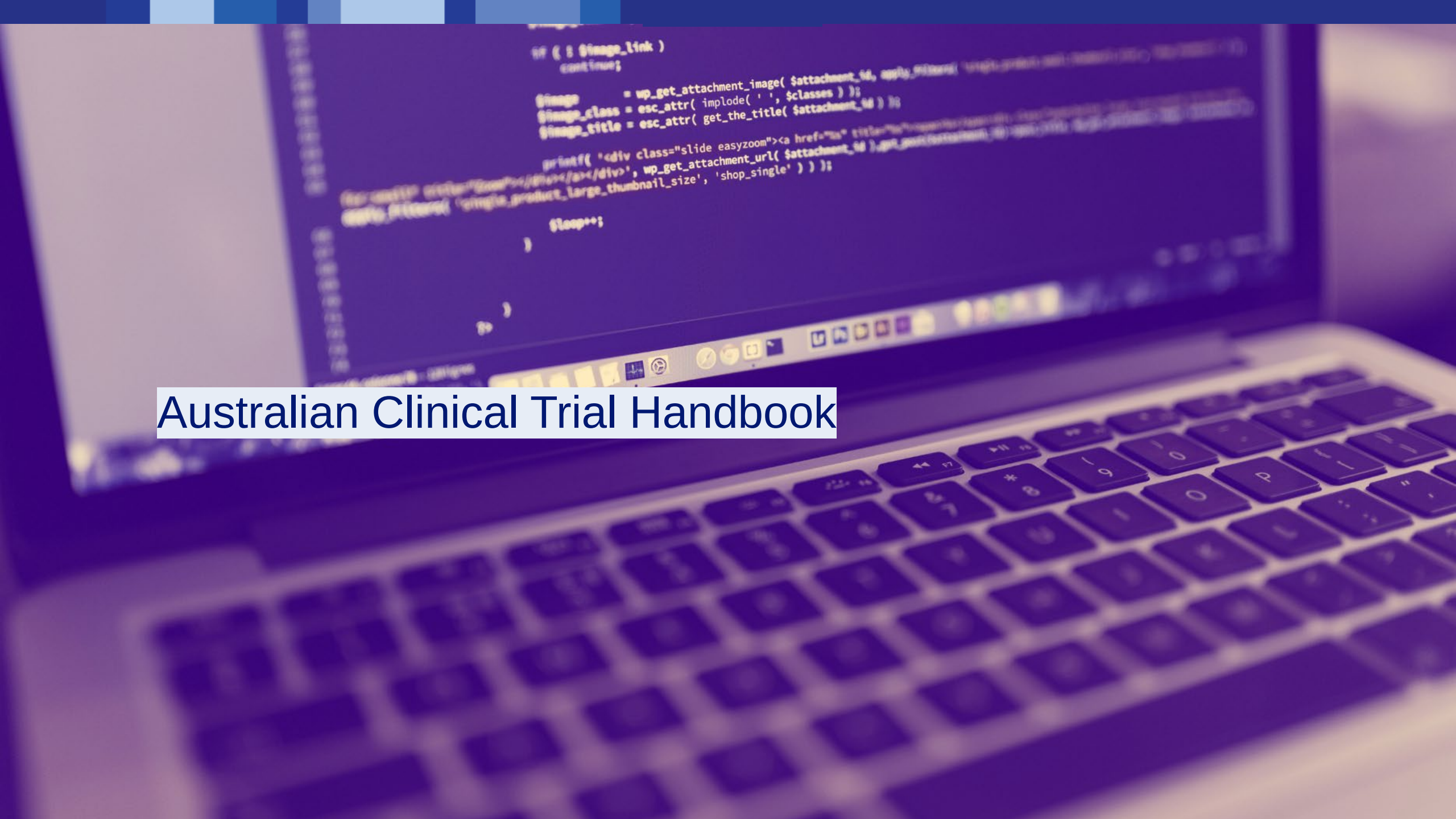
On this page

The TGA committed to undertake a review of the CTA process in response to the MTP Connect report on the Cell, Gene and Tissue Regulatory Framework in Australia.
Stakeholders have called for improved communication about the CTA pathway.

This page will be updated as the review of the CTA scheme progresses. We encourage any stakeholder seeking more information on the CTA process to contact us at clinical.trials@health.gov.au.

Clinical trials



Australian Clinical Trial Handbook

Updating the Australian Clinical Trial Handbook

- Up-to-date
- Consistent
- Enhance accessibility and usability
- Simplify updates

Updated pages incoming…

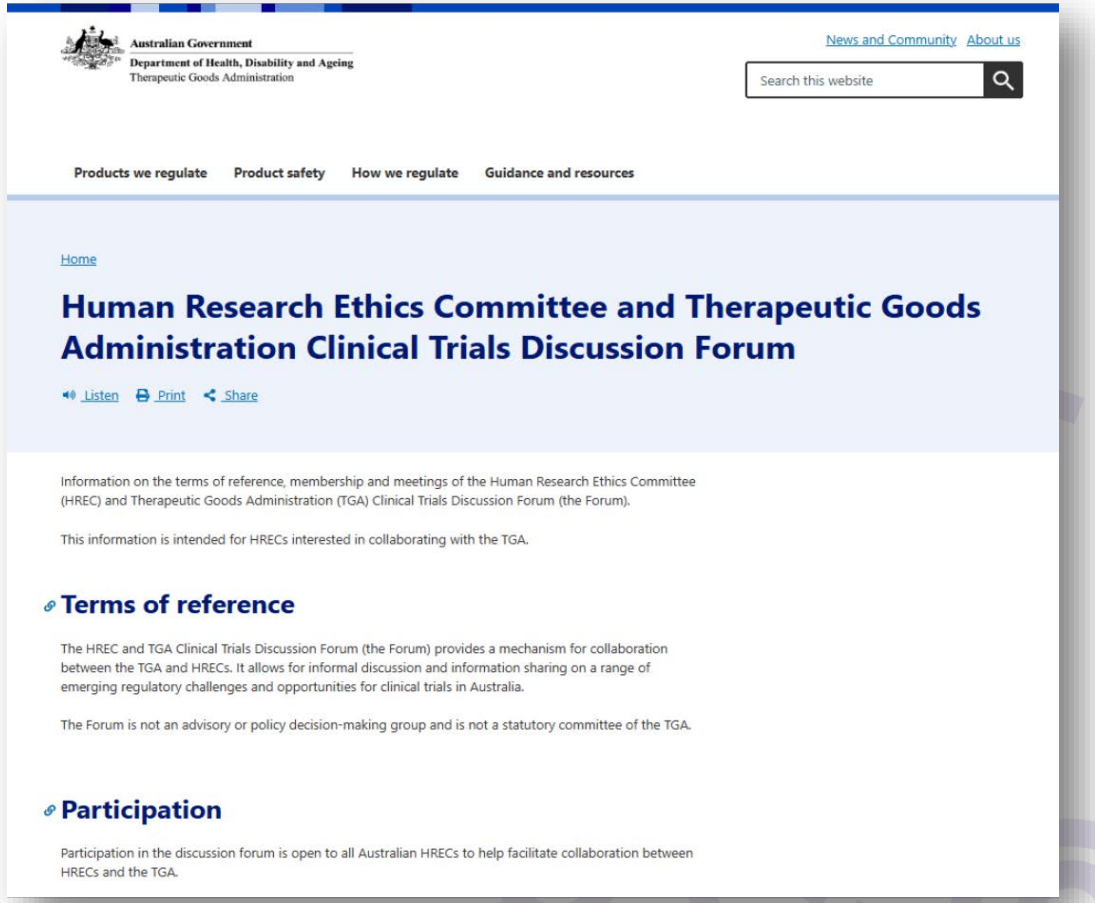
- CTN and CTA schemes
- Advertising
- Manufacturing
- Importing
- Safety Reporting

HREC and TGA Clinical Trials Discussion Forum

Human Research Ethics Committee (HREC) and TGA Clinical Trials Discussion Forum

Improving communication

- Mechanism for collaboration between the TGA and HRECs
- Open group for HREC chairs or their delegates
- Informal discussions and information sharing on range of emerging regulatory challenges and opportunities
- Not an advisory or policy decision-making group, and is not a statutory committee of the TGA
- Communiques are published to the TGA website



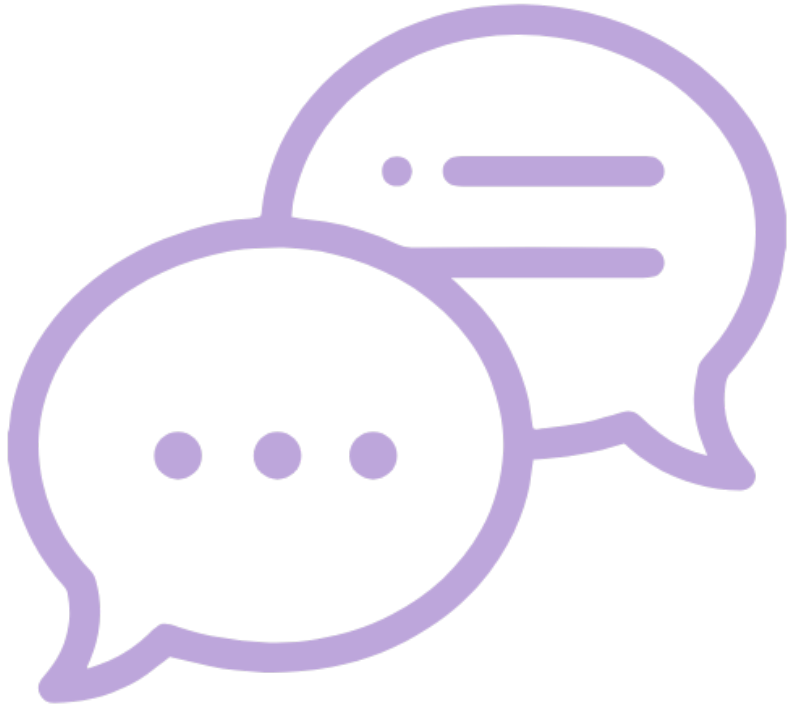
Meeting 5:

- 13 April 2026

Topics discussed:

Understanding Good Manufacturing Practice (GMP) requirements for the manufacture of therapeutic goods used in clinical trials.

- GMP considerations for devices
- How GMP is considered within HREC review processes



Next forum July 2026

Key takeaway: GMP vs legislated manufacturing requirements

Section 3.15.2: The ***sponsor*** should ensure that the investigational product(s) (including active control(s) and placebo……. *is manufactured **in accordance with any applicable GMP**.*

All IMP's **including those for the initial experimental studies in human volunteers** are to be manufactured in accordance with **applicable GMP.**

Legislative requirements - exemptions

SCHEDULE 5A, ITEM 3

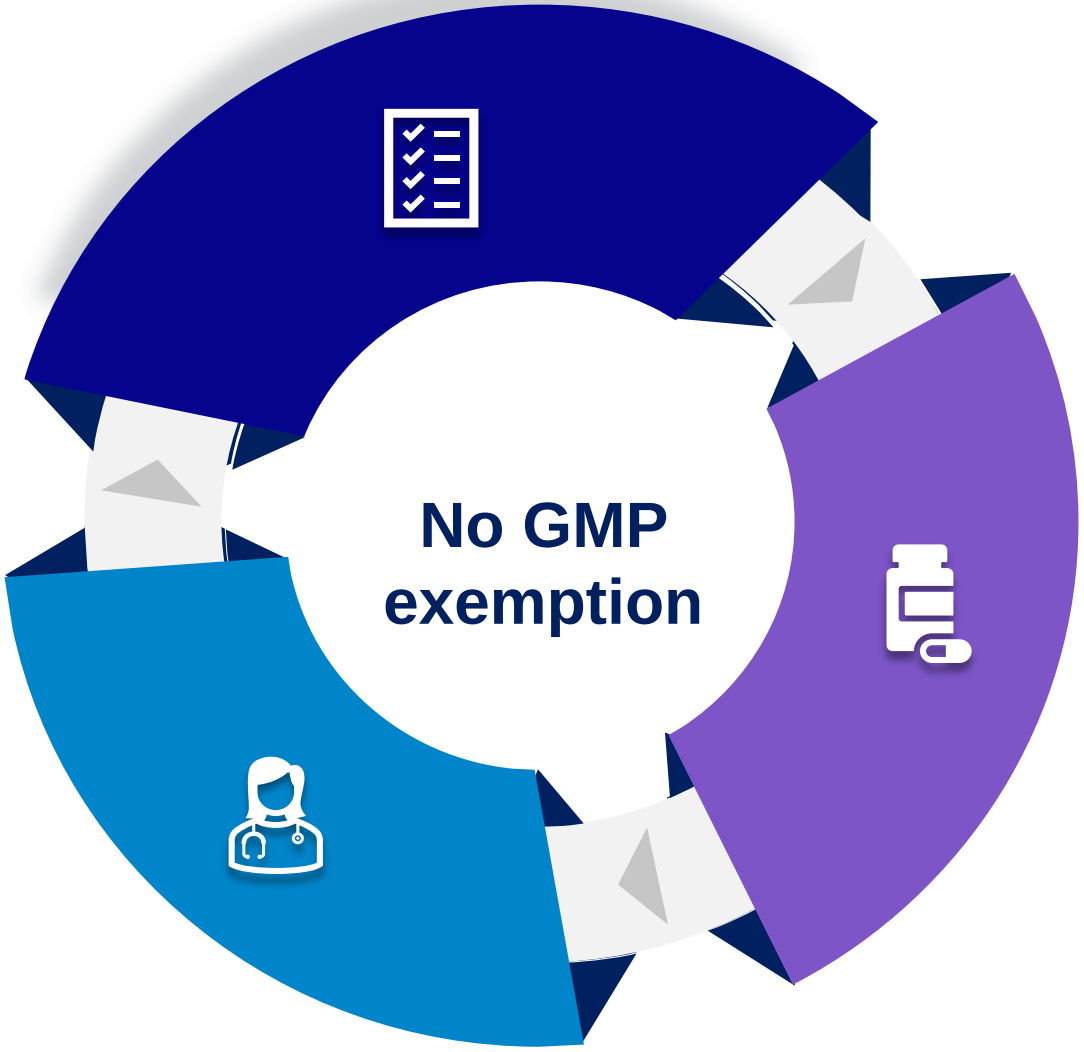
- "*Therapeutic goods to be used in a clinical trial solely for experimental purposes in humans*"
- Exemption from inclusion in ARTG
- Requires notification to TGA (CTN/CTA)

SCHEDULE 7, ITEM 1

- "*Goods prepared for the initial experimental studies in human volunteers*"
- Exemption from TGA manufacturing licence

SCHEDULE 8

- Persons exempt from TGA manufacturing licence



Questions?

GCP enquiries: GCP.Inspection@health.gov.au

Clinical trials enquiries: ClinicalTrials@health.gov.au

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