Insights into Good Clinical Practice (GCP) Inspection Program Activities 2023-2024

Michelle Vo, PhD
Assistant Director
Pharmacovigilance
Compliance and Clinical
Trials Section
TGA

Anastasia Makshakova
Senior GCP Inspector
Pharmacovigilance
Compliance and Clinical
Trials Section
TGA

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

Welcome

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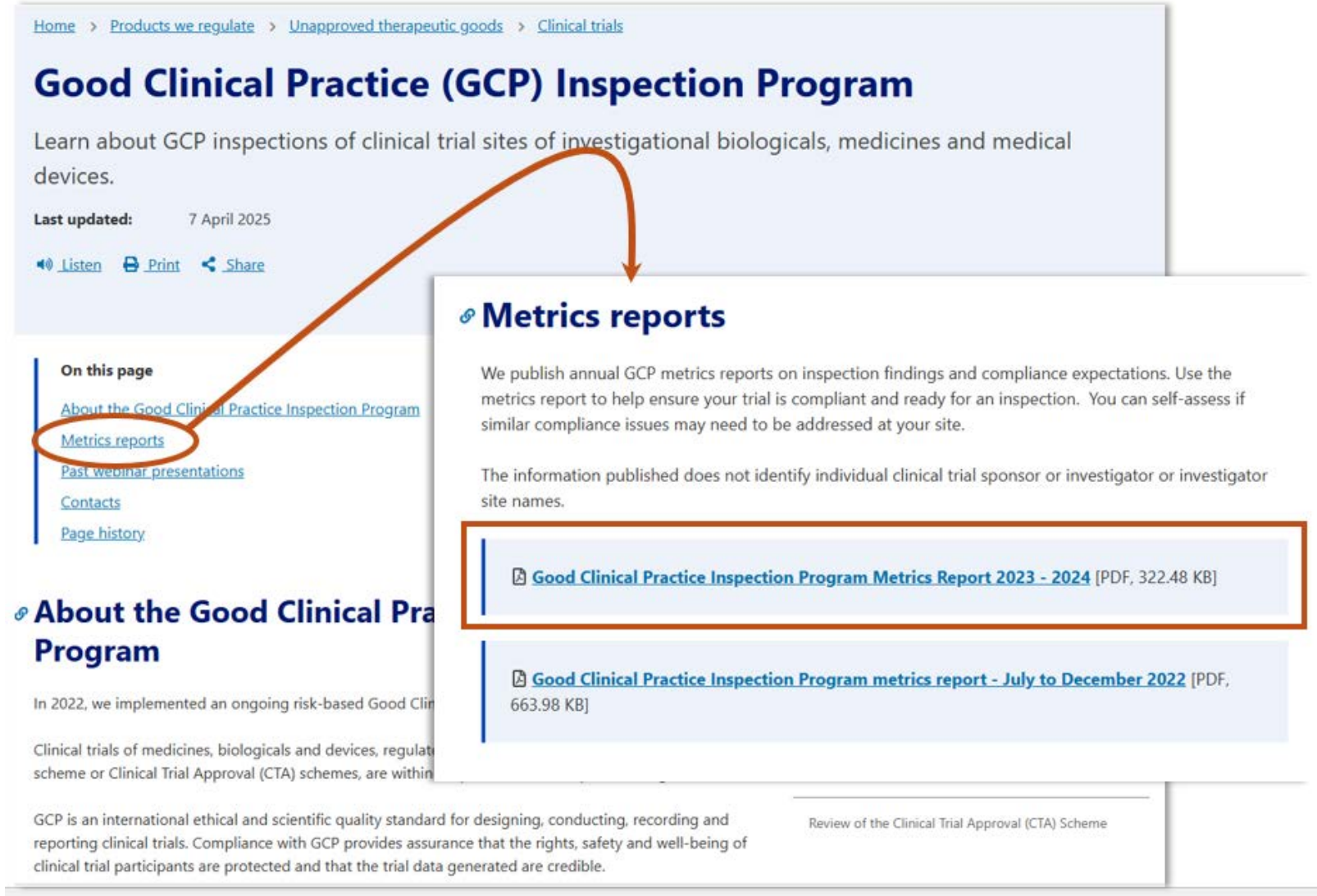
Overview

- GCP Inspection Program Guidance
- Insights from 2023-2024 GCP inspections
- Consultation process on ICH GCP E6(R3)
- Focus for 2025/26
- Q&A session




Good Clinical Practice (GCP) Inspection Program
Learn about GCP inspections of clinical trial sites of investigational biologicals, medicines and medical devices.
Last updated: 7 April 2025
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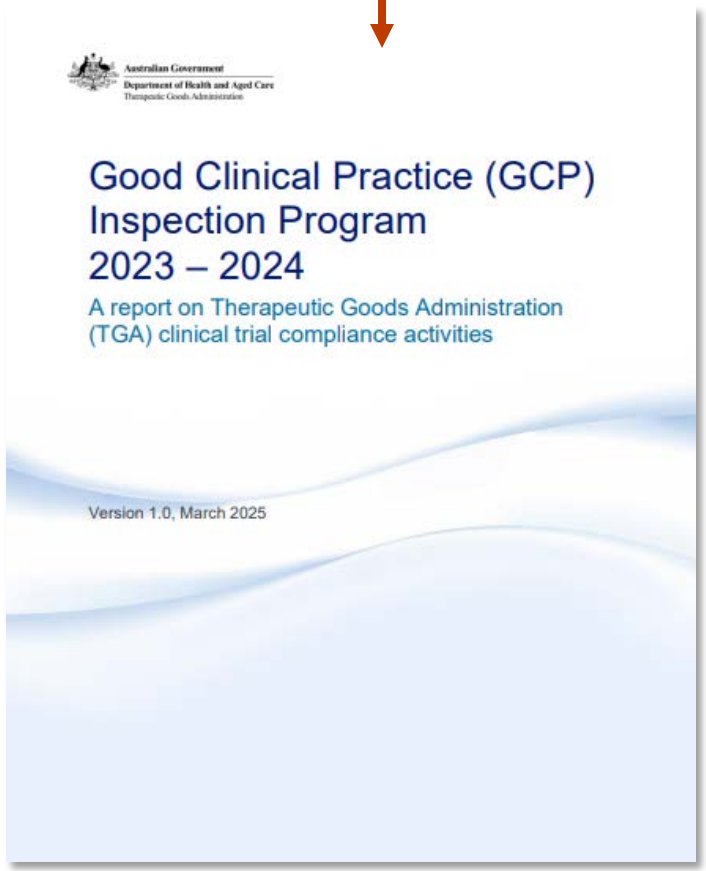
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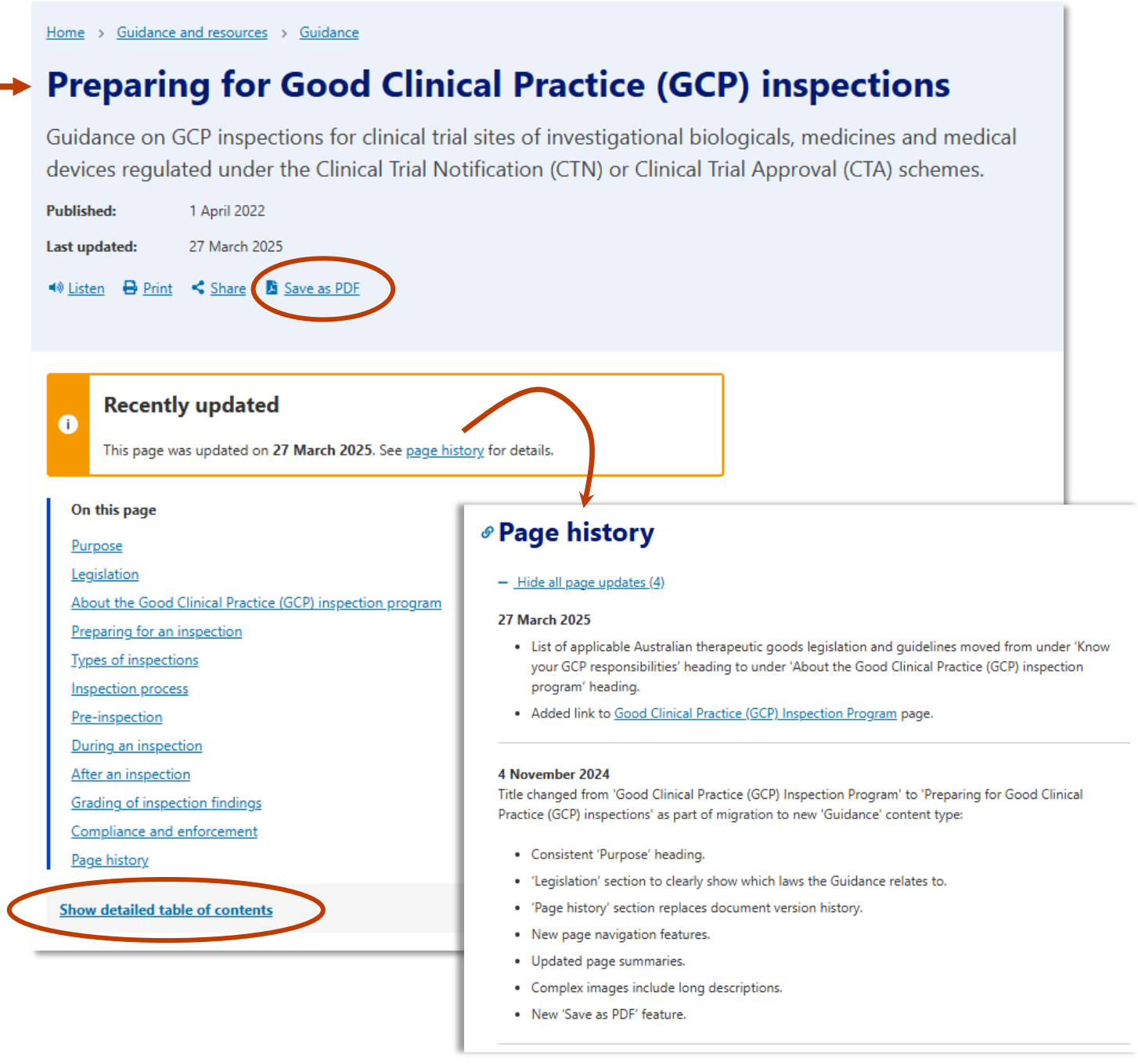
Good Clinical Practice (GCP) Inspection Program 2023 – 2024
A report on Therapeutic Goods Administration (TGA) clinical trial compliance activities
Version 1.0, March 2025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Preparing for Good Clinical Practice (GCP) inspections
Guidance on GCP inspections for clinical trial sites of investigational biologicals, medicines and medical devices regulated under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes.
Published: 1 April 2022
Last updated: 27 March 2025
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27 March 2025
List of applicable Australian therapeutic goods legislation and guidelines moved from under 'Know your GCP responsibilities' heading to under 'About the Good Clinical Practice (GCP) inspection program' heading.
Added link to Good Clinical Practice (GCP) Inspection Program page.
4 November 2024
Title changed from 'Good Clinical Practice (GCP) Inspection Program' to 'Preparing for Good Clinical Practice (GCP) inspections' as part of migration to new 'Guidance' content type:
Consistent 'Purpose' heading.
'Legislation' section to clearly show which laws the Guidance relates to.
'Page history' section replaces document version history.
New page navigation features.
Updated page summaries.
Complex images include long descriptions.
New 'Save as PDF' feature.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials

ICH GCP E6 (R2): International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6) with TGA annotations

ISO 14155:2020: International Organisation for Standardisation (ISO) 14155 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice

Medicines & Biologicals	Medical Devices	Medicines and/or Biologicals and Medical Devices
		
ICH GCP E6 (R2)	ISO 14155:2020	ISO 14155:2020 ICH GCP E6 (R2)

E6 = refers to the guideline on ‘Good Clinical Practice’ published by International Council for Harmonisation (ICH)
R2 = indicates that this is the second revision of the guideline (currently in effect in Australia)

Be inspection ready

GCP Inspection 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

CTN = Clinical Trial Notification
CTA = Clinical Trial Approval

We can inspect…

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

Site-level trial activity contracted to another party

We do **not** inspect…

Human Research Ethics Committee (HREC)

Approving Authority/Research Governance Officer (RGO)

Sponsors

All other types of clinical research **not** subject to CTN/CTA schemes

CTN = Clinical Trial Notification
CTA = Clinical Trial Approval

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 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’.

Example scenarios

- Example scenarios will help illustrate our compliance expectations
- Summary of 2022 example scenarios
- Structure of the example scenarios based on the 2023-2024 metrics report:
    - A scenario based on common deficiencies
    - Questions to support self-evaluation of compliance at your site (**not** all-inclusive)
    - Applicable compliance requirements
    - Key message

Summary of example scenarios from 2023 TGA webinar

Scenario 1

A modified consent form was electronically signed by the participants but not the investigator(s)

Scenario 2

Day 1 post-dose electrocardiograms (ECGs) were completed out of window for all time points

Scenario 3

Decentralised trial (DCT) management

Scenario 4

Investigational Medicinal Product (IMP) management in a DCT

Where to find the recording

Learning from these scenarios are still relevant to all clinical trials regulated under the CTN and CTA schemes:
Insights from the TGA GCP Inspection Program - 2023

Example scenario 1: Communication with HREC/AA

Scenario

As an investigator you need to review the initial document package for completeness and decide which documents to submit to the reviewing HREC and Approving Authority (AA) at your stand-alone clinical trial site.

Applicable compliance requirements

- ICH GCP E6(R2) sections 4.4.1, 4.4.2, 4.4.3, 4.8.1, 4.8.2, 4.8.10, 4.8.15
- ISO 14155:2020 sections 5.8.3.4, 5.8.4, 5.8.6, 10.4
- National Statement 2023 sections 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.11

Document package Included:

- ü Protocol/Clinical Investigation Plan
- ü Trial blinding plan
- ü Pharmacy manual
- ü Laboratory manual
- ü Radiology manual
- ü Operational manual
- ü Initial contract

Document package did NOT include:

- × Investigator's Brochure or equivalent
- × Participant Informed Consent Form (PICF)
- × Recruitment materials

Example scenario 1: Communication with HREC/AA

Scenario

As an investigator you need to review the initial document package for completeness and decide which documents to submit to the reviewing HREC and Approving Authority (AA) at your stand-alone clinical trial site.

Applicable compliance requirements

- ICH GCP E6(R2) sections 4.4.1, 4.4.2, 4.4.3, 4.8.1, 4.8.2, 4.8.10, 4.8.15
- ISO 14155:2020 sections 5.8.3.4, 5.8.4, 5.8.6, 10.4
- National Statement 2023 sections 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.11

Questions to support self-evaluation of compliance at your site

- q Do you know which documents are required to be submitted to the reviewing HREC/AA?
- q Who reviews the document package for completeness? What is the process?
- q How do you assess if any additional documents may be required to be submitted?
- q Who is responsible for ensuring that the submitted documents comply with the National Statement, ICH GCP E6 and ISO 14155 (as applicable)?
- q How are these documents reviewed for compliance at your site?

Key message

The investigator is responsible for ensuring the HRECs and AAs are provided with all information which may influence their approvals/favourable opinions.

Example scenario 2: Protocol amendment

Scenario

As an investigator you received a protocol amendment with significant changes to trial procedures and increased data entry requirements for your trial site staff.

Applicable compliance requirements

- *Therapeutic Goods Regulations 1990* section 12AD (b)
- *Therapeutic Goods (Medical Devices) Regulations 2002* section 7.5 (2)
- ICH GCP E6(R2) sections 4.2.3, 4.5.1
- ISO 14155:2020 section 10.6

HREC = Human Research Ethics Committee
AA = Approving Authority

Questions to support self-evaluation of compliance at your site

- q Do you have a process to assess if you still have appropriate resources to comply with the updated protocol requirements?
- q Have you considered these changes before indicating your acceptance of the protocol/Clinical Investigation Plan (CIP) in writing?
- q Do you have a process to communicate any anticipated issues that may hinder your ability to comply with protocol before amendment is submitted to the reviewing HREC/AA?

Key message

When changes occur, re-evaluate your staff and facilities requirements for the foreseen duration of the trial.

Example scenario 3: Significant changes to IP management

Scenario

As a pharmacist you received a protocol amendment with significant changes to schedule and type of the participant visits and IP management.

Applicable compliance requirements

- *Therapeutic Goods Regulations 1990* section 12AD (b)
- *Therapeutic Goods (Medical Devices) Regulations 2002* section 7.5 (2)
- ICH GCP E6(R2) sections 4.2.3, 4.5.1, 4.6.1, 4.6.2, 4.6.3
- ISO 14155:2020 sections 7.9, 10.6

IP = Investigational Product

Questions to support self-evaluation of compliance at your site

- q Do you have a process to assess if you still have appropriate resources to comply with the updated IP management requirements before you accept this amendment?
- q What is the impact of the changes to IP management at your site?
- q Do you have sufficient space to accommodate the anticipated increase in IP deliveries?
- q Do you have a process to accommodate the change of dispensing process from onsite to remote?
- q Where will participant returns be documented? Who will ensure all returns are accounted for and compliance with IP is calculated?

Key message

Consider impact of change on IP accountability including reconciliation of participant returns of IP.

Example scenario 4: Sponsor-investigator responsibilities in Investigator-initiated trials (IITs)

Scenario

As a sponsor-investigator you are considering conducting an IIT under a CTN scheme.

Applicable compliance requirements

- ICH GCP E6(R2) sections 5, 6, 7
- ISO 14155:2020 sections 6, 7, 9 and Annexes A,B

CTN = Clinical Trial Notification
CTA = Clinical Trial Approval
IP = Investigational Product
ANZCTR = Australian New Zealand Clinical Trials Registry

Points to consider

Sponsor-investigator responsibilities include

- q whether a CTN/CTA is required
- q protocol/CIP design
- q information on IP
- q supply of IP
- q risk management
- q required training and resources
- q clinical trial monitoring
- q electronic systems validation requirements
- q registration on a publicly accessible database, e.g. ANZCTR

Key message

Know your obligations as a sponsor-investigator.

Do not wait until an inspection to be inspection-ready

- Take time to proactively understand the TGA requirements and guidance on clinical trial conduct.
- Compliance with GCP should be integrated into the site's processes – it is not a standalone function.
- TGA GCP inspectors aim to work with clinical trial sites and provide education to improve compliance and protect clinical trial participants.
- TGA GCP inspections aim to cover a range of different clinical trials e.g. phases/stages, enrolment stages, therapeutic areas of trials in our scope

Refresher – How to use Slido
Questions are now open!

Through the Slido application in Webex

- Click on the Apps icon
- Select Slido
- Open the Q&A tab to ask questions
- Live Poll (use survey tab when prompted)

Using the QR code

Scan the QR code to access Slido from your mobile device

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

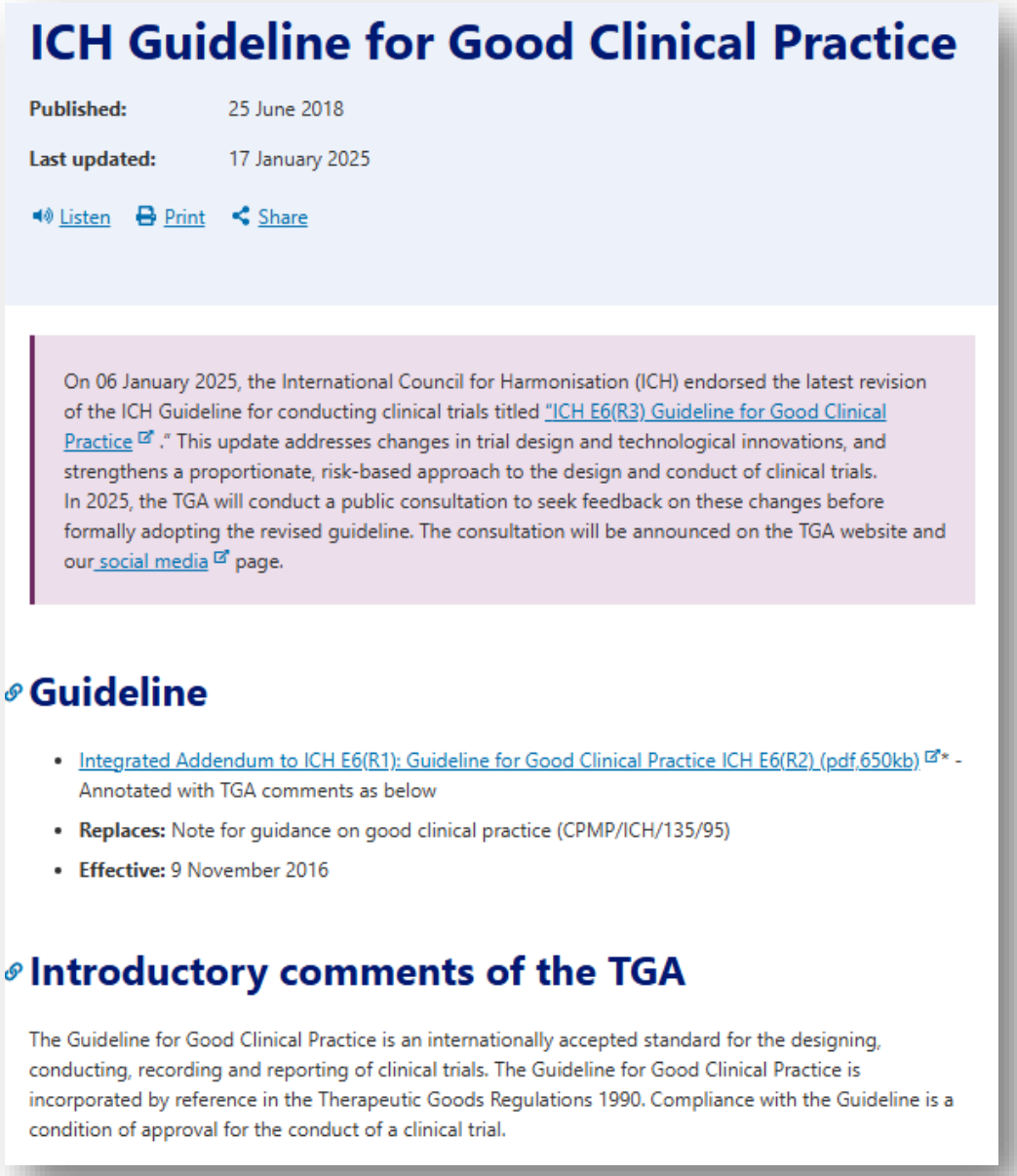
Public consultation commencing in 2025.

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 & Collaboration

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

GCP Inspections

- Ongoing GCP inspections
- Encouraging ongoing feedback from inspected sites

Contact us

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

Clinical trials enquiries:
ClinicalTrials@health.gov.au

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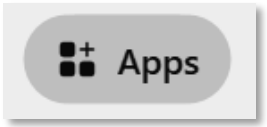

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Questions?

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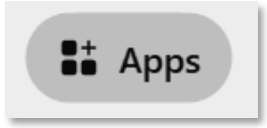

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Websites & Link References

Good Clinical Practice (GCP) Inspection Program | TGA	https://www.tga.gov.au/products/unapproved-therapeutic-goods/clinical-trials/good-clinical-practice-gcp-inspection-program
Preparing for Good Clinical Practice (GCP) inspections Guidance I TGA	https://www.tga.gov.au/resources/guidance/preparing-good-clinical-practice-gcp-inspections
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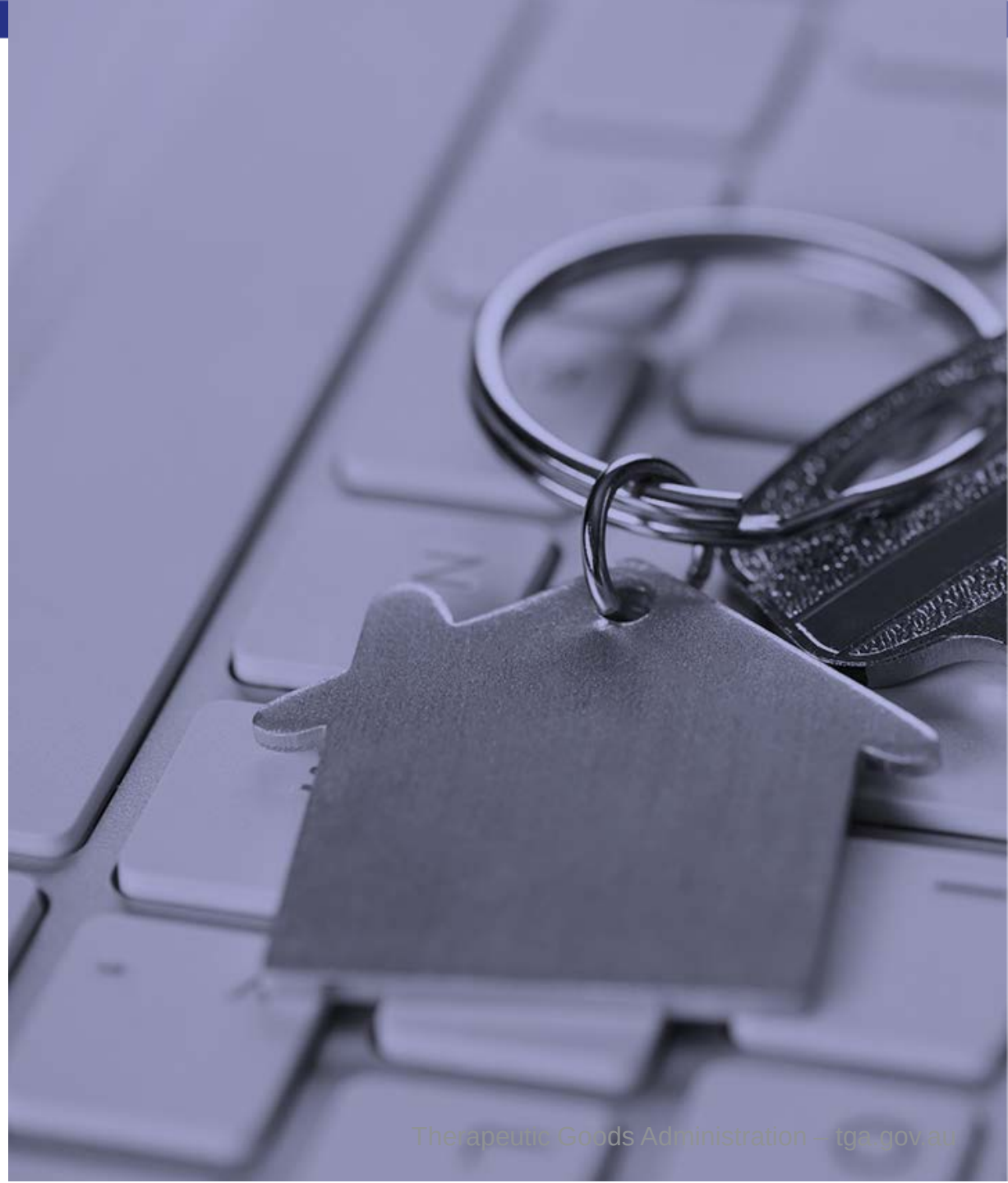

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