TGA Clinical Trial Initiatives

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Pharmacovigilance Branch
Department of Health, Disability and Ageing, TGA

TGA initiatives

- Updates to the TGA website
- Updates to the Clinical Trials Handbook
- Review of the Clinical Trial Approval (CTA) Scheme
- HREC and TGA Clinical Trials Discussion Forum
- High-risk medical device reforms
- Insights from 2024 GCP inspection program metrics report
- Consultation on ICH E6(R3) Guideline for Good Clinical Practice

Updates to the TGA website

Content principles for our TGA website

We follow:

- Australian Government Style Manual
- Web Content Accessibility Guidelines (WCAG) 2
- Digital Experience Policy

User focused: creating content that meets user needs.

Findable: writing and designing content that's easy for users to find on our site and in search engines.

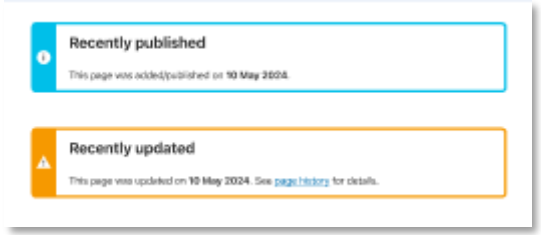
Scannable: using descriptive headings and front-loading information to allow users to easily scan digital content.

Clear and accessible: using plain English, going 'digital first' and meeting accessibility guidelines.

New features make Guidance clearer and more accessible

Visual indicators to flag updates

on individual Guidance pages

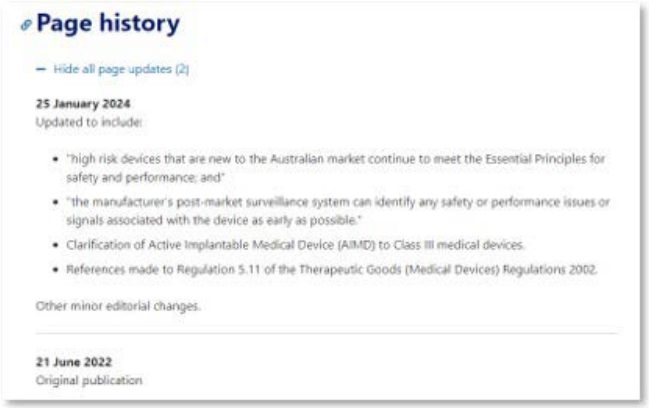


on Guidance listing page

Clear list of related legislation on pages

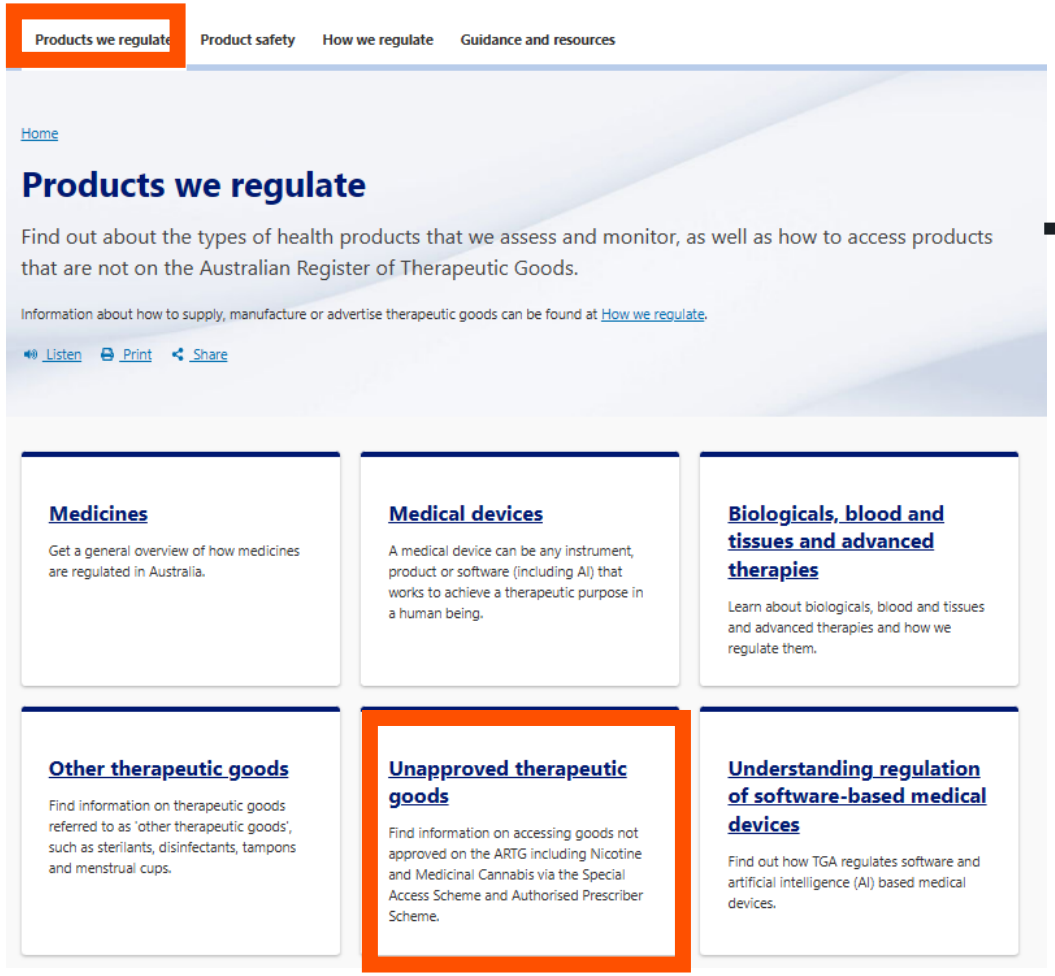
Bookmarkable headings for easy sharing

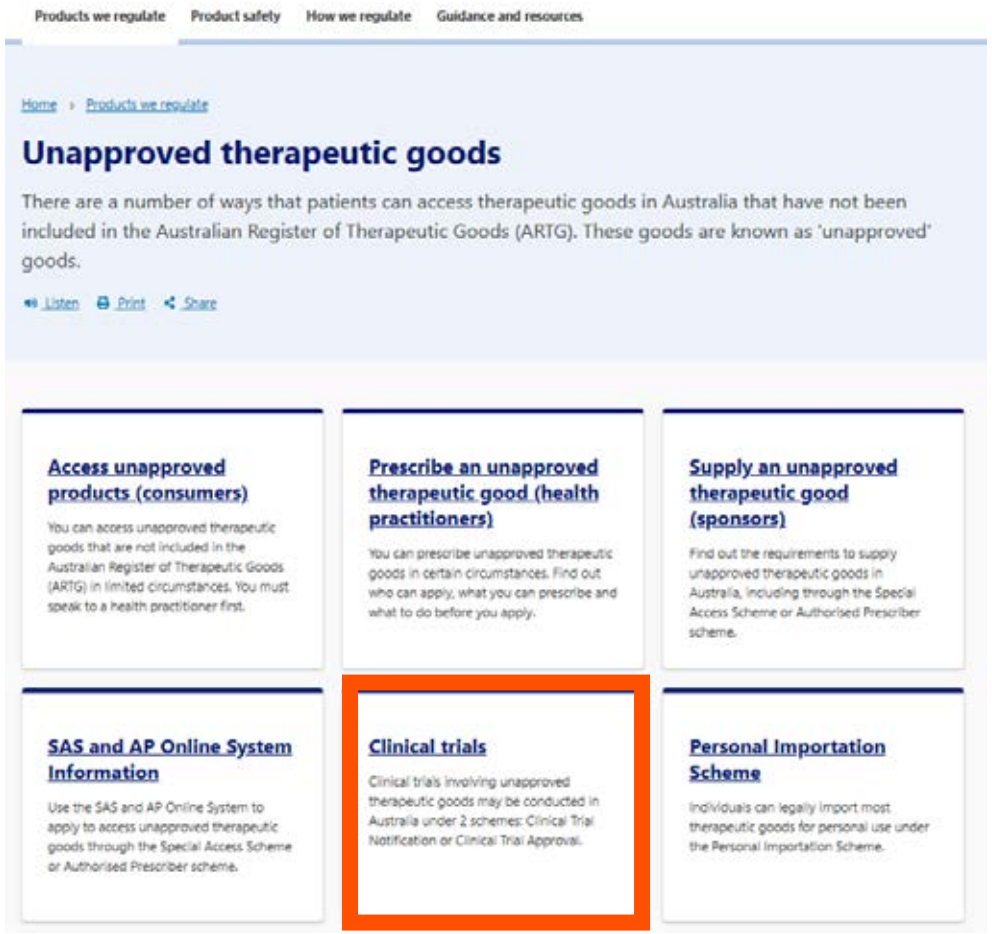
Clear list of changes over time



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

Finding clinical trials information





Phase 1 – the fundamentals

Regulation of clinical trials by the TGA

How we regulate Australian clinical trials that use unapproved therapeutic goods

Find out how we regulate clinical trials in Australia and ensure compliance with Good Clinical Practice.

Clinical Trial Notification (CTN) scheme

Clinical Trial Notification (CTN) scheme

Find out about the Clinical Trial Notification (CTN) scheme.

Clinical trial notification (CTN) form - user guide

The user guide for the Clinical Trial Notification (CTN) form has been updated to reflect the recent updates to the online CTN form.

Clinical Trial Approval (CTA) scheme

Review of the Clinical Trial Approval (CTA) Scheme

We are currently in the process of reviewing the CTA scheme.

CTA scheme forms

CTA applications are submitted using paper-based forms. There are two forms that must be completed by the sponsor.

Phase 1 – Engagement and reforms

Webinars and Consultations

Clinical trials webinars, presentations and consultations

Find webinars and presentations about Australian clinical trials.

Australian clinical trial reforms

Australian clinical trial reforms

On 2 May 2024, the Minister for Health and Aged Care announced an investment of $18.8 million to progress the National One Stop Shop for clinical trials and health research.

Good Clinical Practice

Good Clinical Practice (GCP)

Good Clinical Practice (GCP) Inspection Program

Learn about GCP inspections of clinical trial sites of investigational biologicals, medicines and medical devices.

ICH Guideline for Good Clinical Practice

This guideline is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.

Good Clinical Practice Inspection (GCP) Program

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Published: 1 April 2022

Last updated: 27 March 2025

Listen Print Share Save as PDF

Metrics reports

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Past webinar presentations

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We showcased changes to the Clinical Trials Notifications (CTN) form and explained how the review of CTNs for the highest risk medical device clinical trials will operate in practice.

Phase 2: Publication of clinical trial topic areas

Example: Reporting safety events

How to engage with us

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

Learn more:	You can join our mailing distribution list for regular Program updates.
Get in touch:	You can reach out to our team with questions or suggestions.
Future testing & feedback	If you'd like to contribute to this work, you can sign up for our user research group.

TGAdigitalstakeholders@health.gov.au

Updates to the Clinical Trial Handbook

Knowledge check: When was the original publication of the Australian Clinical Trial Handbook?

Here's your clue!

Updating the Australian Clinical Trial Handbook

- [ ] Up to date
- [ ] Consistent
- [ ] Meets our TGA website content principles

The process


Internal consultation
Targeted external consultation
Publication

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

Progress to date

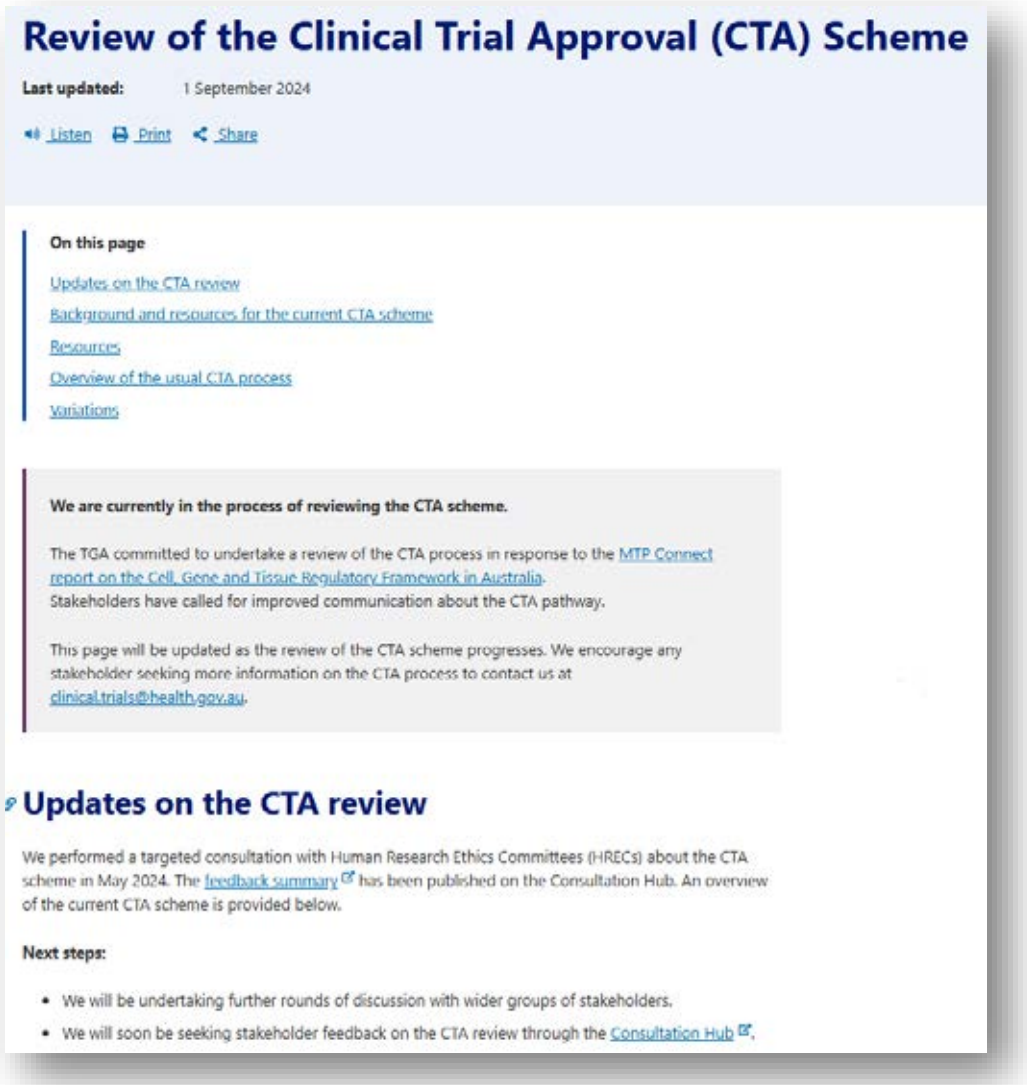
Updates to the TGA website

Review of the Clinical Trial Approval (CTA) scheme

- Overview of the usual CTA process

How we regulate Australian clinical trials that use unapproved therapeutic goods

- When you need a clinical trial supply exemption



Review of the Clinical Trial Approval (CTA) Scheme

Last updated: 1 September 2024

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On this page

Updates on the CTA review
Background and resources for the current CTA scheme
Resources
Overview of the usual CTA process
Variations

We are currently in the process of reviewing the CTA scheme.

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.

Updates on the CTA review

We performed a targeted consultation with Human Research Ethics Committees (HRECs) about the CTA scheme in May 2024. The feedback summary has been published on the Consultation Hub. An overview of the current CTA scheme is provided below.

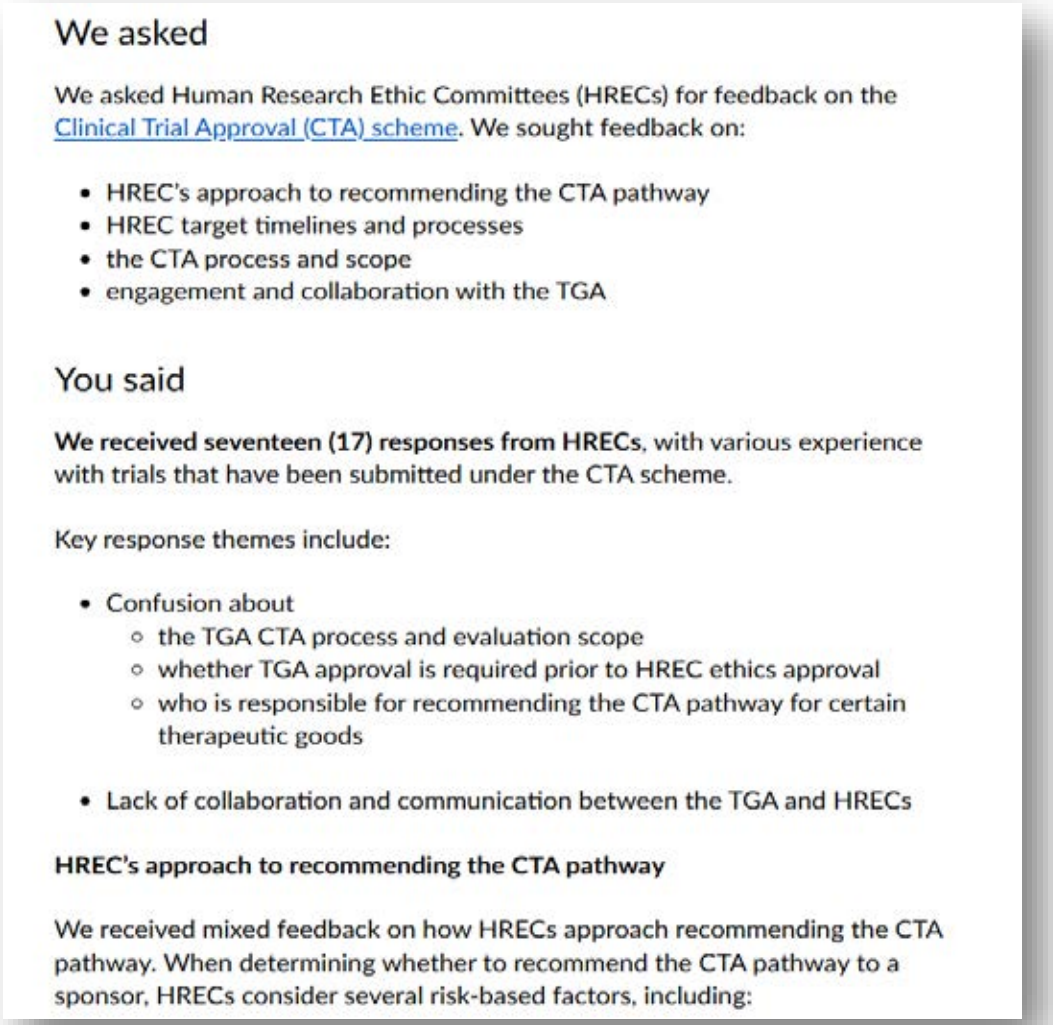
Next steps:

- We will be undertaking further rounds of discussion with wider groups of stakeholders.
- We will soon be seeking stakeholder feedback on the CTA review through the Consultation Hub.

Progress to date

Consultations

- Clinical Trial Approval (CTA) scheme – Targeted consultation with Human Research Ethics Committees (HRECs)



We asked

We asked Human Research Ethic Committees (HRECs) for feedback on the Clinical Trial Approval (CTA) scheme. We sought feedback on:

- HREC's approach to recommending the CTA pathway
- HREC target timelines and processes
- the CTA process and scope
- engagement and collaboration with the TGA

You said

We received seventeen (17) responses from HRECs, with various experience with trials that have been submitted under the CTA scheme.

Key response themes include:

- Confusion about
  - the TGA CTA process and evaluation scope
  - whether TGA approval is required prior to HREC ethics approval
  - who is responsible for recommending the CTA pathway for certain therapeutic goods
- Lack of collaboration and communication between the TGA and HRECs

HREC's approach to recommending the CTA pathway

We received mixed feedback on how HRECs approach recommending the CTA pathway. When determining whether to recommend the CTA pathway to a sponsor, HRECs consider several risk-based factors, including:

Progress to date

Communications

- HREC and TGA Clinical Trials Discussion Forum
- Updated CTA decision letters

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
- Aims to provide a mechanism for collaboration between the TGA and HRECs
- 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
- Next meeting scheduled for 13 August 2025
- clinicaltrials@health.gov.au

2 Forums so far

Meeting 1 – 27 November 2024 - 33 HREC attendees

Review of the Clinical Trial Approval (CTA) scheme

- Participants discussed:
- The optimal points in the CTA process for connection between HRECs and the TGA
- Whether HRECs are seeing trends in trials with high-risk investigational medicinal products (IMPs), particularly in vivo gene therapies
- whether HRECs are experiencing any challenges with evaluating these products

Non-animal models

- Covered the TGA Regulatory Framework, drivers for the adoption of NAMs and challenges

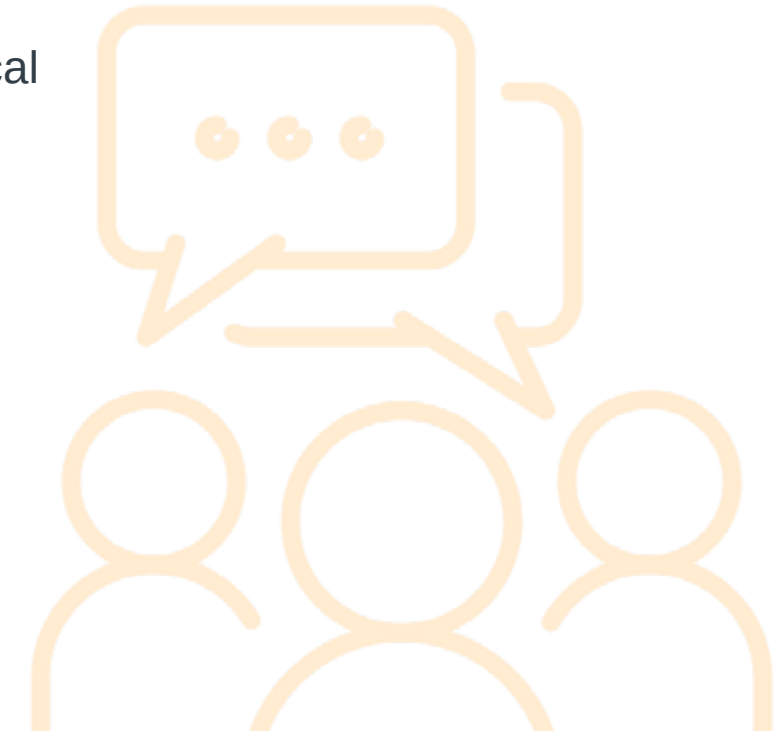
2 Forums so far

Meeting 2 - 1 May 2025 - 26 HREC attendees

When is a clinical trial supply exemption required

Participants discussed:

- Challenges in choosing the appropriate supply exemption pathway in clinical research.
- Participants noted the various supply exemption pathways available to lawfully supply an unapproved therapeutic product, which are the Clinical Trial Notification (CTN), Clinical Trial Approval (CTA), Authorised Prescriber (AP) and Special Access Scheme (SAS).



Clinical trials involving medical devices

- Participants discussed challenges with clinical trials where unapproved medical devices are not the investigational product.

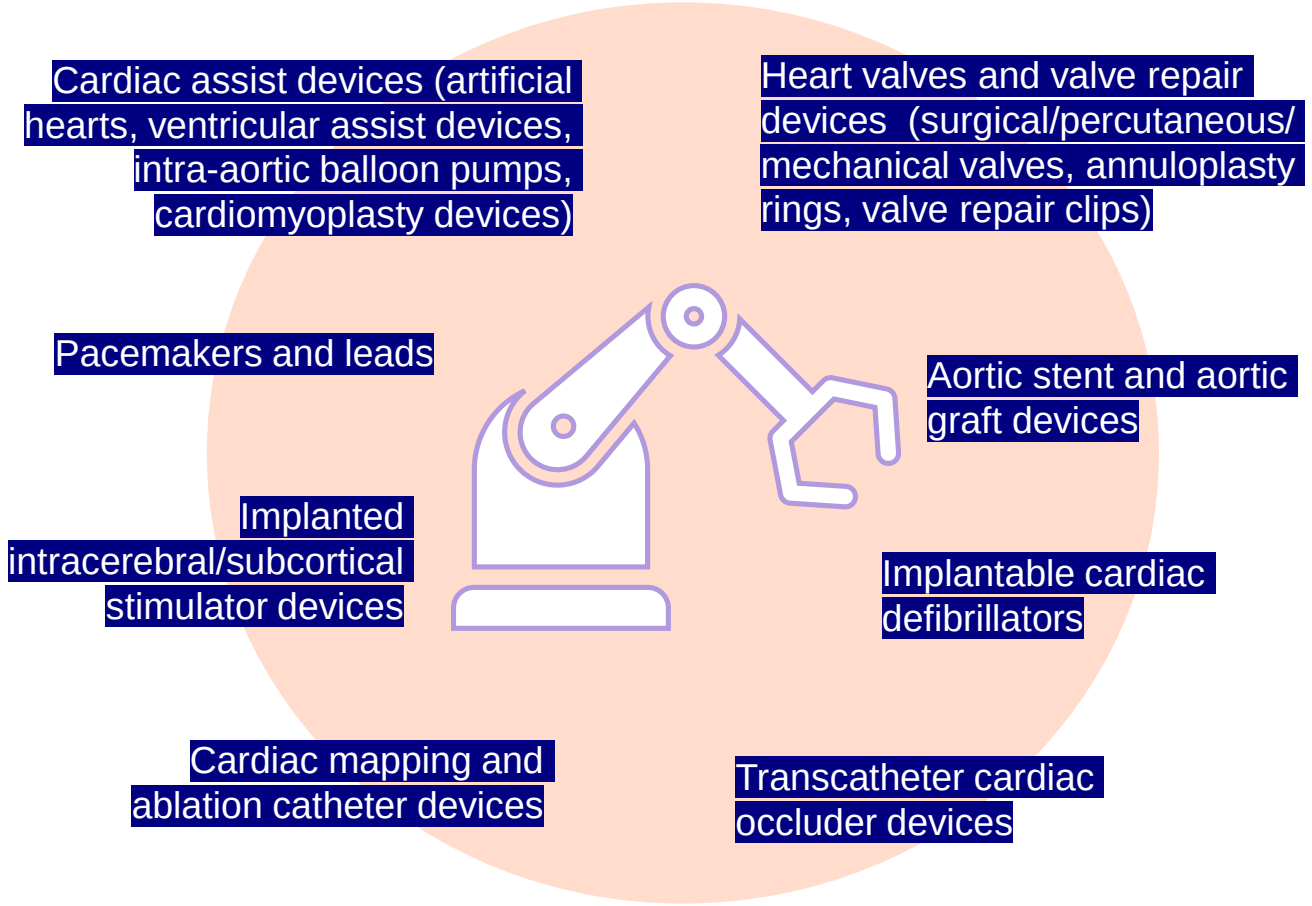
Increased TGA oversight of medical device clinical trials

Proactive monitoring of highest-risk medical device clinical trials

Following stakeholder consultation, two recent changes to clinical trials regulation were instituted:

- Clinical trials of medical devices came within scope of the Good Clinical Practice Inspection Program (GCPIP)
- Review of CTN submissions for first-in-human trials of 8 high-risk device types

CTNs for all other devices types are not assessed by TGA



What happens now when a medical device CTN is submitted?

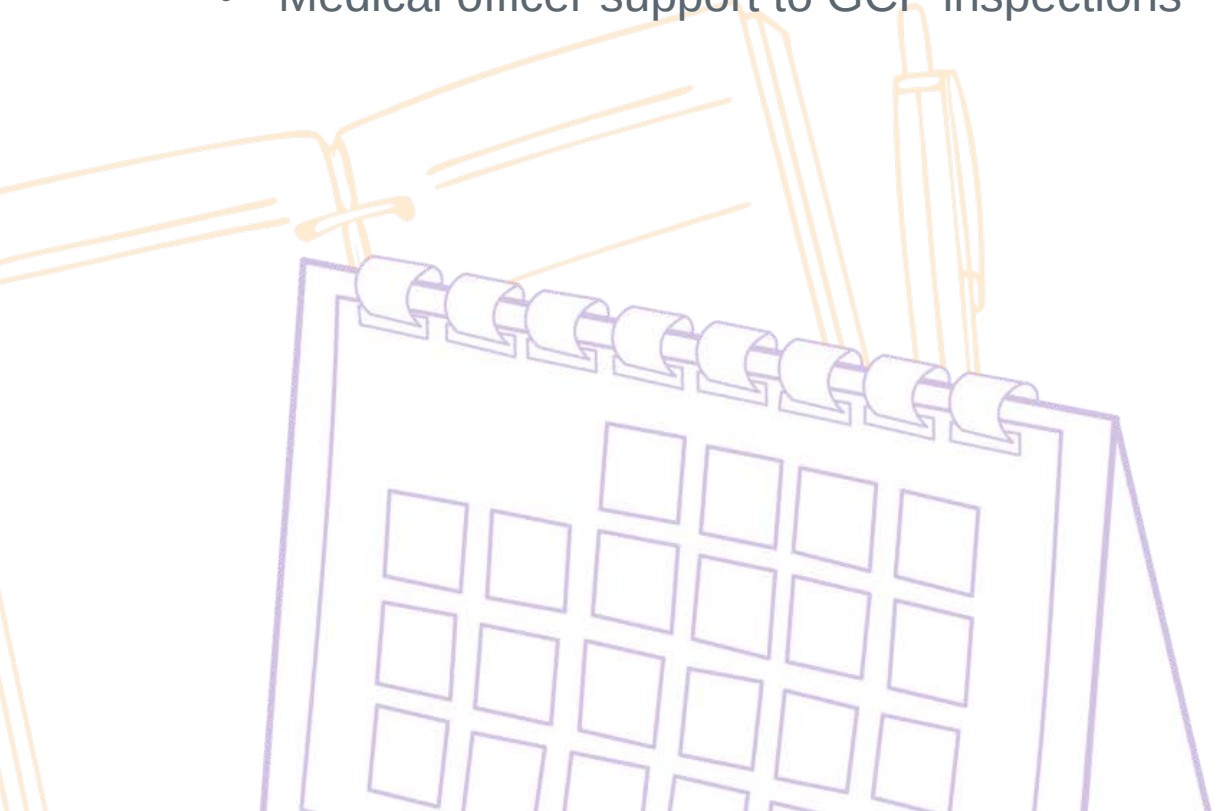
Process

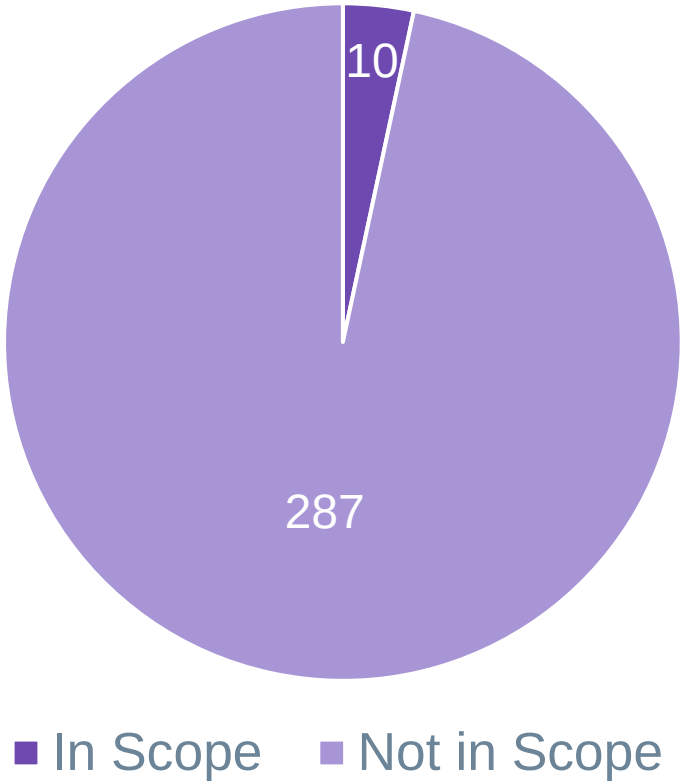
1. The CTN is reviewed by a first line clinician assessor (currently always a pharmacist) for whether it meets risk criteria – 2 days
2. If a device does potentially meet criteria a medical adviser is informed (same day)
3. The medical adviser completes an initial review, identifying areas for concern and what specialist input is needed (1 day, 3 days total)
4. The medical adviser and senior medical adviser agree and requests are sent to specialist areas (e.g. engineering, biomaterial, sterility) as appropriate on the same day the report is complete (3 days total).
5. The specialty areas are given 2 days to review and then a multidisciplinary meeting is convened. Questions to the applicant are formulated, agreed and sent. This initial assessment phase is usually completed within about 6 business days of notification. Sponsors are also asked for permission for us to contact the approving HREC
6. Sponsors provide responses on an individual timeframe (depending on planned recruitment date or urgency of issues identified, anywhere from “on an urgent basis” to 4 weeks).
7. Detailed reports are prepared by all speciality areas, and a final medical report is complete.
8. A delegate of the secretary can issue a direction that a trial be stopped at any point in this process, however the situation has not yet arisen.

A snapshot of trials - numbers

The first 12 months…

- 10 trials selected as “in scope” for proactive review against selection criteria
- 297 trials screened for high-risk device types
- Medical officer support to GCP inspections





Insights from 2023-2024 Good Clinical Practice (GCP) Inspections

Good Clinical Practice Inspection (GCP) Program

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Good Clinical Practice (GCP) Inspection Program

Program Objectives

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).

Inspectors will check your compliance with..

Therapeutic Goods Act 1989

- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods (Medical Devices) Regulations 2002*

GCP Guidelines
- ICH GCP E6 (R2)
- ISO 14155:2020

National Statement on Ethical Conduct in Human Research (National Statement)

HREC approved protocol & amendments

Who we inspect

We can inspect…

Australian investigator sites under the CTN/CTA schemes including investigator-initiated studies (IIT)

Site-level trial activity contracted to another party

CTN = Clinical Trial Notification
CTA = Clinical Trial Approval

We do not inspect…

Human Research Ethics Committee (HREC)

Approving Authority/Research Governance Officer (RGO)

Sponsors

Other clinical research **not** subject to CTN/CTA schemes

What we inspect

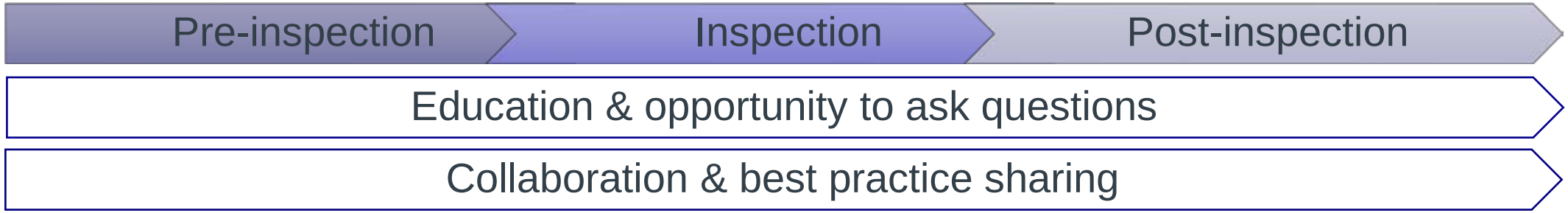
Main categories

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

*used to be referred to as Investigational Medicinal Product (IMP)

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

GCP Inspection Process (routine announced)



Pre-inspection (≈28 days)

- Notification, planning and preparation
- Agenda and logistics with trial site
- Drafting and finalisation of Inspection plan

Inspection (1-2 days)

- Opening meeting
- Facility tour
- Documents and source data review
- Closing meeting with presentation of closing summary

Post-inspection

- Usually issue an inspection report (≤ 30 days)
- Initial CAPA* plan ≤ 30 days from the issue of inspection report
- Evaluation of CAPA* plan and close-out of the inspection
- Enforcement action can be taken

*Corrective And Preventative Action (CAPA)

GCP inspections conducted by the TGA in 2023 – 2024

Types of inspections

- 12 routine announced inspections
- 1 ‘for cause’ announced inspection
- In-person and hybrid

Types of inspected sites

- Private and public
- Different geographical locations (ACT, NSW, QLD, SA, VIC)
- Different types of trials:
  - Commercially sponsored
  - Non-commercially sponsored clinical trials, including investigator-initiated trials (IITs)

Types of inspected trials

- Phases 1-3
- Ongoing and completed
- Different therapeutic goods / investigational products:
  - Medicines
  - Biologicals
  - Medical devices
- 11 therapeutic areas

Summary of deficiencies

2023 - 2024

- At least one deficiency was identified in all inspections
- Critical deficiencies were identified in ‘Protocol compliance’, ‘Trial management’ and ‘Therapeutic Good / Investigational Product’ categories in both years
- No critical deficiencies were identified in commercially sponsored clinical trials
- Full compliance in one or more categories was observed in several inspections
- The highest level of compliance was observed in ‘Therapeutic Good / Investigational Product’.

When will we consult on ICH GCP E6(R3)?

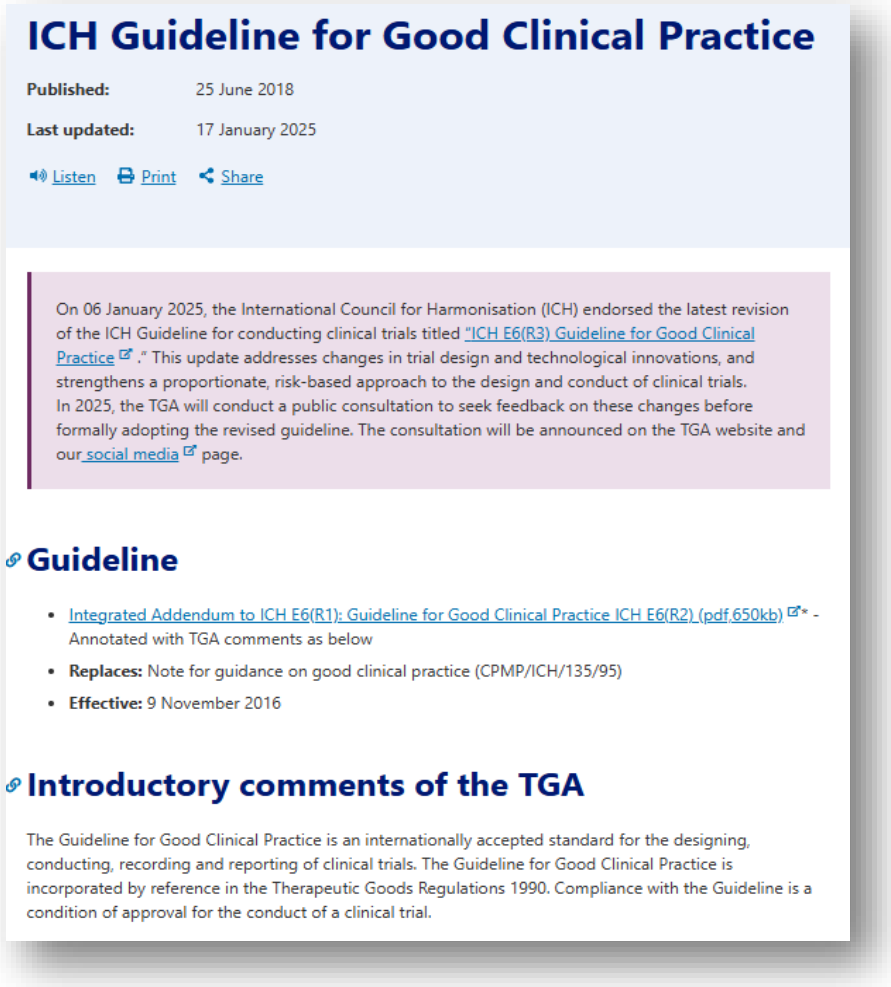
Public consultation commencing in 2025.

Why do we consult on international guidelines?

We will undertake an extensive process of internal and external consultations to ensure guidelines are consistent with prevailing requirements in Australia.

We aim to closely align our regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible.

The consultation will be announced on the TGA website and our LinkedIn page.



ICH Guideline for Good Clinical Practice

Published: 25 June 2018

Last updated: 17 January 2025

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On 06 January 2025, the International Council for Harmonisation (ICH) endorsed the latest revision of the ICH Guideline for conducting clinical trials titled "ICH E6(R3) Guideline for Good Clinical Practice." This update addresses changes in trial design and technological innovations, and strengthens a proportionate, risk-based approach to the design and conduct of clinical trials. In 2025, the TGA will conduct a public consultation to seek feedback on these changes before formally adopting the revised guideline. The consultation will be announced on the TGA website and our social media page.

Guideline

- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (pdf,650kb) - Annotated with TGA comments as below
- **Replaces:** Note for guidance on good clinical practice (CPMP/ICH/135/95)
- **Effective:** 9 November 2016

Introductory comments of the TGA

The Guideline for Good Clinical Practice is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. The Guideline for Good Clinical Practice is incorporated by reference in the Therapeutic Goods Regulations 1990. Compliance with the Guideline is a condition of approval for the conduct of a clinical trial.

GCP Inspection Program Focus for 2025/26

Education and collaboration

- ICH GCP E6(R3) Consultation
- Collaboration with external stakeholders
- Guidance updates
- eLearning

GCP inspections

- Ongoing GCP inspections
- Encouraging ongoing feedback from inspected sites

Questions?

www.tga.gov.au

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

Clinical trials enquiries: ClinicalTrials@health.gov.au

Therapeutic Goods Administration (TGA)

Exhibition booth **No.60**

Want to chat with me further? Come visit us.

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