Good Clinical Practice (GCP) inspection program for clinical trials of medicines, biologicals and devices

Michelle Vo, PhD
Senior GCP Education Compliance Officer
Pharmacovigilance Compliance and Clinical Trials Section
Therapeutic Goods Administration

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

Housekeeping

This webinar is being recorded and will be published in the upcoming weeks

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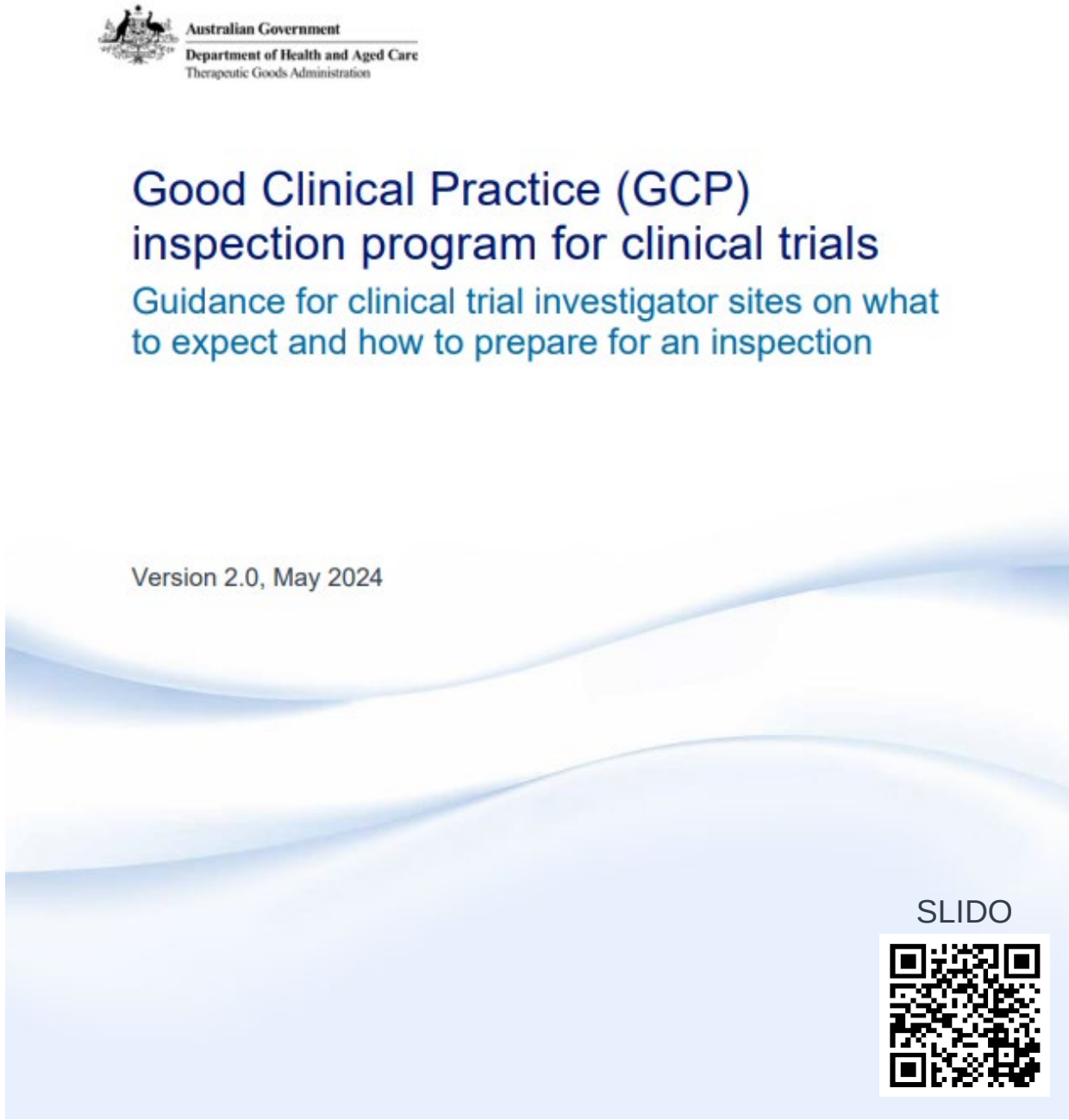
Overview

- About the GCP Inspection Program
- Inspection Process
- Inspection Prioritisation
- Preparing for an inspection
- Future focus
- Q&A



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About the GCP Inspection Program

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

ICH GCP E6 (R2)

Medical Devices

ISO 14155: 2020

Combination Investigational Products

ICH GCP E6 (R2)
ISO 14155: 2020

National Statement on Ethical Conduct in Human Research

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Legislation

Therapeutic Goods Act 1989 (the Act)

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

The Therapeutic Goods (Clinical Trials Inspections) Specification (no.2) 2020

See our Legislation and legislative instruments page on our website for a list of Acts, regulations and legislative instruments.

Who do we inspect?

- Clinical trials included in the Clinical Trial Notification (CTN) & Clinical Trials Approval (CTA) scheme
  - Investigator site = all locations carrying out clinical trial activity except at patient's homes
  - Risk-based selection of a proportion of eligible clinical trials

- Types of Investigational Products / Therapeutic Goods
  - Medicines
  - Biologicals
  - Medical devices

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We inspect…

Australian investigator sites including investigator-initiated studies (IIT)

Site-level trial activity contracted to another party

We don't inspect…

Human Research Ethics Committees (HRECs)

Sponsors

Approving Authority

Why do we inspect?

The GCP inspection program strengthens the TGA's monitoring activities to help protect the rights, safety and well-being of Australian trial participants and assure the quality and credibility of trial data.

Compliance check

- Verify clinical trial sites are compliant with the GCP standard and have met their clinical trial responsibilities.

Education

- Provide guidance and work with the site to ensure there are effective systems in place in alignment with Australian legislation and the relevant GCP guideline(s).

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Inspection prioritisation

Inspection prioritisation

Risk-based approach to scheduling using combination of:

- risk assessment
- internal and external intelligence

Risk assessment of clinical trials:

- risk assessment process as described in the **Risk-based Management and Monitoring of Clinical Trials Involving the Therapeutic Goods**, published in 2018 by National Health and Medical Research Council (NHMRC)
- risk criteria are grouped into 2 categories: the risks associated with
    - **investigational product (medicine, biological, device)**
    - **trial conduct, design and methods**

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Inspection process

Types of inspections

- Routine inspections
- ‘For cause’ inspections
- Announced and unannounced inspections
- Re-inspections
- Remote/hybrid

GCP inspection process (routine announced)

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Pre-inspection → Inspection → Post-inspection

Education & opportunity to ask questions

Collaboration & best practice sharing

Pre-inspection (≈28 days)

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

Inspection (≈3 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)

Inspection Scope

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

Grading inspection findings

- Minor
- Major
- Critical

Preparing for an inspection

Inspectors will check your compliance with…

Therapeutic Goods Act & Regulations

GCP guidelines(s)

National Statement

HREC approved protocol & amendments

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Resources

- Australian Clinical Trials Handbook
- GCP Inspections Metrics Report
- National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia

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Future Focus

- Education & collaboration
- Metrics reports
- Webinars
- eLearning modules
- Ongoing GCP inspections
- Seeking feedback from inspectees

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

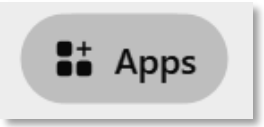
Good Clinical Practice (GCP) inspection program for clinical trials

Guidance for clinical trial investigator sites on what to expect and how to prepare for an inspection

Version 2.0, May 2024

How did we go?

Take a moment to complete our survey



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Questions?

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Website and link references

Clinical trials | TGA	https://www.tga.gov.au/clinical-trials
Good Clinical Practice (GCP) inspection program | TGA: guidance and metrics report	https://www.tga.gov.au/resource/good-clinical-practice-gcp-inspection-program
Clinical Trials Toolkit | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/clinical-trials-toolkit
Consultation on proposed regulatory changes for clinical trials of medical devices I TGA	https://www.tga.gov.au/sites/default/files/2022-08/consultation-proposed-regulatory-changes-clinical-trials-medical-devices.pdf
Learning Modules | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/_files/elearn/index.html
Resources for Clinical Trials in Australia | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/resources-clinical-trials-australia
ICH Guideline for Good Clinical Practice | TGA	https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
About health and medical research in Australia | Department of Health and Aged Care	https://www.health.gov.au/topics/health-data-and-medical-research/about-health-and-medical-research
National Standard Operating Procedures for Clinical Trials | Australian Government Department of Health and Aged Care	https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials
The National Statement 2018 | National Health and Medical Research Council (NHMRC)	https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC	https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Contact us

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